

Cardiovascular Systems Inc  
Form 10-K  
September 10, 2012  
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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-K**

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934  
For the fiscal year ended June 30, 2012

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

Commission file number: 000-52082

**CARDIOVASCULAR SYSTEMS, INC.**

*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**651 Campus Drive**

**St. Paul, Minnesota**  
*(Address of principal executive offices)*

**41-1698056**  
*(I.R.S. Employer  
Identification No.)*

**55112-3495**  
*(Zip Code)*

**Registrant's telephone number, including area code:**

**(651) 259-1600**

**Securities registered pursuant to Section 12(b) of the Act:**

**Title of each class**

**Name of each exchange on which registered**

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Common Stock, One-tenth of One Cent (\$0.001)

The NASDAQ Stock Market LLC

Par Value Per Share

## Securities registered pursuant to Section 12(g) of the Act:

**None.**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of December 31, 2011, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was \$147,598,517 based on the closing sale price as reported on the NASDAQ Global Market.

The number of shares of the registrant's common stock outstanding as of August 27, 2012 was 20,566,881.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the registrant's 2012 Annual Meeting of Stockholders are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this report.

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We make available, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act on our web site, <http://www.csi360.com>, as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the Securities and Exchange Commission ( SEC ). We are not including the information on our web site as a part of, or incorporating it by reference into, our Form 10-K.

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**PART I**

**Item 1. *Business.***

**Special Note Regarding Forward Looking Statements**

This report contains plans, intentions, objectives, estimates and expectations that constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), which are subject to the safe harbor created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expect, plans, anticipates, believes, estimates, projects, predicts, potential, intended to identify forward-looking statements. Examples of these statements include, but are not limited to, any statements regarding our future financial performance, results of operations or sufficiency of capital resources to fund our operating requirements, and other statements that are other than statements of historical fact. Our actual results could differ materially from those discussed in these forward-looking statements due to a number of factors, including the risks and uncertainties that are described more fully by us in Part I, Item 1A and Part II, Item 7 of this report and in our other filings with the SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this report. You should read this report completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

**Corporate Information**

We were incorporated as Replidyne, Inc. in Delaware in 2000. On February 25, 2009, Replidyne, Inc. completed its business combination with Cardiovascular Systems, Inc., a Minnesota corporation (CSI-MN), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of November 3, 2008, by and among Replidyne, Responder Merger Sub, Inc., a wholly-owned subsidiary of Replidyne (Merger Sub), and CSI-MN (the Merger Agreement). Pursuant to the Merger Agreement, Merger Sub merged with and into CSI-MN, with CSI-MN continuing after the merger as the surviving corporation and a wholly-owned subsidiary of Replidyne. At the effective time of the merger, Replidyne changed its name to Cardiovascular Systems, Inc. and CSI-MN changed its name to CSI Minnesota, Inc. Following the merger of Merger Sub with CSI-MN, CSI-MN merged with and into CSI, with CSI continuing after the merger as the surviving corporation.

Our principal executive office is located at 651 Campus Drive, St. Paul, Minnesota 55112. Our telephone number is (651) 259-1600, and our website is www.csi360.com. The information contained in or accessible through our website is not incorporated by reference into, and should not be considered part of, this Annual Report on Form 10-K.

We have received federal registration in the U.S. Patent and Trademark Office, or USPTO, of certain marks, including Diamondback 360°, Predator 360° and Stealth 360°, CSI, a first CSI logo, a second CSI logo, Lumen Library, ViperWire, ViperWire Advance, ViperTrack, and ViperCaddy. We have applied for federal registration with the USPTO of certain marks, including CSI in Class 10, DIAMONDBACK in CL 5, CSI Logo in CL 10, CONQUER 360° in CL 10, and DIAMONDBACK in CL 10. All other trademarks, trade names and service marks appearing in this Form 10-K are the property of their respective owners.

**Business Overview**

We are a medical device company focused on developing and commercializing minimally invasive treatment solutions for vascular disease. Interventional endovascular treatment of peripheral artery disease, or PAD, is our initial area of focus. PAD is caused by the accumulation of plaque in peripheral arteries, most commonly occurring in the pelvis and legs. PAD is a progressive disease, and, if left untreated, can lead to limb amputation or death.

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Our primary products, the Stealth 360° PAD System ( Stealth 360° ), Diamondback 360° PAD System ( Diamondback 360° ), and Diamondback Predator 360° PAD System ( Predator 360° ) are catheter-based platforms capable of treating a broad range of plaque types in leg arteries both above and below the knee and address many of the limitations associated with existing treatment alternatives. We refer to the Stealth 360°, Diamondback 360°, and the Predator 360° collectively in this Annual Report on Form 10-K as the PAD Systems. In August 2007, the U.S. Food and Drug Administration, or FDA, granted us 510(k) clearance for the use of the Diamondback 360° as a therapy in patients with PAD. We commenced a limited commercial introduction of the Diamondback 360° in the United States in September 2007 and began a full commercial launch during the quarter ended March 31, 2008. We received 510(k) clearance of the Predator 360° in March 2009 and commenced commercial launch in April 2009. We received 510(k) clearance of the Stealth 360° in March 2011 and commenced a commercial launch that same month. The Stealth 360° contains additional ease of use and physician control features while incorporating the orbital mechanism of action, optimal shaft and crown configurations of the Diamondback 360° and Predator 360°. As of June 30, 2012, we estimate that the PAD Systems had been utilized in more than 70,000 procedures.

We intend to expand into the interventional coronary market though we need to complete certain clinical trials and receive FDA approval to do so. In May 2011, we received approval from the FDA to complete enrollment of 429 patients in our ORBIT II clinical trial for a coronary application for the Diamondback 360°, which followed the FDA's review of data from the first 50 cases in the ORBIT II trial. In July 2012, we received approval from the FDA to include the new electric coronary device (similar to Stealth 360° technology used in PAD and customized specifically for the coronary application), which improves ease of use. The FDA requires 100 enrollments with the new electric coronary device and will allow up to 50 additional patients in the trial, as needed, to achieve that enrollment level, bringing the maximum trial enrollment to 479. More than 350 patients are now enrolled in the trial.

In addition to the PAD Systems, we have expanded our product portfolio through internal product development and establishment of business relationships with other medical device companies. We offer multiple accessory products designed to complement the use of the PAD Systems, and we have an exclusive distribution agreement with Asahi-Intecc Co., Ltd. to market its peripheral guidewire line in the United States.

## **Market Overview**

### ***Peripheral Artery Disease***

PAD is a circulatory problem in which plaque deposits build up on the walls of the arteries, reducing blood flow to the limbs. The most common early symptoms of PAD are pain, cramping or fatigue in the leg or hip muscles while walking. Symptoms may progress to include numbness, tingling or weakness in the leg and, in severe cases, burning or aching pain in the leg, foot or toes while resting. As PAD progresses, additional signs and symptoms occur, including cooling or color changes in the skin of the legs or feet, and sores on the legs or feet that may not heal. If left untreated, progressing PAD may lead to critical limb ischemia, a condition in which the amount of oxygenated blood being delivered to the limb is insufficient to keep the tissue alive. Critical limb ischemia often leads to large non-healing ulcers, infections, gangrene and, eventually, limb amputation or death.

According to a report by the U.S. Department of Health and Human Services in 2006, PAD affects approximately eight to 12 million people in the United States. According to 2007 statistics from the American Heart Association, PAD becomes more common with age and affects approximately 12% to 20% of the population over 65 years old. An aging population, coupled with increasing incidence of diabetes and obesity, is likely to increase the prevalence of PAD. In many older PAD patients, particularly those with diabetes, PAD is characterized by fibrotic (moderately hard) or calcified (extremely hard) plaque deposits that have not been successfully treated with traditional non-invasive treatment techniques. PAD may involve arteries throughout the leg. Arteries above the knee are generally long, straight and relatively wide, while arteries below the knee are shorter and branch into arteries that are progressively smaller in diameter.

Despite the severity of PAD, it remains relatively underdiagnosed. According to an article published in Podiatry Today in 2006, only approximately 2.5 million of the eight to 12 million people in the United States with PAD are diagnosed. Although we believe the rate of diagnosis of PAD is increasing, underdiagnosis

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continues due to patients failing to display symptoms or physicians misinterpreting symptoms as normal aging. Recent emphasis on PAD education from medical associations, insurance companies and other groups, coupled with publications in medical journals, is increasing physician and patient awareness of PAD risk factors, symptoms and treatment options. The PARTNERS study, which was published in the Journal of the American Medical Association in 2001, advocated increased PAD screening by primary care physicians.

Physicians treat a significant portion of the 2.5 million people in the United States who are diagnosed with PAD using medical management, which includes lifestyle changes, such as diet and exercise and drug treatment. For instance, within a reference group of more than 1,000 patients from the PARTNERS study, 54% of the patients with a prior diagnosis of PAD were receiving antiplatelet medication treatment. While medications, diet and exercise may improve blood flow, they do not treat the underlying obstruction and many patients have difficulty maintaining lifestyle changes. Additionally, many prescribed medications are contraindicated, or inadvisable, for patients with heart disease, which often exists in PAD patients.

### ***Coronary Artery Disease***

Based on data from the 2009 National Discharge Survey, approximately 1,133,000 percutaneous coronary interventions, or PCI, procedures occurred in the United States in 2009. Based on various studies, we believe that approximately 38% of PCI procedures involve moderate to severe levels of calcified coronary arteries and may benefit from the use of our device if approved for commercial use. In addition, approximately 415,000 coronary artery bypass graft surgeries were performed in the United States. These patients generally have higher rates of calcification and we believe they may benefit from the use of our device if approved for commercial use.

## **Our Product**

### ***Components of the PAD Systems***

The PAD Systems each use a single-use, low-profile catheter that travels over our proprietary ViperWire Advance Guide Wire and is powered by either a saline infusion pump (Stealth 360°) or an external control unit (Diamondback 360° or Predator 360°).

*Catheter.* The catheter consists of:

a control handle, which allows precise movement of the crown and predictable crown location;

a flexible drive shaft with a diamond grit coated offset crown, which tracks and orbits over the guidewire; and

a sheath, which covers the drive shaft and permits delivery of saline or medications to the treatment area.

*ViperWire Advance Guidewire.* The ViperWire Advance is the second generation of the ViperWire. The ViperWire Advance was designed to offer an improved ability to maneuver through tortuous, twisting blood vessels and cross challenging lesions. The PAD Systems travel over this wire to the lesion and operate on this wire.

*ViperSlide Lubricant.* ViperSlide is an exclusive lubricant designed to optimize the smooth operation of the PAD Systems. On April 4, 2011, we entered into a five-year supply agreement with Fresenius Kabi AB pursuant to which Fresenius manufactures and serves as a single-source supplier of the ViperSlide lubricant through March 2016.

*Saline Infusion Pump.* Used exclusively with the Stealth 360°, the saline infusion pump mounts directly to the intravenous pole and bathes the device's shaft and crown and provides a power supply for the operation of the catheter.

*Control Unit.* Used in conjunction with the Diamondback 360° and Predator 360° PAD Systems, the control unit incorporates a touch-screen interface on an easily maneuverable pole. Using an external air supply, the control unit regulates air pressure to drive the turbine located in the catheter handle to speeds ranging up to 200,000 revolutions per minute. Saline, delivered by a pumping mechanism on the control unit, bathes the device shaft and crown. The constant flow of saline reduces the risk of heat generation.



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### ***Technology Overview***

***Plaque Modification through Differential Sanding.*** The PAD Systems were designed to allow the devices to differentiate between soft compliant and harder diseased tissue in the artery. The diamond grit crown preferentially engages and sands the harder material, but is designed not to damage more compliant parts of the artery. Arterial lesions tend to be harder and stiffer than compliant, undiseased vessel tissue, and they often are fibrotic or calcified. The PAD Systems also treat soft plaque, which is still harder than a normal vessel wall. The mechanism of action is a function of the centrifugal force generated by the PAD Systems as they rotate. As the crown moves outward, the centrifugal force is offset by the counterforce exerted by the arterial wall. If the tissue is compliant, it should flex away, rather than generating an opposing force that would allow the PAD Systems to engage and sand the wall. Diseased tissue provides resistance and is able to generate an opposing force that allows the PAD Systems to engage and sand the plaque. The sanded plaque is broken down into particles generally smaller than circulating red blood cells that are washed away downstream with the patient's natural blood flow. Testing performed in carbon blocks, animal and cadaver models showed:

>93% of particles were smaller than a red blood cell, and

>99% of particles were smaller than the lumen of the capillaries (which provide the connection between the arterial and venous system). The small particle size minimizes the risk of vascular bed overload, or a saturation of the peripheral vessels with large particles, which may cause slow or reduced blood flow to the foot. The small size of the particles allows them to be managed by the body's natural cleansing of the blood, whereby various types of white blood cells eliminate worn-out cells and other debris in the bloodstream.

***Mechanism of Action.*** The systems operate on the principles of centrifugal force. As the speed of the crown's rotation increases, it creates centrifugal force, which increases the crown's orbit and presses the diamond grit coated offset crown against the lesion or plaque, removing a small amount of plaque with each orbit. The characteristics of the orbit and the resulting lumen size can be adjusted by modifying three variables:

***Speed.*** An increase in speed creates a larger orbital circle, thus accommodating vessels with larger lumens. Our current Stealth 360° system allows the user to choose between three rotational speeds.

***Crown Characteristics.*** The crown can be designed with various weights (as determined by crown geometry and material density) and coated with diamond grit of various types. The crown is available in two configurations—classic and solid. Physicians select crown sizes and configurations based on several case criteria, including reference vessel size, length and degree of stenosis, stenosis morphology, and anatomy tortuosity. Physicians often use the classic crown configuration in small, more tortuous vessels. The solid crown configuration is designed with a tapered, leading edge for frontal sanding, which can be used in tight calcified disease. The Stealth 360° device is available with a 1.50 millimeter and 2.00 millimeter classic crown, and 1.25 millimeter, 1.50 millimeter and 2.00 millimeter solid crown configuration. There is also a 1.25 millimeter micro-solid crown available with the Stealth 360° device, which is designed to provide hybrid performance between the classic and solid configurations. For both configurations, the catheter length is 145 centimeters, which addresses procedural approach and target lesion locations both above and below the knee.

The Diamondback 360° utilizes the classic crown and the Predator 360° utilizes the solid crown. Both systems are available in multiple sizes, including 1.25, 1.50, 1.75, and 2.00 millimeter. There is also a 2.25 millimeter Predator 360° device.

The PAD Systems are versatile in that by adjusting one or more of the speeds in conjunction with crown selection, multiple lesions can be treated.

### ***Applications***

The PAD Systems can be used to treat plaque in multiple anatomic locations.



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*Below-the-Knee and Behind-the-Knee Peripheral Artery Disease.* Arteries below and behind the knee have small diameters and may be diffusely diseased, calcified or both, limiting the effectiveness of traditional

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devices. Behind-the-knee lesions also present challenges if a stent is required because stents frequently fracture due to the forces exerted on the vessels when the knee bends or flexes. The PAD Systems are effective in both diffused and calcified vessels. This was demonstrated in the OASIS trial, where 94.5% of lesions treated with the Diamondback 360° were behind or below the knee.

*Above-the-Knee Peripheral Artery Disease.* Arteries above-the-knee are longer, straighter and wider than below-the-knee vessels. Plaque in these arteries may also be diffuse, fibrotic and calcific. As a result, our products are often used to treat lesions above the knee.

### ***Potential Applications***

*Coronary Artery Disease.* We have developed a modified version of the Diamondback 360° to treat coronary arteries. We have conducted numerous bench studies, pre-clinical animal studies, and our ORBIT I 50-patient human feasibility clinical study to evaluate the Diamondback 360° in coronary artery disease. A coronary application requires us to conduct a clinical trial and file a premarket application, or PMA, and obtain approval from the FDA. We participated in three pre-investigational device exemption, or IDE, meetings with the FDA and completed the human feasibility portion of a coronary trial in the summer of 2008 in India, enrolling 50 patients. The FDA agreed to accept the data from the India trial to support an IDE submission. The FDA granted unconditional approval in April 2010 to begin the ORBIT II coronary study in the United States. In May 2011, we received approval from the FDA to complete enrollment of 429 patients in our ORBIT II clinical trial for a coronary application for the Diamondback 360°, which followed the FDA's review of data from the first 50 cases in the ORBIT II trial. In July 2012 we received approval from the FDA to include the new electric coronary device (similar to Stealth 360° technology used in PAD and customized specifically for the coronary application), which improves ease of use. The FDA requires 100 enrollments with the new electric coronary device and will allow up to 50 additional patients in the trial, as needed, to achieve that enrollment level, bringing the maximum trial enrollment to 479. More than 350 patients are now enrolled in the trial.

### **Our Solution**

The PAD Systems represent an innovative approach to the treatment of PAD that provides physicians and patients with a procedure that addresses many of the limitations of traditional treatment alternatives. The PAD Systems each use single-use catheters that incorporate a flexible drive shaft with an offset diamond grit coated crown. Physicians position the crown at the site of an arterial plaque-containing lesion and remove the plaque by spinning the crown to orbit and sand it away, creating a smooth lumen, or channel, in the vessel. The PAD Systems are designed to differentiate between hard plaque and soft, compliant arterial tissue, a concept that we refer to as differential sanding.

Normal arteries are compliant and have the ability to expand and contract as needed to supply blood flow to the legs and feet. Arteries burdened with fibrotic and/or calcified plaque due to PAD lose their compliance which makes other therapies such as angioplasty, stenting, surgical bypass and atherectomy problematic. The PAD Systems sand plaque into small particles and restore both blood flow and vessel compliance. The particles created by the PAD Systems are generally smaller than red blood cells and are carried away by the bloodstream. The small size of the particles avoids the need for plaque collection reservoirs. The PAD Systems can typically treat the diseased arteries with less than two minutes of sanding time, potentially reducing the overall procedure time.

We believe the PAD Systems offer the following key benefits:

### ***Strong Safety Profile***

*Differential Sanding Reduces Risk of Adverse Events.* The PAD Systems are designed to differentiate between hard plaque and soft compliant arterial tissue. Arteries are composed of three tissue layers. The diamond grit coated offset crown at the working end of the devices engages and removes plaque from the artery wall with minimal likelihood of penetrating or damaging the fragile, inner layer of the arterial wall because soft, compliant tissue flexes away from the crown. Furthermore, the PAD Systems have rarely penetrated the middle or outer layers of the artery's wall. The Diamondback 360°'s perforation rate was

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1.6% during our pivotal OASIS trial. Analysis by an independent pathology laboratory of more than 434 consecutive cross sections of porcine arteries treated with the Diamondback 360° revealed there was minimal to no damage, on average, to the middle layer, which is typically associated with restenosis. In addition, the safety profile of the Diamondback 360° was found to be non-inferior to that of angioplasty, which is a common interventional method.

*Eliminates Need for Distal Protection.* The PAD Systems sand plaque away from artery walls in a manner that produces particles of such a small size generally smaller than red blood cells that they are carried away by the bloodstream. The small size of the particles avoids the need for plaque collection reservoirs on the catheter and reduces the need for ancillary distal protection devices, commonly used with directional cutting atherectomy, and also significantly reduces the risk that larger pieces of removed plaque will block blood flow downstream.

*Allows Continuous Blood Flow During Procedure.* The PAD Systems allow for continuous blood flow during the procedure, except when used in chronic total occlusions. Other devices may restrict blood flow due to the size of the catheter required or the use of distal protection devices, which could result in complications such as excessive heat and tissue damage.

### ***Proven Efficacy***

*Efficacy Demonstrated in a 124-Patient Clinical Trial.* Our pivotal OASIS clinical trial was a prospective 20-center study that involved 124 patients with 201 lesions treated by the Diamondback 360°. Performance targets were established cooperatively with the FDA before the trial began. Despite 55% of the lesions consisting of calcified plaque the Diamondback 360° in the OASIS trial successfully met the FDA's study endpoints. Because the Predator 360° and Stealth 360° mechanism of action is identical to that of the Diamondback 360°, no additional efficacy trials were required by the FDA for 510(k) clearance of either PAD System.

*Treats Difficult, Fibrotic and Calcified Lesions.* The PAD Systems enable physicians to remove plaque from long, fibrotic, calcified or bifurcated lesions in peripheral arteries both above and below the knee.

*Orbital Motion Improves Lesion Compliance.* The orbiting action of the PAD Systems removes the hard plaque in the artery by sanding. As the crown sands away the plaque, the lumen of the artery is opened and the vessel wall becomes more compliant. The orbital motion and speed of the crown increases, thus allowing for continuous removal of plaque as the opening of the lumen increases during the operation of the devices. Non-orbiting rotational atherectomy catheters remove plaque by either abrading the lesion with a spinning, abrasive burr, or by shaving the lesion with sharp blades. The burr-type device acts in a manner similar to a drill and only creates a lumen the same size or slightly smaller than the size of the burr. The shaving devices are not able to discriminate between lesion disease and healthy vessel tissue.

*Differential Sanding Creates Smooth Lumens.* The differential sanding of the PAD Systems creates a smooth surface inside the lumen. We believe that the smooth lumens created by the devices increase the velocity of blood flow and decrease the resistance to blood flow, which may decrease the potential for restenosis, or renarrowing of the arteries.

### ***Ease of Use***

*Utilizes Familiar Techniques.* Physicians using the PAD Systems employ techniques similar to those used in angioplasty, which are familiar to interventional cardiologists, vascular surgeons and interventional radiologists who are trained in endovascular techniques. The devices' simple user interfaces require minimal additional training.

*Single Insertion to Complete Treatment.* The orbital technology and differential sanding process of the PAD Systems allows for a single insertion to treat lesions, in most cases. Because the particles of plaque sanded away are of such small sizes, the PAD Systems do

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not require a collection reservoir that needs to be repeatedly emptied or cleaned during the procedure. Rather, the PAD Systems allow for multiple passes of the device over the lesion until plaque is removed and a smooth lumen is created.

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### ***Treatment Area***

***Treats Entire Leg.*** The PAD Systems have the ability to treat the entire leg, including small vessels below the knee.

***Cost and Time Efficient Procedure***

***Short Procedure Time.*** The PAD Systems have a short treatment time, typically less than two minutes.

***Single Crown Can Create Various Lumen Sizes Limiting Hospital Inventory Costs.*** The orbital mechanism of action with the PAD Systems allows one device to create various diameter lumens inside the artery. Adjusting the rotational speed of the crown changes the orbit to create the desired lumen diameter, thereby potentially avoiding the need to use multiple catheters of different sizes to treat multiple lesions.

***Single Insertion Reduces Procedural Time.*** Since the physician does not need to insert and remove multiple catheters or clean a plaque collection reservoir to complete the procedure, there is a potential for decreased procedure time.

### **Our Strategy**

Our goal is to be the leading provider of minimally invasive solutions for the treatment of vascular disease. The key elements of our strategy include:

***Drive Adoption Through Our Direct Sales Organization and Key Physician Leaders.*** We expect to continue to drive adoption of the PAD Systems through our direct sales force, which targets interventional cardiologists, vascular surgeons and interventional radiologists. As a key element of our strategy, we focus on educating and training physicians on the PAD Systems through our direct sales force and during seminars where physician industry leaders discuss case studies and treatment techniques using the devices.

***Collect Additional Clinical Evidence on Benefits of the PAD Systems.*** Physicians are increasingly requesting clinical study evidence to allow them to make the best treatment decisions to achieve the best possible short-term and long-term outcomes for their patients. We are focused on collecting and using clinical evidence to demonstrate the advantages of the PAD Systems and drive physician acceptance.

***Expand Product Portfolio within the Market for Treatment of Peripheral Arteries.*** In addition to the PAD Systems, we have expanded our product portfolio. We offer multiple accessory devices designed to complement the use of the PAD Systems. We continue to market the following products:

ViperSlide® Lubricant an exclusive lubricant designed to optimize the smooth operation of the PAD Systems

ViperTrack® Radiopaque Tape a radiopaque tape to assist in measuring lesion lengths and marking lesion locations

ViperWire Advance® guidewire offering improved ability to maneuver through tortuous, twisting blood vessels and cross challenging lesions

We are continuing to evaluate internal product development to further expand our portfolio of PAD treatment solutions.

*Evaluate Technology Platform for Coronary Market Use.* We are evaluating our orbital technology to expand into the interventional coronary market. A coronary application would address a large market opportunity, further leveraging our core technology and expanding its market potential. In 2008, we completed the ORBIT I trial, a 50-patient study in India that investigated the safety of the Diamondback 360° device in treating calcified coronary artery lesions. Results successfully met both safety and efficacy endpoints. An IDE application has been approved by the FDA for ORBIT II, a pivotal trial that will enroll up to 479 patients in the United States to evaluate the safety and effectiveness of the PAD Systems in treating severely calcified coronary lesions.

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*Pursue Strategic Acquisitions and Partnerships.* In August 2009, we signed an exclusive distribution agreement with Asahi to market two peripheral guidewire lines in the United States. In August 2011, we signed an amendment to expand the agreement to include three additional peripheral guidewires. The product portfolio now includes the Treasure Floppy and Regalia; and three specialty wires: Astat 20, Astao 30, Treasure 12.

In addition to adding to our product portfolio through internal development efforts, we intend to continue to explore the acquisition of other product lines, technologies or companies that may leverage our sales force or complement our strategic objectives. We plan to continue to evaluate distribution agreements, licensing transactions, other strategic partnerships, and the financial viability of marketing the PAD Systems internationally.

## **Clinical Trials and Studies for Our Products**

We are committed to providing relevant clinical evidence to allow physicians to select and utilize the best treatment options for their patients. We have conducted 13 clinical trials to demonstrate the safety and efficacy of the PAD Systems in treating peripheral vascular disease, enrolling a total of 3,767 patients in our PAD I and PAD II pilot trials, OASIS pivotal trial, OASIS LT, CONFIRM DIAMONDBACK, CONFIRM PREDATOR CONFIRM OUTFLOW Post-Market Registries and the CALCIUM 360° and COMPLIANCE 360° post-market, randomized feasibility studies. The results of these studies consistently demonstrate that the PAD Systems provide predictable, repeatable and durable results that further differentiate themselves from other PAD treatments.

Coronary artery disease, or CAD, continues to be a widespread and growing problem worldwide. Performing PCI on calcified lesions can lead to major adverse cardiac event, or MACE, rates as high as 24% at 30 days, stent malapposition and a number of procedural complications. To demonstrate the safety and effectiveness of orbital atherectomy for use in calcified coronary arteries, the ORBIT I coronary clinical trial was completed in India in 2009. In 2010, we began the ORBIT II pivotal study in the United States, evaluating the use of the Diamondback 360° in coronary arteries. The ORBIT II trial is the first trial in the United States designed specifically for difficult to treat calcified coronary artery disease.

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**Metrics Used in PAD Trials**

The common metrics used to evaluate plaque modification and removal devices for PAD include:

Metric	Description
Change in Compliance	Compliance change as defined in the COMPLIANCE 360 protocol is to achieve $\leq 30\%$ residual stenosis with orbital atherectomy followed by a low-pressure balloon inflation of $\leq 4$ atmospheres pressure (atm).
Absolute Plaque Reduction	Absolute plaque reduction is the difference between the pre-treatment percent stenosis, or the narrowing of the vessel and the post-treatment percent stenosis as measured angiographically.
Target Lesion Revascularization	Target lesion revascularization rate, or TLR rate, is the percentage of patients who have undergone another peripheral intervention in the same lesion as treated during index procedure due to their worsening symptoms. Treatments such as an angioplasty, stenting, surgery or atherectomy may be used to reopen the treated lesion site.
Ankle Brachial Index	The Ankle Brachial Index, or ABI, is a measurement that is useful to evaluate the adequacy of circulation in the legs and improvement or worsening of leg circulation over time. The ABI is a ratio between the blood pressure in a patient's ankle and a patient's arm, with a ratio above 0.9 being normal.

The common metrics used to evaluate atherectomy devices for PAD include:

Metric	Description
Serious Adverse Events	SAEs include any experience that is fatal or life-threatening, is permanently disabling, requires or prolongs hospitalization, or requires intervention to prevent permanent impairment or damage. SAEs may or may not be related to the device.
Perforations	Perforations occur when the artery is punctured during atherectomy treatment. Perforations may be non-serious or serious (referred to as an SAE) depending on the treatment required to repair the perforation.

**PAD Feasibility Trials**

The first clinical trial was a two-site, 17-patient feasibility clinical trial in Europe, referred to as PAD I, which began in March 2005. Patients enrolled in the trial had lesions that were less than 10 cm in length in arteries between 1.5 mm and 6.0 mm in diameter, with Rutherford Class scores of IV or lower. Patients were



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evaluated at the time of the procedure and at 30 days following treatment. The purpose of PAD I was to obtain the first human clinical experience and evaluate the safety of the Diamondback 360°. This was determined by estimating the cumulative incidence of patients experiencing one or more SAEs within 30 days post-treatment.

The results of PAD I confirmed that the Diamondback 360° was safe and established that the Diamondback 360° could be used to treat vessels in the range of 1.5 mm to 4.0 mm, which are found primarily below the knee. PAD I also showed that removal of plaque could be accomplished and the resulting device-to-lumen ratio was approximately 1.0 to 2.0. The SAE rate in PAD I was 6% (one of 17 patients).

After being granted the CE Mark in May 2005, a 66-patient European clinical trial, PAD II, was initiated at seven sites, in August 2005. All patients had stenosis in vessels below the femoral artery of between 1.5 mm and 4.0 mm in diameter, with at least 50% blockage. The primary objectives of this study were to evaluate the acute (30 days or less) risk of experiencing an SAE post procedure and provide evidence of device effectiveness. Effectiveness was confirmed angiographically and based on the percentage of absolute plaque reduction.

The PAD II results demonstrated safe and effective debulking in vessels with diameters ranging from 1.5 mm to 4.0 mm with a mean absolute plaque reduction of 55%. The SAE rate in PAD II was 9% (six of 66 patients), which did not differ significantly from existing non-invasive treatment options.

***OASIS Pivotal Trial***

An IDE was approved in September 2005 to begin our pivotal United States trial, OASIS. OASIS was a 124-patient, 20-center, prospective trial that began enrollment in January 2006. Patients included in the trial had an ABI of less than 0.9, a Rutherford Class score of class V or lower and treated arteries of between 1.5 mm and 4.0 mm or less in diameter via angiogram measurement, with a well-defined lesion of at least 50% diameter stenosis and lesions of no greater than 10.0 cm in length.

The primary efficacy study endpoint was absolute plaque reduction of the target lesions from baseline to immediately post-procedure. The primary safety endpoint was the cumulative incidence of SAEs at 30 days.

In the OASIS trial, 94.5% of lesions treated were behind or below the knee, an area where lesions have traditionally gone untreated until they require bypass surgery or amputation. Of the lesions treated in OASIS, 55% were comprised of calcified plaque, which presents a challenge to proper expansion and apposition of balloons and stents, and 48% were diffuse, or greater than 3 cm in length, which typically requires multiple balloon expansions or stent placements. Competing plaque removal devices are often ineffective with these difficult to treat lesions.

The average time of treatment in the OASIS trial was three minutes per lesion, which compares favorably to the treatment time required by other plaque removal devices. The following table is a summary of the OASIS trial results:

Item	FDA Target	OASIS Result
Absolute Plaque Reduction	55%	59.4%
	8%, with an upper	4.8%, device-related;
SAEs at 30 days	bound of 16%	9.7%, overall
TLR	20% or less	2.4%

\* Mean ± Standard Deviation

In August 2007, the U.S. Food and Drug Administration, or FDA, granted us 510(k) clearance for the use of the Diamondback 360° as a therapy in patients with PAD.

***CLEAR 360° Study***

We conducted the CLEAR 360° study to evaluate the incidence of clinically significant hemolysis associated with orbital atherectomy used to treat severe peripheral arterial disease. This study enrolled 31 patients at four U.S. medical centers and was completed in 2009. This trial concluded that there was no clinically significant hemolysis after orbital atherectomy.



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***Post-Market Feasibility Studies***

In May 2010, enrollment was completed in the COMPLIANCE 360° clinical trial. This post-market prospective, randomized, multi-center study evaluated the clinical and economic benefits of modifying plaque to change large vessel compliance above the knee with the Diamondback 360° or Predator 360°. The study compared the performance of the Diamondback 360° or Predator 360°, plus low-pressure balloon angioplasty, if desired, with that of high-pressure balloon inflation alone. Fifty patients were enrolled at nine U.S. medical centers with six and 12 month follow-up periods. The study proved that compared to balloon angioplasty alone, the Diamondback 360° or Predator 360° plus low pressure balloon angioplasty leads to better luminal gain by improving lesion compliance and decreases the need for adjunctive stenting for the treatment of calcified femoral popliteal disease. Restenosis and TLR were similar at 12 months despite the large disparity of stent usage between the two groups. The results of this trial demonstrated that the Diamondback 360° or Predator 360° can achieve results in calcified plaque by improving lesion compliance through differential sanding, without the need for stent placement.

In April 2010, enrollment was completed in the CALCIUM 360° study, a prospective, randomized, multi-center study comparing the effectiveness of the Diamondback 360° or Predator 360° to balloon angioplasty in treating calcified lesions below the knee. Calcified plaque exists in about 75 percent of lesions below the knee. Fifty patients were enrolled at eight U.S. medical centers. Procedural success was 93.1% (27 out of 29 lesions) for Diamondback 360° or Predator 360° plus balloon angioplasty and 82.4% (28 out of 34 lesions) for balloon angioplasty alone. Bail out stenting was seen in two out of 29 (6.9%) of Diamondback 360° or Predator 360° and five out of 35 (14.3%) of balloon angioplasty treated lesions. At one year follow-up there were no amputations in either group. Freedom from target vessel revascularization and death was seen in 93.3% and 100% in the Diamondback 360° or Predator 360° and 80.0% and 68.4% of the balloon angioplasty group, respectively. Six and 12 month results showed the Diamondback 360° or Predator 360° treatment outperformed balloon angioplasty. A key finding was that by modifying calcified lesions first, the Diamondback 360° or Predator 360° allowed use of a lower-pressure adjunctive balloon therapy, reducing the need for bail out stenting with improved longer-term patient outcomes.

***CONFIRM Post-Market Clinical Registry Series***

We completed enrollment in the CONFIRM Post-Market Clinical Registry Series, that was designed to further evaluate acute parameters related to the use of the PAD Systems. The CONFIRM Series consisted of three registries: CONFIRM I DIAMONDBACK, CONFIRM II PREDATOR, and CONFIRM III OUTFLOW.

Enrollment of 733 patients in the CONFIRM I DIAMONDBACK Post-Market Registry was completed in March 2010. In this prospective registry, 1,146 lesions were treated by 84 investigators at 57 medical centers with the Diamondback 360°. Patient characteristics were as follows: 81.6% were smokers, 60.0% were diabetic, and 89.7% had hypertension. Lesions treated were above the knee (46.5%), behind the knee (17.5%) and below the knee (36.0%). Long and calcified lesions were treated with the Diamondback 360° followed by low pressure balloon angioplasty, if desired. An average residual stenosis of 12.0% was achieved following treatment, which is consistent with that achieved in PAD I, PAD II, and OASIS. Bail out stenting, or stenting required due to tears in the vessel wall, occurred in 4.6% of lesions. This is lower than the 35% to 40% bail-out stent rate reported in the literature for patients treated with high pressure balloon angioplasty alone in this type of challenging patient population. Results of this study were presented at the Complex Cardiovascular Catheter Therapeutic, or C3, conference in Orlando, FL in June 2012.

Enrollment of 1,127 patients by 153 investigators at 122 institutions in the prospective CONFIRM II PREDATOR Post-Market Registry was completed December 2010. Data on acute clinical performance and short-term economic parameters were collected during this study. In this prospective registry, average patient age was 70.7 years; 61.5% were male and 90% had lesion with mild to severe calcium. The average lesion length was 72 mm. Predator 360° was used followed by balloon angioplasty (mean 5.44 atms) in 86% of lesions. Procedural events included minor and major dissection (12.3%), perforation (0.4%), slow flow (3.8%), abrupt closure (1.4%), distal macro embolization (1.9%) and bail-out stenting due to dissection (6.3%). Average stenosis was 87.8% pre-procedure, 33.9% post-orbital and 9.6% post-adjunctive treatment. The CONFIRM II PREDATOR

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study validates the use of the latest iteration of orbital technology in restoring flow by changing lesion compliance, thus allowing low-pressure balloon angioplasty with limited complications and reduced need for bail out stenting. These results were presented at the San Francisco TCT conference in November 2011.

Data from CONFIRM DIAMONDBACK and PREDATOR registries were used to design the CONFIRM III OUTFLOW registry. This was the third study in the CONFIRM series to further evaluate acute procedural outcomes and economic parameters associated with use of the Diamondback Orbital Atherectomy System. Enrollment of 1,275 patients in the CONFIRM III OUTFLOW Post-Market Registry was completed June 2011. In this prospective registry 59% were male and the average patient age was 72 years. Lesions treated above the knee were 42%, behind the knee were 16%, below the knee were 41%, and unknown were 2%. Average lesion length was 69.6mm. Lesions were treated with the Diamondback 360° or Predator 360° followed by low pressure balloon angioplasty, if desired. Pre-procedure stenosis was 87% and the average residual stenosis of 10% was achieved following orbital and adjunctive treatment. Dissections rate was 9.9%, bail-out stenting occurred in 6.0% of lesions and a low perforation rate was 0.7%. The CONFIRM III OUTFLOW registry provides additional evidence of the consistent results obtained using Diamondback 360° or Predator 360° to treat difficult peripheral arterial disease.

### ***ORBIT I Coronary Feasibility Safety Study***

The ORBIT I feasibility study evaluated performance of the Diamondback 360° for the treatment of *de novo* calcified coronary lesions. The ORBIT I trial was completed in India in 2009 and enrolled 50 patients. The endpoints were measured by device performance and MACE rate and TLR at six months. Device performance success was 98%. The observed MACE rate at 30-day and at 6 months was 6% and 8% respectively. The 30 day and 6 month TLR was 2%. The ORBIT I trial demonstrates that the Diamondback system can be used to modify *de novo* calcified coronary lesions and facilitated stent delivery in this difficult-to-treat plaque morphology.

### ***ORBIT II Coronary IDE Study***

To market the Diamondback 360° in the United States for use in the coronary arteries, we are required to conduct further clinical trials and obtain premarket approval from the FDA. In May 2010, the FDA approved the IDE and we began the ORBIT II pivotal clinical trial. This trial plans to enroll up to 479 patients in up to 55 U.S. investigational centers to evaluate the safety and effectiveness of the PAD Systems in treating severely calcified coronary lesions. In May 2011, we received approval from the FDA to complete enrollment of 429 patients in our ORBIT II clinical trial for a coronary application for the Diamondback 360°, which followed the FDA's review of data from the first 50 cases in the ORBIT II trial. In July 2012 we received approval from the FDA to include the new electric coronary device (similar to Stealth 360° technology used in PAD and customized specifically for the coronary application), which improves ease of use. The FDA requires 100 enrollments with the new electric coronary device and will allow up to 50 additional patients in the trial, as needed, to achieve that enrollment level, bringing the maximum trial enrollment to 479. More than 350 patients are now enrolled in the trial.

## **Sales and Marketing**

We market and sell our products through a direct sales force in the United States. Revenues for the PAD Systems for fiscal 2012, fiscal 2011 and fiscal 2010 were \$73.0 million, \$69.3 million and \$57.4 million, respectively. While we sell directly to hospitals and office-based laboratories, we have targeted sales and marketing efforts to interventional cardiologists, vascular surgeons and interventional radiologists with experience using similar catheter-based procedures, such as angioplasty, stenting, and cutting or laser atherectomy. Physician referral programs and peer-to-peer education are other key elements of our sales strategy. Patient referrals come from general practitioners, podiatrists, nephrologists and endocrinologists.

We target our marketing efforts to practitioners through physician education, medical conferences, seminars, peer-reviewed journals and marketing materials. Our sales and marketing program focuses on:

educating physicians regarding the proper use and application of the PAD Systems;

clinical results showing safety and efficacy of products;

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developing relationships with key opinion leaders; and

facilitating regional referral marketing programs.

We are not marketing our products internationally; however, we continue to evaluate international opportunities.

We executed a Purchasing Agreement with HealthTrust Purchasing Group, L.P., or HPG, that became effective on July 15, 2011. HPG acts as a group purchasing organization for the healthcare providers belonging to HPG as participants. Under the Purchasing Agreement, all of HPG's participants located in the United States or its territories are eligible to purchase the PAD Systems and related products at prices set forth in the Purchasing Agreement. HPG has agreed not to contract with more than one alternative supplier from which participants may purchase products comparable to ours under the agreement. During the term of the agreement, we have agreed to not solicit any HPG participant to enter into a separate agreement for our products.

## **Research and Development**

Our research and development efforts are focused in the development of products to penetrate our three key target markets: below and behind-the-knee, above-the-knee and coronary vessels. Research and development projects include the development of electric versions of the PAD Systems, shaft designs, crown designs, and PAD and coronary clinical trials. Research and development expenses for fiscal 2012, fiscal 2011 and fiscal 2010 were \$11.4 million, \$8.9 million and \$10.3 million, respectively.

## **Manufacturing**

We use internally-manufactured and externally-sourced components to manufacture the PAD Systems. Most of the externally-sourced components are available from multiple suppliers; however, a few key components, including the diamond grit coated crown, micro motors, printed circuit board assemblies, and our ViperSlide Lubricant are single sourced. We have strategies and arrangements in place for procuring our key components from alternative suppliers in the event that one or more of our single source suppliers were to discontinue supplying us with a key component. We assemble the shaft, crown and handle components on-site, and test, pack, seal and label the finished assembly before sending the packaged product to a contract sterilization facility. Upon return from the sterilizer, the product is held in inventory prior to shipping to our customers.

Our manufacturing facility in Minnesota, including the shaft manufacturing and the controlled-environment assembly areas, are equipped to accommodate approximately 30,000 devices per shift annually. It also has storage capacity for approximately 8,000 devices and 50 control units. As the control unit becomes obsolete, we will convert our storage space for use with the Stealth 360° PAD System.

Our Pearland, Texas facility is 46,000 square feet and includes a custom-built clean room and production space for future expansion of value-add processes, including machining and electronics assembly. The facility, when it becomes fully staffed and equipped, will have the capacity to produce approximately 75,000 devices per shift annually. This facility has finished goods storage capacity for greater than 15,000 devices of the PAD Systems and other accessory products and over 500 Stealth 360° saline infusion pumps.

We are registered with the FDA as a medical device manufacturer. We have opted to maintain quality assurance and quality management certifications to enable us to market our products in the member states of the European Union, the European Free Trade Association and countries that have entered into Mutual Recognition Agreements with the European Union. We are ISO 13485:2003 certified, and our renewal is due by December 2012.

Since commercialization, we have had three minor instances of recall, involving a single lot of Diamondback 360° devices (8 units), two boxes of ViperWires (10 wires), and 70 lots of Stealth 360° devices (145 units), related to Use By date labeling issues. While these recalls were reported to the FDA, according to regulations, they did not present a risk to patient safety. A separate recall, initiated in 2009 and completed in 2010, involved the ViperSheath, which is owned and manufactured by Thomas Medical Products. As the distributor for the ViperSheath, we were required to recall all unused units from our customers and return them to

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Thomas Medical Products. All of the unused ViperSheaths were captured and subsequently destroyed by Thomas Medical Products, with FDA observance. We also completed a recall in June 2012 involving six lots of Stealth 360° micro crown devices (45 units) due to the potential for an insufficient solder bond. All unused devices were returned and no patient injuries resulted from this recall.

### **Third-Party Reimbursement and Pricing**

Third-party payors, including private insurers, and government insurance programs, such as Medicare and Medicaid, pay for a significant portion of patient care provided in the United States. The single largest payor in the United States is the Medicare program, a federal governmental health insurance program administered by the Centers for Medicare and Medicaid Services, or CMS. Medicare covers certain medical care expenses for eligible elderly and disabled individuals, including a large percentage of the population with PAD who could be treated with the PAD Systems. In addition, private insurers often follow the coverage and reimbursement policies of Medicare. Consequently, Medicare's coverage and reimbursement policies are important to our operations.

CMS has established Medicare reimbursement codes describing atherectomy products and procedures using atherectomy products. We believe that physicians and hospitals that treat PAD with the PAD Systems will generally be eligible to receive reimbursement from Medicare and private insurers for the cost of the single-use catheter and the physician's services.

### **Competition**

The medical device industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other activities of industry participants. The PAD Systems compete with a variety of other products or devices for the treatment of vascular disease, including stents, balloon angioplasty catheters and atherectomy catheters, as well as products used in vascular surgery. Large competitors in the stent and balloon angioplasty market segments include Abbott Laboratories, Boston Scientific, Cook Medical, Johnson & Johnson and Medtronic. We also compete against manufacturers of atherectomy catheters including, among others, Covidien, Spectranetics, Boston Scientific and MEDRAD, a business of Bayer HealthCare, as well as other manufacturers that may enter the market due to the increasing demand for treatment of vascular disease. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of mild to moderate PAD and companies that provide products used by surgeons in peripheral bypass procedures. We are not aware of any competing catheter systems either currently on the market or in development that also use an orbital motion to create lumens larger than the catheter itself.

Because of the size of the peripheral opportunities, competitors and potential competitors have historically dedicated significant resources to aggressively promote their products. We believe that the PAD Systems compete primarily on the basis of:

safety and efficacy;

predictable clinical performance;

ease of use;

price;

physician relationships;

customer service and support; and

adequate third-party reimbursement.

### **Patents and Intellectual Property**

## Edgar Filing: Cardiovascular Systems Inc - Form 10-K

We rely on a combination of patent, copyright and other intellectual property laws, trade secrets, nondisclosure agreements and other measures to protect our proprietary rights. As of July 31, 2012, we held 24 issued U.S. patents and have 28 U.S. patent applications pending, as well as 85 issued or granted foreign patents

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and 123 foreign patent applications, each of which corresponds to aspects of our U.S. patents and applications. Our issued U.S. patents expire between 2012 and 2032, and our most important patent, U.S. Patent No. 6,494,890, is due to expire in 2017. Our issued patents and patent applications relate primarily to the design and operation of certain interventional atherectomy devices, including the PAD Systems. These patents and applications include claims covering key aspects of certain rotational atherectomy devices, including the design, manufacture and therapeutic use of certain atherectomy abrasive heads, drive shafts, control systems, handles and couplings. As we continue to research and develop our atherectomy technology, we intend to file additional U.S. and foreign patent applications related to the design, manufacture and therapeutic uses of atherectomy devices. In addition, we hold 12 registered U.S. trademarks, six registered marks in Europe, five registered marks in Canada, one registered mark in Mexico, and five U.S. trademark applications pending.

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information and other intellectual property by requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement. Agreements with our employees also forbid them from bringing the proprietary rights of third parties to us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

### **Government Regulation of Medical Devices**

Governmental authorities in the United States at the federal, state and local levels and in other countries extensively regulate, among other things, the development, testing, manufacture, labeling, promotion, advertising, distribution, marketing and export and import of medical devices such as the PAD Systems.

Failure to obtain approval to market our products under development and to meet the ongoing requirements of these regulatory authorities could prevent us from marketing and continuing to market our products.

#### ***United States***

The Federal Food, Drug, and Cosmetic Act, or FDCA, and the FDA's implementing regulations govern medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Medical devices and their manufacturers are also subject to inspection by the FDA. The FDCA, supplemented by other federal and state laws, also provides civil and criminal penalties for violations of its provisions. We manufacture and market medical devices that are regulated by the FDA, comparable state agencies and regulatory bodies in other countries.

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require marketing authorization from the FDA prior to distribution. The two primary types of FDA marketing authorization are premarket notification (also called 510(k) clearance) and premarket approval (also called PMA approval). The type of marketing authorization applicable to a device—510(k) clearance or PMA approval—is generally linked to classification of the device. The FDA classifies medical devices into one of three classes (Class I, II or III) based on the degree of risk FDA determines to be associated with a device and the extent of control deemed necessary to ensure the device's safety and effectiveness. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are deemed to pose the least risk and are subject only to general controls applicable to all devices, such as requirements for device labeling, premarket notification, and adherence to the FDA's current good manufacturing practice requirements, as reflected in its Quality System Regulation, or QSR. Class II devices are intermediate risk devices that are subject to general controls and may also be subject to special controls such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or postmarket surveillance. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls, and include life-sustaining, life-supporting or implantable devices, and devices not substantially equivalent to a device that is already legally marketed.



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Most Class I devices and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from FDA. Class I and Class II devices that have not been so exempted are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require PMA approval prior to commercial marketing. The PMA approval process is generally more stringent, time-consuming and expensive than the 510(k) clearance process.

*510(k) Clearance.* To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is substantially equivalent to a predicate device legally marketed in the United States. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics or (ii) different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. A showing of substantial equivalence sometimes, but not always, requires clinical data. Generally, the 510(k) clearance process can exceed 90 days and may extend to a year or more.

After a device has received 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, such as a significant change in the design, materials, method of manufacture or intended use, will require a new 510(k) clearance or PMA approval (if the device as modified is not substantially equivalent to a legally marketed predicate device). The determination as to whether new authorization is needed is initially left to the manufacturer; however, the FDA may review this determination to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

We received 510(k) clearance for use of the Diamondback 360° as a therapy in patients with PAD in the United States on August 22, 2007. We received additional 510(k) clearances for the control unit used with the Diamondback 360° on October 25, 2007 and for the solid crown version of the Diamondback 360° on November 9, 2007. We were granted 510(k) clearance of the Predator 360° in March 2009 and Stealth 360° in March 2011.

*Premarket Approval.* A PMA application requires the payment of significant user fees and must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device. A PMA application must also include a complete description of the device and its components, a detailed description of the methods, facilities and controls used to manufacture the device, and proposed labeling. After a PMA application is submitted and found to be sufficiently complete, the FDA begins an in-depth review of the submitted information. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the FDA's Quality System Regulations, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures.

FDA review of a PMA application is required by statute to take no longer than 180 days, although the process typically takes significantly longer, and may require several years to complete. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

the systems may not be safe or effective to the FDA's satisfaction;

the data from preclinical studies and clinical trials may be insufficient to support approval;

the manufacturing process or facilities used may not meet applicable requirements; and

changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the



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satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device for certain indications. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Even if a PMA application is approved, the FDA may approve the device with an indication that is narrower or more limited than originally sought. The agency can also impose restrictions on the sale, distribution or use of the device as a condition of approval, or impose post approval requirements such as continuing evaluation and periodic reporting on the safety, efficacy and reliability of the device for its intended use.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling, device specifications, materials or design of a device that is approved through the PMA process. PMA approval supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application and may not require as extensive clinical data or the convening of an advisory panel.

We are currently enrolling patients in an FDA approved IDE trial to support a PMA to use the Diamondback 360° as a therapy in treating patients with calcified coronary artery disease. The FDA granted unconditional approval in April 2010 to begin the ORBIT II coronary trial in the United States. This pivotal trial is set up in two phases; Phase I allowed us to enroll up to 100 patients at as many as 50 U.S. sites, Phase II allows us to expand the trial to the full complement of 429 patients. In May 2011, we received approval from the FDA to complete enrollment of 429 patients in our ORBIT II clinical trial for a coronary application for the Diamondback 360°, which followed the FDA's review of data from the first 50 cases in the ORBIT II trial. In July 2012 we received approval from the FDA to include the new electric coronary device (similar to Stealth 360° technology used in PAD and customized specifically for the coronary application), which improves ease of use. The FDA requires 100 enrollments with the new electric coronary device and will allow up to 50 additional patients in the trial, as needed, to achieve that enrollment level, bringing the maximum trial enrollment to 479. More than 350 patients are now enrolled in the trial

*Clinical Trials.* Clinical trials are almost always required to support a PMA application and are sometimes required for a 510(k) clearance. These trials generally require submission of an application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites.

FDA approval of an IDE allows clinical testing to go forward but does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria. With certain exceptions, changes made to an investigational plan after an IDE is approved must be submitted in an IDE supplement and approved by FDA (and by governing institutional review boards when appropriate) prior to implementation.

All clinical trials must be conducted in accordance with regulations and requirements collectively known as good clinical practice. Good clinical practices include the FDA's IDE regulations, which describe the conduct of clinical trials with medical devices, including the recordkeeping, reporting and monitoring responsibilities of sponsors and investigators, and labeling of investigation devices. They also prohibit promotion, test marketing or commercialization of an investigational device and any representation that such a device is safe or effective for the purposes being investigated. Good clinical practices also include the FDA's regulations for institutional review board approval and for protection of human subjects (such as informed consent), as well as disclosure of financial interests by clinical investigators.

Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered

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sufficient for the FDA to grant approval or clearance of a product. The commencement or completion of any clinical trials may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a premarket notification for numerous reasons, including, but not limited to, the following:

the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial (or a change to a previously approved protocol or trial that requires approval), or place a clinical trial on hold;

patients do not enroll in clinical trials or follow up at the rate expected;

patients do not comply with trial protocols or experience greater than expected adverse side effects;

institutional review boards and third-party clinical investigators may delay or reject the trial protocol or changes to the trial protocol;

third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreements, good clinical practices or other FDA requirements;

third-party organizations do not perform data collection and analysis in a timely or accurate manner;

regulatory inspections of the clinical trials or manufacturing facilities, which may, among other things, require corrective action or suspension or termination of the clinical trials;

changes in governmental regulations or administrative actions;

the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and

the FDA concludes that the trial design is inadequate to demonstrate safety and efficacy.

*Continuing Regulation.* After a device is approved and placed in commercial distribution, numerous regulatory requirements continue to apply. These include:

establishment registration and device listing upon the commencement of manufacturing;

the QSR, which requires manufacturers, including third-party manufacturers, to follow design, testing, control, documentation and other quality assurance procedures during medical device design and manufacturing processes;

labeling regulations, which prohibit the promotion of products for unapproved or off-label uses and impose other restrictions on labeling and promotional activities;

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medical device reporting regulations, which require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if malfunctions were to recur;

corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections; and

product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health.

In addition, the FDA may require a company to conduct postmarket surveillance studies or order it to establish and maintain a system for tracking its products through the chain of distribution to the patient level.

Failure to comply with applicable regulatory requirements, including those applicable to the conduct of clinical trials, can result in enforcement action by the FDA, which may lead to any of the following sanctions:

warning letters or untitled letters;

fines, injunctions and civil penalties;

product recall or seizure;

unanticipated expenditures;

delays in clearing or approving or refusal to clear or approve products;

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withdrawal or suspension of FDA approval;

orders for physician notification or device repair, replacement or refund;

operating restrictions, partial suspension or total shutdown of production or clinical trials; and

criminal prosecution.

We and our contract manufacturers, specification developers and suppliers are also required to manufacture our products in compliance with current Good Manufacturing Practice, or GMP, requirements set forth in the QSR.

The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing and record keeping. The FDA enforces the QSR through periodic announced and unannounced inspections that may include the manufacturing facilities of subcontractors. If the FDA believes that we or any of our contract manufacturers or regulated suppliers is not in compliance with these requirements, it can shut down our manufacturing operations, require recall of our products, refuse to clear or approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees. Any such action by the FDA would have a material adverse effect on our business.

***Fraud and Abuse***

Our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the FDCA, federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, these laws require us to screen individuals and other companies, suppliers and vendors in order to ensure that they are not debarred by the federal government and therefore prohibited from doing business in the healthcare industry.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Various states have also enacted laws modeled after the federal False Claims Act.

In addition to the laws described above, the Health Insurance Portability and Accountability Act of 1996 created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Voluntary industry codes, federal guidance documents and a variety of state laws address the tracking and reporting of marketing practices relative to gifts given and other expenditures made to doctors and other healthcare professionals. In addition to impacting our marketing and educational programs, internal business processes will be affected by the numerous legal requirements and regulatory guidance at the state, federal and industry levels.



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### ***International Regulation***

International sales of medical devices are subject to foreign government regulations, which may vary substantially from country to country. The time required to obtain approval in a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ. For example, the primary regulatory environment in Europe with respect to medical devices is that of the European Union, which includes most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the European Union, although actual implementation of these directives may vary on a country-by-country basis. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of submission of a design dossier, self-assessment by the manufacturer, a third-party assessment and, review of the design dossier by a Notified Body. This third-party assessment generally consists of an audit of the manufacturer's quality system and manufacturing site, as well as review of the technical documentation used to support application of the CE Mark to one's product and possibly specific testing of the manufacturer's product. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. We obtained CE marking approval for sale of the Diamondback 360° in May 2005.

### **Environmental Regulation**

Our operations are subject to regulatory requirements relating to the environment, waste management and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal and remediation of hazardous substances. We are currently classified and licensed as a Very Small Quantity Hazardous Waste Generator within Ramsey County, Minnesota. There are no regulated wastes requiring licensing in our Texas facility.

### **Employees**

As of June 30, 2012, we had 290 employees, including 69 employees in manufacturing, 162 employees in sales, 10 employees in marketing, 13 employees in clinical, 21 employees in general and administrative, and 15 employees in research and development, all of which are full-time employees. None of our employees are represented by a labor union or are parties to a collective bargaining agreement, and we believe that our employee relations are good.

### **Item 1A. Risk Factors.**

#### **Risks Relating to Our Business and Operations**

***We have a history of net losses and a short commercialization experience, and we are likely to continue to incur losses.***

We are not profitable and have incurred net losses in each fiscal year since our formation in 1989. In particular, we had net losses of \$16.8 million in fiscal 2012, \$11.1 million in fiscal 2011, and \$23.9 million in fiscal 2010. As of June 30, 2012, we had an accumulated deficit of approximately \$179.2 million. We commenced commercial sales of the Diamondback 360° in September 2007, and our short commercialization experience makes it difficult for us to predict future performance. We also expect to incur significant additional expenses for sales and marketing and manufacturing as we continue to commercialize the PAD Systems and additional expenses as we seek to develop and commercialize future versions of the PAD Systems, a coronary application for our technology, and other products. Additionally, we expect that our general and administrative expenses will increase as our business grows. As a result, our operating losses are likely to continue.



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### ***We may be unable to sustain our revenue growth.***

Our revenue has grown in each of the fiscal years since we commenced commercial sales of the Diamondback 360° in September 2007. Our ability to continue to increase our revenues in future periods will depend on our ability to increase sales of the PAD Systems and new and improved products we introduce, including growing our customer base and reorders of the PAD Systems from those customers, and obtaining new applications for our technology. We may not be able to generate, sustain or increase revenues on a quarterly or annual basis. If we cannot achieve or sustain revenue growth for an extended period, our financial results will be adversely affected and our stock price may decline.

### ***Economic conditions may adversely affect our business.***

Adverse worldwide economic conditions may have adverse implications on our business. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in our receivable collections and additional allowances may be required, which could adversely affect our operating results. Adverse worldwide economic conditions may also adversely impact our suppliers' ability to provide us with materials and components, which could adversely affect our business and operating results.

### ***The PAD Systems and future products may never achieve broad market acceptance.***

The PAD Systems and future products we may develop may never gain broad market acceptance among physicians, patients and the medical community. The degree of market acceptance of any of our products will depend on a number of factors, including:

the actual and perceived effectiveness and reliability of our products;

the prevalence and severity of any adverse patient events involving our products;

the results of any clinical trials relating to use of our products;

the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for conditions treated by our products;

the degree to which treatments using our products are approved for reimbursement by public and private insurers;

the degree to which physicians adopt the PAD Systems;

the extent to which we are successful in educating physicians about PAD in general and the existence of the PAD Systems in particular;

the strength of our marketing and distribution infrastructure; and

the level of education and awareness among physicians and hospitals concerning our products.

Failure of the PAD Systems to significantly penetrate current or new markets would negatively impact our business, financial condition and results of operations.

***Our customers may not be able to achieve adequate reimbursement for using the PAD Systems, which could affect the acceptance of our products and cause our business to suffer.***

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The availability of insurance coverage and reimbursement for newly approved medical devices and procedures is uncertain. The commercial success of our products is substantially dependent on whether third-party insurance coverage and reimbursement for the use of such products and related services are available. We expect the PAD Systems to generally be purchased by hospitals and other providers who will then seek reimbursement from various public and private third-party payors, such as Medicare, Medicaid and private insurers, for the services provided to patients. We can give no assurance that these third-party payors will provide adequate reimbursement for use of the PAD Systems to permit hospitals and doctors to consider the products cost-effective for patients requiring PAD treatment, or that current reimbursement levels for the PAD Systems will continue. In addition, the overall amount of reimbursement available for PAD treatment could decrease in the future. Failure by hospitals and other users of our products to obtain sufficient reimbursement could cause our business to suffer.

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Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement, and, as a result, they may not cover or provide adequate payment for use of the PAD Systems. In order to position the PAD Systems for acceptance by third-party payors, we may have to agree to lower prices than we might otherwise charge.

Governmental and private sector payors have instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. It is uncertain whether the PAD Systems or any future products we may develop will be viewed as sufficiently cost-effective to warrant adequate coverage and reimbursement levels.

If third-party coverage and reimbursement for the PAD Systems is limited or not available, the acceptance of the PAD Systems and, consequently, our business will be substantially harmed.

### ***Healthcare reform legislation could adversely affect our operating results and financial condition.***

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control healthcare costs and, more generally, to reform the U.S. healthcare system, some of which have been enacted into law, such as the Patient Protection and Affordable Care Act, or the Patient Act. Certain of these proposals and laws could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. The Patient Act also imposes significant new taxes on medical device makers. The adoption of some or all of these proposals, including the recent federal legislation, could adversely affect our revenue and financial condition.

### ***We have limited data and experience regarding the safety and efficacy of the PAD Systems. Any long-term data that is generated may not be positive or consistent with our limited short-term data, which would affect market acceptance of these products.***

Because our technology is relatively new in the treatment of PAD, we have performed clinical trials only with limited patient populations. The long-term effects of using the PAD Systems in a large number of patients are not known and the results of short-term clinical use of the PAD Systems do not necessarily predict long-term clinical benefit or reveal long-term adverse effects.

Clinical trials conducted with the PAD Systems have involved procedures performed by physicians who are very technically proficient. Consequently, both short and long-term results reported in these studies may be significantly more favorable than typical results achieved by physicians, which could negatively impact market acceptance of the PAD Systems.

### ***We face significant competition, must innovate to stay competitive, and may be unable to sell the PAD Systems at profitable levels.***

The market for medical devices is highly competitive, dynamic and marked by rapid and substantial technological development and product innovations. Our ability to compete depends on our ability to innovate successfully, and while certain barriers exist to entry into our market we cannot assure that new entrants or existing competitors will not be able to develop products that compete directly with our products. We compete against very large and well-known stent and balloon angioplasty device manufacturers, atherectomy catheter manufacturers, pharmaceutical companies, and companies that provide products used by surgeons in peripheral bypass procedures. We may have difficulty competing effectively with these competitors because of their well-established positions in the marketplace, significant financial and human capital resources, established reputations and worldwide distribution channels.

Our competitors may:

develop and patent processes or products earlier than we will;

obtain regulatory clearances or approvals for competing medical device products more rapidly than we will;

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market their products more effectively than we will; or

develop more effective or less expensive products or technologies that render our technology or products obsolete or non-competitive. We have encountered and expect to continue to encounter potential customers who, due to existing relationships with our competitors, are committed to or prefer the products offered by these competitors. If we are unable to compete successfully, our revenue will suffer. Increased competition might lead to price reductions and other concessions that might adversely affect our operating results. Competitive pressures may decrease the demand for our products and could adversely affect our financial results.

***We have limited commercial manufacturing experience and could experience difficulty in producing the PAD Systems or will need to depend on third parties to manufacture the products.***

We have limited experience in commercially manufacturing the PAD Systems and have no experience manufacturing these products in the volume that we anticipate will be required if we achieve planned levels of commercial sales. As a result, we may not be able to develop and implement efficient, low-cost manufacturing capabilities and processes that will enable us to manufacture the PAD Systems or future products in significant volumes, while meeting the legal, regulatory, quality, price, durability, engineering, design and production standards required to market our products successfully.

The forecasts of demand we use to determine order quantities and lead times for components purchased from outside suppliers may be incorrect. Failure to obtain required components or subassemblies when needed and at a reasonable cost would adversely affect our business.

In addition, we may in the future need to depend upon third parties to manufacture the PAD Systems and future products. Any difficulties in locating and hiring third-party manufacturers, or in the ability of third-party manufacturers to supply quantities of our products at the times and in the quantities we need, could have a material adverse effect on our business.

***We depend upon third-party suppliers, including single source suppliers to us and our customers, making us vulnerable to supply problems and price fluctuations.***

We rely on third-party suppliers to provide us with certain components of our products and to provide key components or supplies to our customers for use with our products. We rely on single source suppliers for certain components of the PAD Systems. We depend on our suppliers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand and our customers' demands.

Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components used in our products would limit our ability to manufacture our products and could have a material adverse effect on our business, financial condition and results of operations.

***We may need to increase the size of our organization and we may experience difficulties managing growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected.***

The growth we may experience in the future may provide challenges to our organization, requiring us to rapidly expand our sales and marketing personnel and manufacturing operations. Rapid expansion in personnel may result in less experienced people producing and selling our products, which could result in unanticipated costs and disruptions to our operations. If we cannot scale and manage our business appropriately, our anticipated growth may be impaired and our financial results will suffer.

***We may require additional financing, and our failure to obtain additional financing when needed could force us to delay, reduce or eliminate our product development programs or commercialization efforts.***

We may be dependent on additional financing to execute our business plan. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available on a

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timely basis, we may terminate or delay the development of one or more of our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products.

In the event we need or desire additional financing, we may be unable to obtain it by borrowing money in the credit markets or raising money in the capital markets.

### ***We face a risk of non-compliance with the financial covenants in our loan and security agreements with Silicon Valley Bank and Partners for Growth.***

We are party to loan and security agreements with Silicon Valley Bank and Partners for Growth. These agreements require us to maintain, among other things, a monthly specified liquidity ratio and a monthly adjusted earnings before interest, taxes, depreciation and amortization, or EBITDA, level. The agreements contain customary events of default, including, among others, the failure to comply with certain covenants or other agreements. Upon the occurrence and during the continuation of an event of default, amounts due under the agreements may be accelerated by Silicon Valley Bank or Partners for Growth. If we are unable to meet the financial or other covenants under the current loan and security agreements or negotiate future waivers or amendments of such covenants, events of default could occur under the agreements. Upon the occurrence and during the continuance of an event of default under the agreements, Silicon Valley Bank and Partners for Growth have available a range of remedies customary in these circumstances, including declaring all outstanding debt, together with accrued and unpaid interest thereon, to be due and payable, foreclosing on the assets securing the agreements and/or ceasing to provide additional loans, which could have a material adverse effect on us.

The restrictive covenants under these agreements could limit our ability to obtain future financing, withstand a future downturn in our business or the economy in general or otherwise conduct necessary corporate activities. The financial and restrictive covenants contained in the agreements could also adversely affect our ability to respond to changing economic and business conditions and place us at a competitive disadvantage relative to other companies that may be subject to fewer restrictions. Transactions that we may view as important opportunities, such as acquisitions, may be subject to the consent of Silicon Valley Bank and Partners for Growth, which consents may be withheld or granted subject to conditions specified at the time that may affect the attractiveness or viability of the transaction.

### ***We are dependent on our senior management team and highly skilled personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.***

We are highly dependent on our senior management. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including scientists, clinicians, engineers and other highly skilled personnel and to integrate current and additional personnel in all departments. The loss of members of our senior management, scientists, clinical and regulatory specialists, engineers and sales personnel could prevent us from achieving our objectives of continuing to grow the Company. We do not carry key person life insurance on any of our employees.

### ***Our stock price is volatile and subject to significant fluctuations.***

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, medical device, biotechnology and other life sciences companies have historically been particularly volatile. Our common stock traded as low as \$7.26 and as high as \$16.25 per share during the 12-month period ended June 30, 2012. Factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

announcements of technological or medical innovations for the treatment of vascular disease;

quarterly variations in our or our competitors' results of operations;

failure to meet estimates or recommendations by securities analysts who cover our stock;

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accusations that we have violated a law or regulation;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;

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changes in accounting principles; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

### **Risks Related to Government Regulation**

*Our ability to market the PAD Systems in the United States is limited to use as a therapy in patients with PAD, and if we want to expand our marketing claims, we will need to file for additional FDA clearances or approvals and conduct further clinical trials, which would be expensive and time consuming and may not be successful.*

The PAD Systems received FDA 510(k) clearances in the United States for use as a therapy in patients with PAD. This general clearance restricts our ability to market or advertise the PAD Systems beyond this use and could affect our growth.

If we determine to market our orbital technology in the United States for other uses, for instance, use in the coronary arteries, we would need to conduct further clinical trials and obtain premarket approval from the FDA. Clinical trials are complex, expensive, time consuming, uncertain and subject to substantial and unanticipated delays. Any delays in receiving, or failure to receive, FDA approval for a coronary application for the Diamondback 360° would delay or prevent us from accessing a substantial market segment and would have a substantial adverse effect on our potential future revenue.

*The PAD Systems may in the future be subject to product recalls that could harm our reputation and product liability claims that could exceed the limits of available insurance coverage.*

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. Any recalls of our products or products that we distribute would divert managerial and financial resources, harm our reputation with customers and have an adverse effect on our financial condition and results of operations.

Also, if the PAD Systems are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation by our customers or their patients. The use, misuse or off-label use of the PAD Systems may result in injuries that lead to product liability suits, which could be costly to our business. We cannot prevent a physician from using the PAD Systems for off-label applications. While we have product liability insurance coverage for our products and intend to maintain such insurance coverage in the future, there can be no assurance that we will be adequately protected from the claims that will be brought against us.

*We are subject to many laws and governmental regulations and any adverse regulatory action may materially adversely affect our financial condition and business operations.*

The PAD Systems and related manufacturing processes, clinical data, adverse events, recalls or corrections and promotional activities are subject to extensive regulation by the FDA and other regulatory bodies. In particular, we are required to comply with the FDA's Quality System Regulation, or QSR, and other regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing clearance or approval. We are also responsible for the quality of components received by our suppliers. Failure to comply with the QSR requirements or other statutes and regulations administered by the FDA and other regulatory bodies, or failure to adequately respond to any observations, could result in, among other things:

warning or other letters from the FDA;

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finances, injunctions and civil penalties;

product recall or seizure;

unanticipated expenditures;

delays in clearing or approving or refusal to clear or approve products;

withdrawal or suspension of approval or clearance by the FDA or other regulatory bodies;

orders for physician notification or device repair, replacement or refund;

operating restrictions, partial suspension or total shutdown of production or clinical trials; and

criminal prosecution.

If any of these actions were to occur, it would harm our reputation and cause our product sales to suffer.

Our operations are also subject to regulatory requirements relating to the environment, waste management and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal and remediation of hazardous substances. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations.

In addition, our relationships with physicians, hospitals and the marketers of our products are subject to scrutiny under various federal anti-kickback, self-referral, false claims and similar laws, often referred to collectively as healthcare fraud and abuse laws.

If our operations are found to be in violation of these laws, we, as well as our employees, may be subject to penalties, including monetary fines, civil and criminal penalties, exclusion from federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs, workers' compensation programs and TRICARE (the healthcare system administered by or on behalf of the U.S. Department of Defense for uniformed services beneficiaries, including active duty and their dependents, retirees and their dependents), and forfeiture of amounts collected in violation of such prohibitions, which could materially adversely affect our financial condition and business operations.

### **Risks Relating to Our Intellectual Property**

***Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technology, which could substantially impair our ability to compete.***

Our success and ability to compete depends, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patents, copyrights and trademarks, as well as trade secrets and nondisclosure agreements, to protect our intellectual property. Our issued patents and related intellectual property may not be adequate to protect us or permit us to gain or maintain a competitive advantage. Also, we cannot assure you that any of our pending patent applications will result in the issuance of patents to us. Further, if any patents we obtain or license are deemed invalid and unenforceable, or have their scope narrowed, it could impact our ability to commercialize or license our technology.

Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, if at all.



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We may, in the future, need to assert claims of infringement against third parties to protect our intellectual property. The outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is highly unpredictable, could result in substantial costs and diversion of resources, and could have a material adverse effect on our financial condition, reputation and results of operations regardless of the final outcome of such litigation.

Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not be successful in doing so or the steps taken by us in this regard may not be adequate to detect or deter

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misappropriation of our technology or to prevent an unauthorized third party from copying or otherwise obtaining and using our products, technology or other information that we regard as proprietary. In addition, we may not have sufficient resources to litigate, enforce or defend our intellectual property rights. Additionally, third parties may be able to design around our patents.

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. In this regard, we seek to protect our proprietary information and other intellectual property by having a policy that our employees, consultants, contractors, outside scientific collaborators and other advisors execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement. We cannot provide any assurance that employees and third parties will abide by the confidentiality or assignment terms of these agreements, or that we will be effective in securing necessary assignments from these third parties.

***Claims of infringement or misappropriation of the intellectual property rights of others could prohibit us from commercializing products, require us to obtain licenses from third parties or require us to develop non-infringing alternatives, and subject us to substantial monetary damages and injunctive relief.***

The medical technology industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. The likelihood that patent infringement or misappropriation claims may be brought against us increases as we achieve more visibility in the marketplace and introduce products to market. We are aware of numerous patents issued to third parties that relate to the manufacture and use of medical devices for interventional cardiology. The owners of each of these patents could assert that the manufacture, use or sale of our products infringes one or more claims of their patents. There could also be existing patents of which we are unaware that one or more aspects of our technology may inadvertently infringe. In some cases, litigation may be threatened or brought by a patent-holding company or other adverse patent owner who has no relevant product revenues and against whom our patents may provide little or no deterrence.

Any infringement or misappropriation claim could cause us to incur significant costs, place significant strain on our financial resources, divert management's attention from our business and harm our reputation. If the relevant patents were upheld in litigation as valid and enforceable and we were found to infringe, we could be prohibited from commercializing any infringing products unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain a license on terms acceptable to us, if at all, and we may not be able to redesign any infringing products to avoid infringement.

### **Item 1B. *Unresolved Staff Comments.***

Not applicable.

### **Item 2. *Properties.***

Our principal executive offices are located in a 47,000 square foot facility located in St. Paul, Minnesota. We have leased this facility through November 2015 with an option to renew through November 2020. This facility accommodates our research and development, sales, marketing, manufacturing, finance and administrative activities.

In September 2009, we entered into an agreement to lease a 46,000 square foot production facility in Pearland, Texas beginning on April 1, 2010. We have leased this facility through March 2020. This facility primarily accommodates additional manufacturing activities.

We believe that our current premises are substantially adequate for our current and anticipated future needs for the foreseeable future.

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**Item 3. *Legal Proceedings.***

***Dr. Leonid Shturman Claim***

On October 27, 2009, Dr. Leonid Shturman, CSI-MN's founder, filed a complaint (the First Action) in the U.S. District Court in Minnesota (the Court) against us. The First Action asserted that our filing of an action in Switzerland against Dr. Shturman violated provisions of a settlement agreement that we and Dr. Shturman entered into in September 2008. The 2008 settlement resolved a lawsuit we had brought against Dr. Shturman for breach of his employment agreement with us. Dr. Shturman's complaint sought an award of damages and injunctive relief to bar us from litigating the action in Switzerland. Dr. Shturman died subsequent to the filing of the complaint. Within three months of Dr. Shturman's death, demands for settlement were made on behalf of the sole heir of Dr. Shturman's estate, his wife, Lela Nadirashvili (Mrs. Shturman). Mrs. Shturman filed a writ to dismiss our patent lawsuit in Switzerland based on res judicata and collateral estoppel (the Switzerland Action). The judge ruled in our favor regarding the requested writ. The Switzerland Action subsequently settled. Under the settlement, Mrs. Shturman assigned the patent application in issue to us in exchange for our forgiveness of approximately \$3,000 in costs Mrs. Shturman had been ordered to pay.

In early 2011, the Court issued an order requesting counsel for Dr. Shturman to advise the Court regarding the status of the First Action. Subsequent to the Court's order, Mrs. Shturman again began making demands for money in exchange for Dr. Shturman's alleged patent portfolio. We again declined Mrs. Shturman's demands but instead made our own offer of settlement. Counsel for Mrs. Shturman rejected the offer and instead informed us that they intended to file an amended complaint in the U.S. District Court in Minnesota.

On August 24, 2011, Mrs. Shturman filed a claim against us in the Court seeking a declaration that she is the true owner of certain counterweight patent applications, as well as compensation for wrongful actions she alleges we perpetrated against her and harm resulting from our alleged wrongful actions (the Second Action). We filed a motion to dismiss the Second Action on October 20, 2011. In December 2011, the Court dismissed the Second Action. The Court found that it did not have jurisdiction over the Second Action and did not address the merits of the claims.

In February 2012, Mrs. Shturman re-filed her lawsuit in Hennepin County District Court (the Third Action). We removed the Third Action to federal court. In the Third Action, Mrs. Shturman sought a declaration that she is the sole owner of six United States patents that have issued naming Dr. Leonid Shturman as the sole inventor. In addition, Mrs. Shturman asserted claims for slander of title, tortious interference with prospective business relations, and unfair competition. Mrs. Shturman sought an unspecified sum of damages. We asserted counterclaims seeking a declaration that the patents are invalid, imposition of a constructive trust, and unjust enrichment damages. The parties settled the Third Action on August 27, 2012, resolving all claims and disputes between them.

***Michael Kallok Claim***

On July 18, 2011, we received a demand letter from legal counsel for Michael Kallok, a former officer, director and consultant to us, claiming that Mr. Kallok is entitled to 42,594 shares of our common stock or, alternatively, the value of those shares as of July 15, 2011, which was \$610,798. Mr. Kallok asserts that we improperly deemed such shares forfeited under a restricted stock agreement with Mr. Kallok. This matter is proceeding to arbitration, which is scheduled to take place on September 10 and 11, 2012.

We are defending this claim vigorously, and believe that an adverse outcome of this dispute would not have a materially adverse effect on our business, operations, cash flows or financial condition. We have not recognized any expense related to the settlement of this matter as we believe an adverse outcome of this action is not probable.

**Item 4. *Mine Safety Disclosures.***

None.

**Table of Contents****Executive Officers of the Registrant.**

The names, ages and positions of our executive officers are as follows:

<b>Name</b>	<b>Age</b>	<b>Position</b>
David L. Martin	48	President and Chief Executive Officer
Laurence L. Betterley	58	Chief Financial Officer
James E. Flaherty	58	Chief Administrative Officer and Secretary
Kevin Kenny	47	Executive Vice President of Sales and Marketing
Paul Koehn	49	Vice President of Quality and Operations
Robert J. Thatcher	57	Executive Vice President

*David L. Martin, President and Chief Executive Officer.* Mr. Martin has been our President and Chief Executive Officer since February 2007, and a director since August 2006. Mr. Martin also served as our Interim Chief Financial Officer from January 2008 to April 2008. Prior to joining us, Mr. Martin was Chief Operating Officer of FoxHollow Technologies, Inc. from January 2004 to February 2006, Executive Vice President of Sales and Marketing of FoxHollow Technologies, Inc. from January 2003 to January 2004, Vice President of Global Sales and International Operations at CardioVenton Inc. from October 2001 to May 2002, Vice President of Global Sales for RITA Medical Systems, Inc. from March 2000 to October 2001 and Director of U.S. Sales, Cardiac Surgery for Guidant Corporation from September 1999 to March 2000. Mr. Martin has also held sales and sales management positions for The Procter & Gamble Company and Boston Scientific Corporation.

*Laurence L. Betterley, Chief Financial Officer.* Mr. Betterley joined us in April 2008 as our Chief Financial Officer. Previously, Mr. Betterley was Chief Financial Officer at Cima NanoTech, Inc. from May 2007 to April 2008, Senior Vice President and Chief Financial Officer of PLATO Learning, Inc. from June 2004 to January 2007, Senior Vice President and Chief Financial Officer of Diametrics Medical, Inc. from 1996 to 2003, and Chief Financial Officer of Cray Research Inc. from 1994 to 1996.

*James E. Flaherty, Chief Administrative Officer and Secretary.* Mr. Flaherty has been our Chief Administrative Officer since January 14, 2008. Mr. Flaherty was our Chief Financial Officer from March 2003 to January 14, 2008. As Chief Administrative Officer, Mr. Flaherty reports directly to our Chief Executive Officer and has responsibility for information technology, facilities, legal matters, financial analysis of business development opportunities and business operations. Prior to joining us, Mr. Flaherty served as an independent financial consultant from 2001 to 2003 and Chief Financial Officer of Zomax Incorporated from 1997 to 2001 and Racotek, Inc. from 1990 to 1996. On June 9, 2005, the Securities and Exchange Commission filed a civil injunctive action charging Zomax Incorporated with violations of federal securities law by filing a materially misstated Form 10-Q for the period ended June 30, 2000. The SEC further charged that in a conference call with analysts, certain of Zomax's executive officers, including Mr. Flaherty, misrepresented or omitted to state material facts regarding Zomax's prospects of meeting quarterly revenue and earnings targets, in violation of federal securities law. Without admitting or denying the SEC's charges, Mr. Flaherty consented to the entry of a court order enjoining him from any violation of certain provisions of federal securities law. In addition, Mr. Flaherty agreed to disgorge \$16,770 plus prejudgment interest and pay a \$75,000 civil penalty.

*Kevin Kenny, Executive Vice President of Sales and Marketing.* Mr. Kenny joined us in May 2011 as Executive Vice President of Sales and Marketing. From 2002 to 2011, Mr. Kenny served in various positions with Medtronic Inc.'s U.S. Spine and Biologics division, including Vice President of Sales. Previously, Mr. Kenny served as Vice President of U.S. sales for Bausch and Lomb and held various sales and marketing leadership roles with B. Braun/McGaw and Smithkline Beecham.

*Paul Koehn, Vice President of Quality and Operations.* Mr. Koehn joined us in March 2007 as Director of Manufacturing and was promoted to Vice President of Quality and Manufacturing in October 2007. In August 2011, Mr. Koehn became Vice President of Quality and Operations. Previously, Mr. Koehn was Vice President of Operations for Sewall Gear Manufacturing from 2000 to March 2007 and before joining Sewall Gear, Mr. Koehn held various quality and manufacturing management roles with Dana Corporation.

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*Robert J. Thatcher, Executive Vice President.* Mr. Thatcher joined us as Senior Vice President of Sales and Marketing in October 2005 and became Vice President of Operations in September 2006. Mr. Thatcher became Executive Vice President in August 2007. Previously, Mr. Thatcher was Senior Vice President of TriVirix Inc. from October 2003 to October 2005. Mr. Thatcher has more than 29 years of medical device experience in both large and start-up companies. Mr. Thatcher has held various sales management, marketing management and general management positions at Medtronic, Inc., Schneider USA, Inc. (a former division of Pfizer Inc.), Boston Scientific Corporation and several startup companies.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities. Price Range of Common Stock and Dividend Policy**

Prior to the closing of the merger on February 25, 2009, the stock of Replidyne was traded on the Nasdaq Global Market under the symbol RDYN. On February 26, 2009, the stock of CSI began trading on the Nasdaq Global Market under the symbol CSII. The following table sets forth the high and low sales prices for our common stock (based upon intra-day trading) as reported by the Nasdaq Global Market:

	Common Stock	
	High	Low
<b>Fiscal Year Ended June 30, 2012</b>		
First quarter	\$ 16.25	\$ 11.10
Second quarter	11.39	7.26
Third quarter	10.55	8.54
Fourth quarter	10.20	8.24
<b>Fiscal Year Ended June 30, 2011</b>		
First quarter	\$ 5.50	\$ 3.75
Second quarter	12.00	5.03
Third quarter	13.40	8.75
Fourth quarter	15.72	10.32

The number of record holders of our common stock on August 27, 2012 was approximately 540. No cash dividends have been previously paid on our common stock and none are anticipated during fiscal year 2012. We are restricted from paying dividends under our Loan and Security Agreements with Silicon Valley Bank and Partners for Growth.

**Recent Sales of Unregistered Securities**

On June 29, 2012, in connection with and as additional consideration for entering into a Second Amendment to Loan and Security Agreement (the Amendment) with Silicon Valley Bank (SVB), we issued a ten-year warrant to purchase 18,649 shares of our common stock to SVB, which warrant SVB immediately transferred to its parent company, SVB Financial Group. The warrant's exercise price was set at \$9.652 per share, which price was based on the five-day average closing share price of our common stock prior to the date of the Amendment. The warrant is filed as an exhibit to this annual report on Form 10-K. We issued the warrant pursuant to Section 4(2) of the Securities Act of 1933, as amended. SVB represented that it is an accredited investor.

**Issuer Purchases of Equity Securities**

None.

**Securities Authorized For Issuance Under Equity Compensation Plans**

For information on our equity compensation plans, refer to Item 12, Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

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**Performance Graph**

The graph below compares the five-year total return to stockholders on our common stock with the return of the Standard & Poor's 500 Stock Index ( S&P ) and the S&P Health Care Equipment Index ( S&P HCE ). The graph assumes \$100 was invested in the common stock of our predecessor company, Replidyne Inc., and in each of the named indices on December 31, 2007, and that all dividends were reinvested, if any. The graph reflects our Merger, as more fully described in Part I, Item 1 of this Annual Report on Form 10-K, and the effects of our 1-for-10 reverse stock split and our change in fiscal year from December 31 to June 30, both effective February 25, 2009.

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The following supplemental graph compares the five-year total return to stockholders of the common stock of Cardiovascular Systems, Inc., a Minnesota corporation ( CSI-MN ), with the return of the S&P and S&P HCE. The graph assumes \$100 was invested in the common stock of CSI-MN and in each of the named indices on December 31, 2007, and that all dividends were reinvested, if any. Please note that at 12/31/07 and 12/31/08, CSI-MN was a private company and the values presented are based on estimates of fair market value made by management of CSI-MN for accounting purposes. The graph reflects our Merger, in which each share of CSI-MN was converted into the right to receive 0.647 shares of CSI, and our change in fiscal year from December 31 to June 30, both effective February 25, 2009.



**Table of Contents****Item 6. Selected Financial Data.  
Five-Year Selected Financial Data**

(in thousands, except per share amounts)

	2012	2011	2010	2009	2008
<b>SUMMARY OF OPERATIONS FOR THE FISCAL YEAR:</b>					
Revenues	\$ 82,490	\$ 78,780	\$ 64,829	\$ 56,461	\$ 22,177
Loss from operations	\$ (14,466)	\$ (8,809)	\$ (22,899)	\$ (34,233)	\$ (38,144)
Net loss available to common stockholders	\$ (16,790)	\$ (11,125)	\$ (23,904)	\$ (31,895)	\$ (58,589)
Basic and diluted loss per share	\$ (0.93)	\$ (0.70)	\$ (1.62)	\$ (1.13)	\$ (13.25)
Cash dividends declared per share	\$	\$	\$	\$	\$
<b>FINANCIAL POSITION AT YEAR END:</b>					
Total assets	\$ 63,124	\$ 46,758	\$ 42,722	\$ 72,370	\$ 41,958
Total long-term liabilities	\$ 13,083	\$ 9,937	\$ 11,602	\$ 5,864	\$ 4,086
Stockholders' equity (deficiency)	\$ 32,189	\$ 21,635	\$ 17,715	\$ 30,332	\$ (81,692)

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**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*You should read the following discussion and analysis of financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this Form 10-K. This discussion and analysis contains forward-looking statements about our business and operations, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those we currently anticipate as a result of many important factors, including the factors we describe under Risk Factors and elsewhere in this Form 10-K.*

**OVERVIEW**

We are a medical device company focused on developing and commercializing interventional treatment systems for vascular disease. Our primary products, the Diamondback 360° PAD System ( Diamondback 360° ), Diamondback Predator 360° PAD System ( Predator 360° ) and Stealth 360° PAD System ( Stealth 360° ), are catheter-based platforms capable of treating a broad range of plaque types in arteries throughout the leg and address many of the limitations associated with existing treatment alternatives. We also intend to pursue approval of our products for coronary use. We refer to the Diamondback 360°, Predator 360° and Stealth 360° collectively in this report as the PAD Systems.

We were incorporated as Replidyne, Inc. in Delaware in 2000. On February 25, 2009, Replidyne, Inc. completed its business combination with Cardiovascular Systems, Inc., a Minnesota corporation ( CSI-MN ), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of November 3, 2008 (the Merger Agreement ). Pursuant to the Merger Agreement, CSI-MN continued after the merger as the surviving corporation and a wholly-owned subsidiary of Replidyne. Replidyne changed its name to Cardiovascular Systems, Inc. ( CSI ) and CSI-MN merged with and into CSI, with CSI continuing after the merger as the surviving corporation. These transactions are referred to herein as the merger. Unless the context otherwise requires, all references herein to the Company, CSI, we, us and our refer to CSI-MN the completion of the merger and to CSI following the completion of the merger and the name change, and all references to Replidyne refer to Replidyne prior to the completion of the merger and the name change. Replidyne was a biopharmaceutical company focused on discovering, developing, in-licensing and commercializing anti-infective products.

CSI was incorporated in Minnesota in 1989. From 1989 to 1997, we engaged in research and development on several different product concepts that were later abandoned. Since 1997, we have devoted substantially all of our resources to the development of the PAD Systems.

From 2003 to 2005, we conducted numerous bench and animal tests in preparation for application submissions to the FDA. We initially focused our testing on providing a solution for coronary in-stent restenosis, but later changed the focus to PAD. In 2006, we obtained an investigational device exemption from the FDA to conduct our pivotal OASIS clinical trial, which was completed in January 2007. The OASIS clinical trial was a prospective 20-center study that involved 124 patients with 201 lesions.

In August 2007, the FDA granted us 510(k) clearance for the use of the Diamondback 360° as a therapy in patients with PAD. We commenced commercial introduction of the Diamondback 360° in the United States in September 2007. We were granted 510(k) clearance of the Predator 360° in March 2009 and Stealth 360° in March 2011. We market the PAD Systems in the United States through a direct sales force and expend significant capital on our sales and marketing efforts to expand our customer base and utilization per customer. We assemble at our facilities the saline infusion pump used with our Stealth 360° product and the single-use catheter used in the PAD Systems with components purchased from third-party suppliers, as well as with components manufactured in-house. The control unit and guidewires are purchased from third-party suppliers.

As of June 30, 2012, we had an accumulated deficit of \$179.2 million. We expect our losses to continue in fiscal 2013 as we invest in sales, marketing, and clinical studies for our next phase of growth in the peripheral market and a potential coronary application. To date, we have financed our operations primarily from the issuance of common and preferred stock, convertible promissory notes, and debt.

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### **FINANCIAL OVERVIEW**

*Revenues.* We derive substantially all of our revenues from the sale of PAD Systems and other ancillary products. The PAD Systems each use a disposable, single-use, low-profile catheter that travels over our proprietary ViperWire guidewire. The air powered Diamondback 360° and Predator 360° PAD Systems use an external control unit that powers the system, while the electric powered Stealth 360° PAD System uses a saline infusion pump as a power supply for the operation of the catheter. Our ancillary products include the ViperSlide Lubricant and ViperTrack Radiopaque Tape. We also have an exclusive distribution agreement with Asahi to market its peripheral guide wire line in the United States.

*Cost of Goods Sold.* We assemble the single-use catheter with components purchased from third-party suppliers, as well as with components manufactured in-house. The control unit and guidewires are purchased from third-party suppliers. Our cost of goods sold consists primarily of raw materials, direct labor, and manufacturing overhead.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses include compensation for executive, sales, marketing, finance, information technology, human resources and administrative personnel, including stock-based compensation. Other significant expenses include travel and marketing costs and professional fees.

*Research and Development Expenses.* Research and development expenses include costs associated with the design, development, testing, enhancement and regulatory approval of our products. Research and development expenses include employee compensation including stock-based compensation, supplies and materials, patent expenses, consulting expenses, travel and facilities overhead. We also incur significant expenses to operate clinical trials, including trial design, third-party fees, clinical site reimbursement, data management and travel expenses. All research and development expenses are expensed as incurred. Approved patent applications are capitalized and amortized using the straight-line method over their remaining estimated lives. Patent amortization begins at the time of patent application approval, and does not exceed 20 years.

*Interest and Other Income (Expense).* Interest and other income (expense) primarily includes interest expense (including premium and discount amortization), interest income, change in the fair value of conversion option, debt refinancing costs, and net write-offs upon conversion (option and unamortized premium or discount).

*Interest Expense (Including Premium and Discount Amortization).* Interest expense results from outstanding debt balances, and debt premium and discount amortization.

*Interest Income.* Interest income is attributed to interest earned on deposits in investments that consist of money market funds.

*Change in Fair Value of Conversion Option.* Change in fair value of conversion option represents the period to period change in fair value of the conversion option associated with outstanding convertible debt.

*Net Write-offs Upon Conversion (Option and Unamortized Premium or Discount).* Net write-offs upon conversion (option and unamortized premium) are the result of the conversion of convertible debt, and include the write-off of the related conversion option and any unamortized debt premium or discount.

*Other.* Other consists of miscellaneous non-operating expenses, including state taxes.

*Net Operating Loss Carryforwards.* We have established valuation allowances to fully offset our deferred tax assets due to the uncertainty about our ability to generate the future taxable income necessary to realize these deferred assets, particularly in light of our historical losses. The future use of net operating loss carryforwards is dependent on us attaining profitable operations and will be limited in any one year under Internal Revenue Code Section 382 due to significant ownership changes (as defined in Section 382) resulting from our equity financings. At June 30, 2012, we had net operating loss carryforwards for federal and state income tax reporting purposes of approximately \$129.0 million, which will expire at various dates through fiscal 2032.



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**CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES**

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect amounts reported in those statements. Our estimates, assumptions and judgments, including those related to revenue recognition, allowance for doubtful accounts, excess and obsolete inventory, debt conversion option, stock-based compensation, and preferred stock warrants are updated as appropriate at least quarterly. We use authoritative pronouncements, our technical accounting knowledge, cumulative business experience, judgment and other factors in the selection and application of our accounting policies. While we believe that the estimates, assumptions and judgments that we use in preparing our consolidated financial statements are appropriate, these estimates, assumptions and judgments are subject to factors and uncertainties regarding their outcome. Therefore, actual results may materially differ from these estimates.

Some of our significant accounting policies require us to make subjective or complex judgments or estimates. An accounting estimate is considered to be critical if it meets both of the following criteria: (1) the estimate requires assumptions about matters that are highly uncertain at the time the accounting estimate is made, and (2) different estimates that reasonably could have been used, or changes in the estimate that are reasonably likely to occur from period to period, would have a material impact on the presentation of our financial condition, results of operations, or cash flows. We believe that the following are our critical accounting policies and estimates:

*Revenue Recognition.* We sell the majority of our products via direct shipment to hospitals or office-based labs. We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sales price is fixed or determinable; and collectability is reasonably assured. These criteria are generally met at the time of delivery when the risk of loss and title passes to the customer. We record estimated sales returns, discounts and rebates as a reduction of net sales in the same period revenue is recognized.

Costs related to products delivered are recognized in the period revenue is recognized. Cost of goods sold consists primarily of raw materials, direct labor, and manufacturing overhead.

*Allowance for Doubtful Accounts.* We maintain an allowance for doubtful accounts. This allowance is an estimate and is regularly evaluated for adequacy by taking into consideration factors such as past experience, credit quality of the customer base, age of the receivable balances, both individually and in the aggregate, and current economic conditions that may affect a customer's ability to pay. Provisions for the allowance for doubtful accounts attributed to bad debt are recorded in general and administrative expenses.

*Excess and Obsolete Inventory.* We have inventories that are principally comprised of capitalized direct labor and manufacturing overhead, raw materials and components, and finished goods. Due to the technological nature of our products, there is a risk of obsolescence to changes in our technology and the market, which is impacted by technological developments and events. Accordingly, we write down our inventories as we become aware of any situation where the carrying amount exceeds the estimated realizable value based on assumptions about future demands and market conditions. The evaluation includes analyses of inventory levels, expected product lives, product at risk of expiration, sales levels by product and projections of future sales demand.

*Debt Conversion Option.* The fair value of the conversion option is related to the loan and security agreement with Partners for Growth and has been included as a component of debt conversion option and other assets on our balance sheet. The Monte Carlo option pricing model used to determine the value of the conversion option includes various inputs including historical volatility, stock price simulations, and the assessed behavior of us and Partners for Growth based on those simulations.

*Stock-Based Compensation.* We recognize stock-based compensation expense in an amount equal to the fair value of share-based payments computed at the date of grant. The fair value of all restricted stock awards and units are expensed in the consolidated statements of operations over the related vesting period.

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All restricted stock awards and units we have granted become exercisable over periods established at the date of grant. The fair value of each restricted stock award and unit was equal to the fair market value of our common stock at the date of grant, as determined by management and the board of directors.

*Legal Proceedings.* In accordance with FASB guidance, we record a liability in our consolidated financial statements related to legal proceedings when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is possible, but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed in the notes to the consolidated financial statements. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded. Our significant legal proceedings are discussed in Note 12 to the consolidated financial statements.

**RESULTS OF OPERATIONS**

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts (in thousands), and, for certain line items, the changes between the specified periods expressed as percent increases or decreases:

	Year Ended June 30,			Year Ended June 30,		
	2012	2011	Percent Change	2011	2010	Percent Change
Revenues	\$ 82,490	\$ 78,780	4.7%	\$ 78,780	\$ 64,829	21.5%
Cost of goods sold	19,216	16,277	18.1	16,277	15,003	8.5
Gross profit	63,274	62,503	1.2	62,503	49,826	25.4
Expenses:						
Selling, general and administrative	66,366	62,372	6.4	62,372	62,447	(0.1)
Research and development	11,374	8,940	27.2	8,940	10,278	(13.0)
Total expenses	77,740	71,312	9.0	71,312	72,725	(1.9)
Loss from operations	(14,466)	(8,809)	64.2	(8,809)	(22,899)	(61.5)
Interest and other expense	(2,324)	(2,316)	0.3	(2,316)	(1,005)	130.4
Net loss	(16,790)	(11,125)	50.9	(11,125)	(23,904)	(53.5)

**Comparison of Fiscal Year Ended June 30, 2012 with Fiscal Year Ended June 30, 2011**

*Revenues.* Revenues increased by \$3.7 million, or 4.7%, from \$78.8 million for the year ended June 30, 2011 to \$82.5 million for the year ended June 30, 2012. This increase was primarily attributable to a \$3.7 million, or 5.4%, increase driven by increased average selling prices of PAD Systems during the year ended June 30, 2012 compared to the year ended June 30, 2011. Currently, all of our revenues are in the United States; however, we may potentially sell internationally in the future. We expect our revenue to increase as we continue to increase the number of physicians using the devices, and increase the usage per physician as we continue to focus on physician education programs, introduce new and improved products, and generate clinical data.

*Cost of Goods Sold.* Cost of goods sold increased by \$2.9 million, or 18.1%, from \$16.3 million for the year ended June 30, 2011 to \$19.2 million for the year ended June 30, 2012. These amounts represent the cost of materials, labor and overhead for single-use catheters, guidewires, control units, pumps, and other supplemental products. The decrease in gross margin from 79.3% during the year ended June 30, 2011 to 76.7% for the year ended June 30, 2012 was primarily due to a higher mix of Stealth 360° sales, which currently carry higher unit costs due to limited initial component purchasing volumes, and reserves for inventory transitions. Also, the addition of our second manufacturing facility in Texas for future production capacity has temporarily increased production costs but we believe will enhance efficiencies over time. Cost of goods sold for the years ended June 30, 2012 and 2011 includes \$296,000 and \$312,000, respectively, for stock-based compensation. We expect



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that gross margin in fiscal 2013 will be similar to fiscal 2012 as cost improvements made throughout the year will be offset by the 2.3% medical device tax, effective January 1, 2013. Quarterly fluctuations could occur based on production volumes, timing of new product introductions, sales mix, pricing changes, or other unanticipated circumstances.

*Selling, General and Administrative Expenses.* Selling, general, and administrative expense increased by \$4.0 million, or 6.4%, from \$62.4 million for the year ended June 30, 2011 to \$66.4 million for the year ended June 30, 2012. Our selling, general and administrative expenses for the year ended June 30, 2012 have increased due to the expansion of our marketing organization, increased variable compensation, and increased medical education programs, partially offset by lower stock-based compensation. Selling, general, and administrative expenses for the years ended June 30, 2012 and 2011 includes \$4.4 million and \$5.6 million, respectively, for stock-based compensation. We expect our selling, general and administrative expenses to increase in the future as a result of the costs associated with expanding our sales and marketing organization and programs to further commercialize our products and prepare for a potential future coronary application.

*Research and Development Expenses.* Research and development expenses increased by \$2.4 million, or 27.2%, from \$8.9 million for the year ended June 30, 2011 to \$11.4 million for the year ended June 30, 2012. Research and development expenses relate to specific projects to improve our product or expand into new markets, such as the development of electric versions of the PAD Systems, shaft designs, crown designs, and PAD and coronary clinical trials. The increase in these expenses related to advancement of the ORBIT II coronary trial, partially offset by lower stock-based compensation. Research and development expenses for the year ended June 30, 2012 and 2011 includes \$474,000 and \$587,000, respectively, for stock-based compensation. As we continue to expand our product portfolio within the market for the treatment of peripheral arteries and leverage our core technology into the coronary market, we generally expect to incur research and development expenses above amounts incurred for the year ended June 30, 2012. Fluctuations could occur based on the number of projects and studies and the timing of expenditures.

*Interest and Other Expense.* Interest and other expense was (\$2.3 million) for the years ended June 30, 2012 and 2011. Significant changes in interest and other expense during these periods included:

*Interest Expense.* Interest expense was \$1.4 million for the years ended June 30, 2012 and 2011. Interest expense results from outstanding debt balances and debt premium and discount amortization.

*Interest Income.* Interest income decreased by \$7,000, from \$12,000 for the year ended June 30, 2011 to \$5,000 for the year ended June 30, 2012. The decrease in interest income was due to lower yields earned on deposits in investments that consist of money market funds.

*Change in Fair Value of Conversion Option.* The change in fair value of the conversion option was \$491,000 for the year ended June 30, 2011 and (\$554,000) for the year ended June 30, 2012. The change in fair value of the conversion option is primarily driven by the change in the market value of our common stock. The change in the fair value of the conversion option represents the period to period change in fair value of the conversion option associated with outstanding convertible debt.

*Net Write-offs Upon Conversion (Option and Unamortized Premium or Discount).* Net write-offs upon conversion was (\$1.4 million) during the year ended June 30, 2011 and (\$182,000) during the year ended June 30, 2012. Net write-offs upon conversion are the result of the conversion of convertible debt and include the write-off of the conversion option and any unamortized debt premium or discount.

*Other.* Other expenses increased by \$85,000, from \$52,000 for the year ended June 30, 2011 to \$237,000 for the year ended June 30, 2012. The increase in other expenses was primarily due to increased state taxes.

*Net Loss.* Net loss for the year ended June 30, 2012 was \$16.8 million, or \$0.93 per basic and diluted share, compared to \$11.1 million, or \$0.70 per basic and diluted share for the year ended June 30, 2011.

***Comparison of Fiscal Year Ended June 30, 2011 with Fiscal Year Ended June 30, 2010***



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*Revenues.* Revenues increased by \$14.0 million, or 21.5%, from \$64.8 million for the year ended June 30, 2010 to \$78.8 million for the year ended June 30, 2011. This increase was attributable to an \$11.5 million, or

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20.1%, increase driven by an increase in the number of PAD Systems sold and a \$2.4 million, or 32.0%, increase in sales of supplemental and other revenue during the year ended June 30, 2011 compared to the year ended June 30, 2010. Supplemental products include our Viper product line and distribution partner products.

*Cost of Goods Sold.* Cost of goods sold increased by \$1.3 million, or 8.5%, from \$15.0 million for the year ended June 30, 2010 to \$16.3 million for the year ended June 30, 2011. These amounts represent the cost of materials, labor and overhead for single-use catheters, guidewires, control units, pumps, and other supplemental products. The increase in gross margin from 76.9% during the year ended June 30, 2010 to 79.3% for the year ended June 30, 2011 was primarily due to operating efficiencies, product cost reductions, and a favorable product mix resulting in a reduction in shipments of lower margin control units. Cost of goods sold for the years ended June 30, 2011 and 2010 includes \$312,000 and \$548,000, respectively, for stock-based compensation.

*Selling, General and Administrative Expenses.* Selling, general, and administrative expense was \$62.4 million for the years ended June 30, 2010 and June 30, 2011. Increases for the year ended June 30, 2011 to build our sales organization, along with increased professional fees were offset by lower stock-based compensation. Selling, general, and administrative expenses for the years ended June 30, 2011 and 2010 includes \$5.6 million and \$7.3 million, respectively, for stock-based compensation.

*Research and Development Expenses.* Research and development expenses decreased by \$1.4 million, or 13.0%, from \$10.3 million for the year ended June 30, 2010 to \$8.9 million for the year ended June 30, 2011. Research and development expenses relate to specific projects to improve our product or expand into new markets, such as the development of electric versions of the PAD Systems, shaft designs, crown designs, and PAD and coronary clinical trials. The reduction in these expenses related to the decreased numbers and sizes of PAD development projects in fiscal 2011, as well as the timing of those projects, and reduced stock-based compensation. Research and development expenses for the year ended June 30, 2011 and 2010 includes \$587,000 and \$1.3 million, respectively, for stock-based compensation.

*Interest and Other Expense.* Interest and other expense decreased by \$1.3 million, or 130.4%, from (\$1.0 million) for the year ended June 30, 2010 to (\$2.3 million) for the year ended June 30, 2011. Significant changes in interest and other expense during these periods included:

*Interest Income.* Interest income decreased by \$390,000, from \$402,000 for the year ended June 30, 2010 to \$12,000 for the year ended June 30, 2011. The decrease in interest income was a result of all auction rate securities being redeemed by the issuers at par value or repurchased by UBS at par value during the year ended June 30, 2010.

*Change in Fair Value of Conversion Option.* The change in the fair value of the conversion option represents the period to period change in fair value of the conversion option associated with outstanding convertible debt. Change in fair value of conversion option was \$491,000 for the year ended June 30, 2011, which was primarily driven by an increase in the market value of our common stock since the convertible debt issuance date. There was no change in fair value of the conversion option during the year ended June 30, 2010.

*Net Write-offs Upon Conversion (Option and Unamortized Premium or Discount).* Net write-offs upon conversion was \$(1.4 million) during the year ended June 30, 2011. There were no net write-offs upon conversion during the year ended June 30, 2010. Net write-offs upon conversion are the result of the conversion of convertible debt, and include the write-off of the conversion option and any unamortized debt premium or discount.

*Net Loss Available to Common Stockholders.* Net loss available to common stockholders for the year ended June 30, 2011 was \$11.1 million, or \$0.70 per basic and diluted share, compared to \$23.9 million, or \$1.62 per basic and diluted share for the year ended June 30, 2010.

**Table of Contents****NON-GAAP FINANCIAL INFORMATION**

To supplement our consolidated financial statements prepared in accordance with GAAP, our management uses a non-GAAP financial measure referred to as Adjusted EBITDA. The following table sets forth, for the periods indicated, a reconciliation of Adjusted EBITDA to the most comparable U.S. GAAP measure expressed as dollar amounts (in thousands):

	<b>Year Ended June 30,</b>	
	<b>2012</b>	<b>2011</b>
Loss from operations	\$ (14,466)	\$ (8,809)
Add: Stock-based compensation	5,165	6,468
Add: Depreciation and amortization	872	716
Adjusted EBITDA	\$ (8,429)	\$ (1,625)

The decrease in Adjusted EBITDA of \$6.8 million, or 418.7%, is primarily the result of the \$5.7 million, or 64.2%, increase in the loss from operations. The loss from operations was significantly impacted by increases in operating expenses.

Adjusted EBITDA was also impacted by a decrease in stock-based compensation and increase in depreciation and amortization. Stock-based compensation decreased \$1.3 million, or 20.1%, from \$6.5 million for the year ended June 30, 2011 to \$5.2 million for the year ended June 30, 2012. Stock-based compensation decreased as a result of the timing and market price of previously granted shares that became fully vested. Depreciation and amortization increased as a result of additional investment in capital equipment.

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

We use Adjusted EBITDA as a supplemental measure of performance and believe this measure facilitates operating performance comparisons from period to period and company to company by factoring out potential differences caused by depreciation and amortization expense and non-cash charges such as stock-based compensation. Our management uses Adjusted EBITDA to analyze the underlying trends in our business, assess the performance of our core operations, establish operational goals and forecasts that are used to allocate resources and evaluate our performance period over period and in relation to our competitors' operating results. Additionally, our management is partially evaluated on the basis of Adjusted EBITDA when determining achievement of their incentive compensation performance targets.

We believe that presenting Adjusted EBITDA provides investors greater transparency to the information used by our management for its financial and operational decision-making and allows investors to see our results through the eyes of management. We also believe that providing this information better enables our investors to understand our operating performance and evaluate the methodology used by our management to evaluate and measure such performance. Adjusted EBITDA is also used to measure performance in our financial covenants as required by Silicon Valley Bank and Partners for Growth.

The following is an explanation of each of the items that management excluded from Adjusted EBITDA and the reasons for excluding each of these individual items:

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

*Depreciation and amortization expense.* We exclude depreciation and amortization expense from our non-GAAP financial measures primarily because such expenses, while constituting ongoing and recurring



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expenses, are not expenses that require cash settlement and are not used by our management to assess the core profitability of our business operations. Our management also believes that excluding these items from our non-GAAP results is useful to investors to understand our operational performance, liquidity and ability to make additional investments in the Company.

### ***Material Limitations Associated with the Use of Non-GAAP Financial Measures and Manner in which We Compensate for these Limitations***

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

Items such as stock-based compensation do not directly affect our cash flow position; however, such items reflect economic costs to us and are not reflected in our 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 we do, limiting the usefulness of those measures for comparative purposes.

Our management exercises judgment in determining which types of charges or other items should be excluded from the non-GAAP financial measures we use.

We compensate for these limitations by relying primarily upon our GAAP results and using non-GAAP financial measures only supplementally.

## **LIQUIDITY AND CAPITAL RESOURCES**

We had cash and cash equivalents of \$35.5 million and \$21.2 million at June 30, 2012 and 2011, respectively. During the year ended June 30, 2012, net cash used in operations amounted to \$11.3 million. As of June 30, 2012, we had an accumulated deficit of \$179.2 million. We have historically funded our operating losses primarily from the issuance of common and preferred stock, convertible promissory notes, debt, and the merger with Replidyne in February 2009.

### ***Loan and Security Agreement with Silicon Valley Bank***

On March 29, 2010, we entered into an amended and restated loan and security agreement with Silicon Valley Bank. The agreement was amended on December 27, 2011 to increase outstanding borrowings, and subsequently amended on June 29, 2012 to modify financial covenants and reduce the interest rate and other fees. The agreement, as amended, includes a \$12.0 million term loan and a \$15.0 million line of credit. The terms of each of these loans are as follows:

The \$12.0 million term loan has an initial interest rate of 8.0%, which can be reduced to 7.0% based on the achievement of positive EBITDA for the trailing six month period. The term loan has a 36 month maturity, with repayment terms that include interest only payments during the first six months, followed by 30 equal principal payments of \$400,000 plus interest, and a final payment of \$100,000 due at maturity. This term loan also includes an acceleration provision that requires us to pay the entire outstanding balance, plus a penalty ranging from 1.0% to 3.0% of the commitment amount, upon prepayment or the occurrence and continuance of an event of default. The balance outstanding on the term loan at June 30, 2012, including the unamortized discount, was \$11.7 million. The unamortized discount associated with warrants issued to Silicon Valley Bank in connection with the loan and other fees paid to the lender will be amortized over the 36 month maturity period.

The \$15.0 million line of credit expires on June 30, 2014 and has a floating interest rate equal to the Wall Street Journal's prime rate, plus 1.25%, with an interest rate floor of 4.5%. Interest on borrowings is due monthly and the principal balance is due at maturity. Borrowings on the line of credit are based on 85% of eligible accounts. Accounts receivable receipts are deposited into a lockbox account in the name of



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Silicon Valley Bank. The line of credit is subject to non-use fees, annual fees, and cancellation fees. There was not an outstanding balance on the line of credit at June 30, 2012.

Borrowings from Silicon Valley Bank are secured by all of our assets. The borrowings are subject to prepayment penalties and financial covenants, including maintaining certain liquidity and fixed charge coverage ratios, and certain three-month EBITDA targets. We were in compliance with all financial covenants as of June 30, 2012. The agreement also includes subjective acceleration clauses that permit Silicon Valley Bank to accelerate the due date under certain circumstances, including, but not limited to, material adverse effects on our financial status or otherwise. Any non-compliance by us under the terms of debt arrangements could result in an event of default under the Silicon Valley Bank loan, which, if not cured, could result in the acceleration of this debt.

In connection with and as additional consideration for entering into the amendment to the amended and restated loan agreement with Silicon Valley Bank on December 27, 2011, we issued a warrant to purchase 12,760 shares of our common stock to Silicon Valley Bank, which Silicon Valley Bank immediately transferred to its parent company, SVB Financial Group. The warrant's exercise price was set at \$9.796 per share, which price was based on the five-day average closing share price of our common stock prior to the date of the amendment. The warrant expires on the tenth anniversary of the issue date, subject to earlier expiration in accordance with its terms.

In connection with and as additional consideration for entering into the subsequent amendment to the amended and restated loan agreement with Silicon Valley Bank on June 29, 2012, we issued a warrant to purchase 18,649 shares of our common stock to Silicon Valley Bank, which Silicon Valley Bank immediately transferred to its parent company, SVB Financial Group. The warrant's exercise price was set at \$9.652 per share, which price was based on the five-day average closing share price of our common stock prior to the date of the amendment. The warrant expires on the tenth anniversary of the issue date, subject to earlier expiration in accordance with its terms.

***Loan and Security Agreement with Partners for Growth***

On April 14, 2010, we entered into a loan and security agreement with Partners for Growth III, L.P. (PFG). The agreement was amended on August 23, 2011 to provide that PFG will make loans to us up to \$5.0 million, December 27, 2011 to raise the total amount of indebtedness that we may accrue under the term loan portion of the amended and restated loan and security agreement with Silicon Valley Bank from \$10.0 million to \$12.0 million, and June 30, 2012 to modify financial covenants. The amended agreement provides that PFG will make loans to us up to \$5.0 million. The agreement has a maturity date of April 14, 2015. The loans bear interest at a floating per annum rate equal to 2.75% above Silicon Valley Bank's prime rate, and such interest is payable monthly. The principal balance of and any accrued and unpaid interest on any notes are due on the maturity date and may not be prepaid by us at any time in whole or in part.

As of June 30, 2012, PFG has provided us the following three loans totaling \$5.0 million that are outstanding: (i) a \$3.5 million loan dated June 30, 2011 with a conversion price of \$13.64, (ii) a \$500,000 loan dated August 4, 2011, as amended and restated August 24, 2011, with a conversion price of \$15.30, and (iii) a \$1.0 million loan dated August 24, 2011 with a conversion price of \$13.42. At any time prior to the maturity date, PFG may at its option convert any of the outstanding loans into shares of our common stock at the applicable conversion price, which in each case equaled the ten-day volume weighted average price per share of our common stock prior to the issuance date of each note. We may also effect at any time a mandatory conversion of amounts, subject to certain terms, conditions and limitations provided in the agreement, including a requirement that the ten-day volume weighted average price of our common stock prior to the date of conversion is at least 15% greater than the conversion price. We may reduce the conversion price to a price that represents a 15% discount to the ten-day volume weighted average price of our common stock to satisfy this condition and effect a mandatory conversion. During the year ended June 30, 2012, PFG, at its option, converted a \$500,000 loan (at par) into 40,323 shares of our common stock in accordance with the conversion terms set forth in the agreement. We have reflected a net expense of \$736,000 for the year ended June 30, 2012 as a component of interest and other, net on the accompanying statement of operations, which represents the net effect of (i) the

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write-off of the conversion option on the converted loan, (ii) the write-off of the unamortized debt premium on the converted loan and (iii) the change in fair value of the conversion options on all outstanding loans. The balance outstanding under the loan and security agreement at June 30, 2012 was \$5.6 million. The net unamortized premium associated with warrants issued to PFG in connection with the loan, a beneficial conversion feature, and other fees paid to the lender will be amortized over the remaining maturity period.

The loans are secured by certain of our assets, and the agreement contains customary covenants limiting our ability to, among other things, incur debt or liens, make certain investments and loans, effect certain redemptions of and declare and pay certain dividends on its stock, permit or suffer certain change of control transactions, dispose of collateral, or change the nature of its business. In addition, the PFG loan and security agreement contains financial covenants requiring us to maintain certain liquidity and fixed charge coverage ratios and certain three-month EBITDA targets. We were in compliance with all financial covenants at June 30, 2012. If we do not comply with the various covenants, PFG may, subject to various customary cure rights, decline to provide additional loans, require amortization of the loan over its remaining term, or require the immediate payment of all amounts outstanding under the loan and foreclose on any or all collateral, depending on which financial covenants are not maintained.

In connection with the initial agreement in April 2010, we issued PFG a warrant to purchase 66,299 shares of our common stock at an exercise price of \$5.43 per share. In connection with the same agreement, PFG Equity Investors, LLC and Silicon Valley Bank were also issued warrants to purchase 9,724 and 71,307 shares of our common stock, respectively, at an exercise price of \$5.43 per share. One-half of each warrant was immediately exercisable, and the remaining half became exercisable as additional funds were drawn during the year ended June 30, 2011. The warrants were exercised in June 2011. In connection with and as additional consideration for entering into the amendment to the loan and security agreement with PFG on December 27, 2011, we issued one warrant to purchase 23,151 shares of our common stock to PFG, one warrant to purchase 3,396 shares of our common stock to PFG Equity Investors, LLC, an affiliate of PFG, and one warrant to purchase 24,900 shares of our common stock to Silicon Valley Bank. Each warrant expires on the fifth anniversary of the issue date, subject to earlier expiration in accordance with its terms, and the exercise price for each of the warrants was set at \$9.33 per share, which was based on the ten-day average closing share price of our common stock prior to the date of the amendment.

*Cash and Cash Equivalents.* Cash and cash equivalents was \$35.5 million and \$21.2 million at June 30, 2012 and 2011, respectively. This increase is primarily attributable to net proceeds from our equity financing in May 2012 and refinancing of long-term debt, partially offset by cash used in operations during the year ended June 30, 2012.

*Operating Activities.* Net cash used in operating activities was \$11.3 million, \$8.4 million, and \$13.6 million for the years ended June 30, 2012, 2011, and 2010, respectively. For the years ended June 30, 2012, 2011, and 2010, we had a net loss of \$16.8 million, \$11.1 million, and \$23.9 million, respectively. Changes in working capital accounts also contributed to the net cash used in the years ended June 30, 2012, 2011, and 2010. Significant changes in working capital during these periods included:

Cash used in accounts receivable of \$391,000, \$3.7 million, and \$1.1 million during the years ended June 30, 2012, 2011, and 2010 respectively. The decrease in cash used between periods is due to lower revenue growth in fiscal year 2012 compared to fiscal year 2011, and higher revenue growth in fiscal year 2011 compared to fiscal year 2010.

Cash used in inventories of \$1.2 million, \$1.5 million, and \$1.0 million during the years ended June 30, 2012, 2011, and 2010, respectively. For the years ended June 30, 2012, 2011, and 2010, cash used in inventories was primarily due to the timing of inventory purchases and sales.

Cash (used in) provided by prepaid expenses and other current assets of (\$119,000), \$323,000, and \$6,000 during the years ended June 30, 2012, 2011, and 2010 respectively. For the years ended June 30, 2012, 2011, and 2010, cash provided by prepaid expenses and other current assets was primarily due to payment timing of vendor deposits and other expenditures.



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Cash provided by (used in) accounts payable of \$269,000, \$1.8 million, and (\$1.4 million) during the years ended June 30, 2012, 2011, and 2010, respectively. For the years ended June 30, 2012, 2011, and 2010, cash provided by accounts payable was primarily due to timing of purchases and vendor payments.

Cash provided by (used in) accrued expenses and other liabilities of \$7,000, (\$2.4 million), and \$3.8 million during the years ended June 30, 2012, 2011, and 2010 respectively. For the years ended June 30, 2012 and 2011, cash used in accrued expenses and other liabilities was primarily related to the timing and payment of accruals. For the year ended June 30, 2010, cash provided by accrued expenses and other liabilities was primarily due to receipt of \$3.5 million in net cash incentives under the agreement to establish a manufacturing facility in Texas.

*Investing Activities.* Net cash (used in) provided by investing activities was (\$975,000), (\$1.7 million), and \$21.8 million for the years ended June 30, 2012, 2011, and 2010, respectively. For the years ended June 30, 2012 and 2011, cash used in investing activities resulted from investment in property, plant and equipment, and patents. For the year ended June 30, 2010, cash provided by investing activities primarily resulted from the selling of investments in the amount of \$23.0 million.

*Financing Activities.* Net cash provided by (used in) financing activities was \$26.7 million, \$7.5 million, and (\$17.9 million) during the years ended June 30, 2012, 2011, and 2010, respectively. Cash provided by financing activities during these periods included:

proceeds from long-term debt of \$7.9 million, \$7.5 million, and \$5.9 million during the years ended June 30, 2012, 2011, and 2010, respectively;

employee stock purchase plan purchases of \$1.4 million, \$1.0 million, and \$1.2 million during the years ended June 30, 2012, 2011, and 2010, respectively;

proceeds from the sale of common stock, net of issuance costs, of \$14.9 million during the year ended June 30, 2012; and

exercise of stock options and warrants of \$4.4 million, \$1.5 million, and \$285,000 during the years ended June 30, 2012, 2011, and 2010, respectively.

Cash used in financing activities in these periods included payments on long-term debt of \$1.9 million, \$2.4 million, and \$25.3 million during the years ended June 30, 2012, 2011, and 2010, respectively.

Our future liquidity and capital requirements will be influenced by numerous factors, including the extent and duration of future operating losses, the level and timing of future sales and expenditures, the results and scope of ongoing research and product development programs, working capital required to support our sales growth, the receipt of and time required to obtain regulatory clearances and approvals, our sales and marketing programs, the continuing acceptance of our products in the marketplace, competing technologies and market and regulatory developments. As of June 30, 2012, we believe our current cash and cash equivalents and available debt will be sufficient to fund working capital requirements, capital expenditures and operations for at least the next 12 months. We intend to retain any future earnings to support operations and to finance the growth and development of our business, and we do not anticipate paying any dividends in the foreseeable future. We may raise additional capital in the future, to fund acceleration of our current growth initiatives or additional growth opportunities, if we believe it will significantly enhance our value.

*Contractual Cash Obligations.* Our contractual obligations and commercial commitments as of June 30, 2012 are summarized below:

Contractual Obligations	Total	Payments Due by Period (in thousands)			
		Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Operating leases(1)	\$ 4,972	\$ 884	\$ 1,722	\$ 1,101	\$ 1,265

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Purchase commitments(2)	5,875	5,875			
Debt maturities(3)	17,250	4,800	12,450		
Total	\$ 28,097	\$ 11,559	\$ 14,172	\$ 1,101	\$ 1,265

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(1) The amounts reflected in the table above for operating leases represent future minimum payments under a non-cancellable operating lease for our office and production facility along with equipment.

(2) This amount reflects open purchase orders.

(3) The amounts reflected in the table above represents debt maturities under various debt agreements.

**INFLATION**

We do not believe that inflation has had a material impact on our business and operating results during the periods presented.

**OFF-BALANCE SHEET ARRANGEMENTS**

Since inception, we have not engaged in any off-balance sheet activities as defined in Item 303(a)(4) of Regulation S-K.

**RECENT ACCOUNTING PRONOUNCEMENTS**

In May 2011, the FASB issued guidance to amend the accounting and disclosure requirements on fair value measurements. The new guidance limits the highest-and-best-use measure to nonfinancial assets, permits certain financial assets and liabilities with offsetting positions in market or counterparty credit risks to be measured at a net basis, and provides guidance on the applicability of premiums and discounts. Additionally, the new guidance expands the disclosures on Level 3 inputs by requiring quantitative disclosure of the unobservable inputs and assumptions, as well as description of the valuation processes and the sensitivity of the fair value to changes in unobservable inputs. The new guidance became effective for us beginning January 1, 2012. Other than requiring additional disclosures, there was no material impact on our consolidated financial statements upon adoption.

In June 2011, the FASB issued guidance requiring that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In the two-statement approach, the first statement should present total net income and its components followed consecutively by a second statement that should present total other comprehensive income, the components of other comprehensive income, and the total of comprehensive income. The new guidance will be effective for us beginning July 1, 2012. Other than requiring additional disclosures, we do not anticipate material impacts on our consolidated financial statements upon adoption as we have no other comprehensive income.

**PRIVATE SECURITIES LITIGATION REFORM ACT**

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements. Such forward-looking information is included in this Form 10-K and in other materials filed or to be filed by us with the Securities and Exchange Commission (as well as information included in oral statements or other written statements made or to be made by us). Forward-looking statements include all statements based on future expectations. This Form 10-K contains forward-looking statements that involve risks and uncertainties, including our expectations regarding the adoption of the PAD Systems through our direct sales force; the use of the PAD Systems to treat coronary lesions and the potential market for this application in the interventional coronary market; our clinical trials and clinical evidence expectations; our plans to explore the acquisition of other product lines, technologies or companies and to continue to evaluate distribution agreements, licensing transactions and other strategic partnerships; compliance with the conditions in our Corporate Job Creation Agreement with the PEDC; future reimbursement for the PAD Systems; the possibility that we may sell internationally in the future; the conversion of and future capacity of our facilities; patent expiration expectations; an increase in revenues; future efficiencies resulting from an increase in production costs; gross margins in the first half of fiscal 2013 will be fairly consistent with fiscal 2012 and second half of fiscal 2013 gross margins will decline compared to the first half of fiscal 2013; an increase in selling, general and administrative expenses; research and development expenses being above amounts incurred in fiscal 2012; no payment of dividends in the foreseeable future; and the sufficiency of our current and anticipated financial

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resources to fund operating expenses for at least the next 12 months and our expectations regarding raising additional capital. In some cases, you can identify forward-looking statements by the following words: anticipate, believe, continue, could, estimate, expect, intend, ma plan, potential, predict, project, should, will, would, or the negative of these terms or other comparable terminology, although forward-looking statements contain these words. Forward-looking statements are only predictions and are not guarantees of performance. These statements are based on our management's beliefs and assumptions, which in turn are based on their interpretation of currently available information.

These statements involve known and unknown risks, uncertainties and other factors that may cause our results or our industry's actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. These factors include regulatory developments in the U.S. and foreign countries; the experience of physicians regarding the effectiveness and reliability of the PAD Systems; the potential for unanticipated delays in enrolling medical centers and patients for clinical trials; actual clinical trial results; dependence on market growth; the reluctance of physicians to accept new products; the effectiveness of the Stealth 360°; the difficulty of successfully managing operating costs; FDA clearances and approvals; the impact of competitive products and pricing; approval of products for reimbursement and the level of reimbursement; unanticipated developments affecting our estimates regarding expenses, future revenues and capital requirements; fluctuations in results and expenses based on new product introductions, sales mix, unanticipated warranty claims, and the timing of project expenditures; our inability to expand our sales and marketing organization and research and development efforts; our ability to obtain and maintain intellectual property protection for product candidates; our actual financial resources; general economic conditions; and those matters identified and discussed in Item 1A of this Form 10-K under Risk Factors.

You should read these risk factors and the other cautionary statements made in this Form 10-K as being applicable to all related forward-looking statements wherever they appear in this Form 10-K. We cannot assure you that the forward-looking statements in this Form 10-K will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. You should read this Form 10-K completely. Other than as required by law, we undertake no obligation to update these forward-looking statements, even though our situation may change in the future.

### **Item 7A. *Quantitative and Qualitative Disclosures About Market Risk.***

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk or availability. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and investments in a variety of marketable securities, including money market funds, U.S. government securities, and certain bank obligations. Our cash and cash equivalents as of June 30, 2012 include liquid money market accounts. Due to the short-term nature of these investments, we believe that there is no material exposure to interest rate risk.

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**Item 8. *Financial Statements and Supplementary Data.***

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of

Cardiovascular Systems, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of changes in shareholders equity (deficiency) and comprehensive loss and of cash flows present fairly, in all material respects, the financial position of Cardiovascular Systems, Inc. at June 30, 2012 and 2011, and the results of their operations and cash flows for each of the three years in the period ended June 30, 2012 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2012, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our audits (which were integrated audits in 2012 and 2011). We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Minneapolis, MN

September 10, 2012

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**Table of Contents****Cardiovascular Systems, Inc.****Consolidated Balance Sheets**

	June 30, 2012	June 30, 2011
	(Dollars in thousands, except per share and share amounts)	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 35,529	\$ 21,159
Accounts receivable, net	13,644	13,254
Inventories	7,061	5,818
Prepaid expenses and other current assets	1,536	797
Total current assets	57,770	41,028
Property and equipment, net	2,163	2,383
Patents, net	2,635	2,314
Debt conversion option and other assets	556	1,033
Total assets	\$ 63,124	\$ 46,758
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities		
Current maturities of long-term debt	\$ 4,678	\$ 3,813
Accounts payable	5,610	5,181
Deferred grant incentive	302	647
Accrued expenses	7,262	5,545
Total current liabilities	17,852	15,186
Long-term liabilities		
Long-term debt, net of current maturities	12,842	8,331
Other liabilities	241	1,606
Total long-term liabilities	13,083	9,937
Total liabilities	30,935	25,123
Commitments and contingencies		
Common stock, \$0.001 par value at June 30, 2012 and 2011; authorized 100,000,000 common shares at June 30, 2012 and 2011; issued and outstanding 20,089,556 at June 30, 2012 and 16,987,068 at June 30, 2011	20	17
Additional paid in capital	201,793	174,157
Common stock warrants	9,614	9,909
Accumulated deficit	(179,238)	(162,448)
Total stockholders equity	32,189	21,635
Total liabilities and stockholders equity	\$ 63,124	\$ 46,758

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The accompanying notes are an integral part of these consolidated financial statements.

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**Cardiovascular Systems, Inc.**  
**Consolidated Statements of Operations**

	2012	Year Ended June 30, 2011	2010
	(Dollars in thousands, except per share and share amounts)		
Revenues	\$ 82,490	\$ 78,780	\$ 64,829
Cost of goods sold	19,216	16,277	15,003
Gross profit	63,274	62,503	49,826
Expenses			
Selling, general and administrative	66,366	62,372	62,447
Research and development	11,374	8,940	10,278
Total expenses	77,740	71,312	72,725
Loss from operations	(14,466)	(8,809)	(22,899)
Interest and other, net	(2,324)	(2,316)	(1,005)
Net loss	\$ (16,790)	\$ (11,125)	\$ (23,904)
Loss per common share			
Basic and diluted	(0.93)	\$ (0.70)	\$ (1.62)
Weighted average common shares used in computation			
Basic and diluted	18,035,635	15,915,800	14,748,293

The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents****Cardiovascular Systems, Inc.****Consolidated Statements of Changes in Stockholders Equity (Deficiency) and Comprehensive Loss**

	Common Stock		Additional		Accumulated	Total	Comprehensive
	Shares	Amount	Paid In Capital	Warrants	Deficit		Loss
	(Dollars in thousands, except per share and share amounts)						
<b>Balances at June 30, 2009</b>	14,113,904	\$ 14	\$ 146,455	\$ 11,282	\$ (127,419)	\$ 30,332	\$ (31,895)
Stock-based compensation related to restricted stock awards, net	686,509	1	5,014			5,015	
Stock-based compensation related to stock options			4,255			4,255	
Exercise of stock options and warrants at \$1.55-\$8.83 per share	38,192		288	(3)		285	
Issuance/expiration of common stock warrants			71	26		97	
Employee Stock Purchase Plan Activity	309,944		1,635			1,635	
Net loss and comprehensive loss					(23,904)	(23,904)	(23,904)
<b>Balances at June 30, 2010</b>	15,148,549	\$ 15	\$ 157,718	\$ 11,305	\$ (151,323)	\$ 17,715	\$ (23,904)
Stock-based compensation related to restricted stock awards, net	604,249	1	4,814			4,815	
Stock-based compensation related to stock options			1,306			1,306	
Exercise of stock options and warrants at \$5.43-\$8.83 per share	435,709		3,234	(1,606)		1,628	
Issuance/expiration of common stock warrants			6	210		216	
Employee Stock Purchase Plan Activity	160,000		1,313			1,313	
Conversion of convertible debt	638,561	1	5,530			5,531	
Beneficial conversion feature on convertible debt			236			236	
Net loss and comprehensive loss					(11,125)	(11,125)	(11,125)
<b>Balances at June 30, 2011</b>	16,987,068	\$ 17	\$ 174,157	\$ 9,909	\$ (162,448)	\$ 21,635	\$ (11,125)
Stock-based compensation related to restricted stock awards, net	564,068	1	4,754			4,755	
Exercise of stock options and warrants at \$7.90-\$12.15 per share	548,097		5,261	(776)		4,485	
Issuance/expiration of common stock warrants			16	481		497	
Employee Stock Purchase Plan Activity	170,000		2,118			2,118	
Conversion of convertible debt	40,323		600			600	
Sale of common stock, net of issuance costs of \$1,131	1,780,000	2	14,887			14,889	
Net loss and comprehensive loss					(16,790)	(16,790)	(16,790)
<b>Balances at June 30, 2012</b>	20,089,556	\$ 20	\$ 201,793	\$ 9,614	\$ (179,238)	\$ 32,189	\$ (16,790)

The accompanying notes are an integral part of these consolidated financial statements.



**Table of Contents****Cardiovascular Systems, Inc.****Consolidated Statements of Cash Flows**

	2012	Year Ended June 30, 2011	2010
	(Dollars in thousands)		
<b>Cash flows from operating activities</b>			
Net loss	\$ (16,790)	\$ (11,125)	\$ (23,904)
Adjustments to reconcile net loss to net cash used in operations			
Depreciation and amortization of property and equipment	817	662	548
Provision for (recoveries of) doubtful accounts	60	(36)	137
Amortization of patents	55	54	51
Write-off of patent costs	162		
Amortization of debt (premium) discount	(68)	(25)	257
Debt conversion and valuation of conversion options, net	736	859	
Stock-based compensation	5,165	6,468	9,094
Other	260	250	
Gain on investments			(150)
Changes in assets and liabilities			
Accounts receivable	(391)	(3,718)	(1,057)
Inventories	(1,243)	(1,499)	(950)
Prepaid expenses and other assets	(379)	323	6
Accounts payable	269	1,828	(1,398)
Accrued expenses and other liabilities	7	(2,402)	3,799
Net cash used in operations	(11,340)	(8,361)	(13,567)
<b>Cash flows from investing activities</b>			
Expenditures for property and equipment	(437)	(1,081)	(793)
Sales of investments			22,950
Costs incurred in connection with patents	(538)	(656)	(400)
Net cash (used in) provided by investing activities	(975)	(1,737)	21,757
<b>Cash flows from financing activities</b>			
Issuance of common stock under employee stock purchase plan	1,418	965	1,197
Exercise of stock options and warrants	4,428	1,523	285
Proceeds from long-term debt	7,885	7,500	5,911
Payments on long-term debt	(1,935)	(2,448)	(25,277)
Proceeds from sale of common stock, net of issuance costs	14,889		
Net cash provided by (used in) financing activities	26,685	7,540	(17,884)
Net change in cash and cash equivalents	14,370	(2,558)	(9,694)
<b>Cash and cash equivalents</b>			
Beginning of period	21,159	23,717	33,411
End of period	\$ 35,529	\$ 21,159	\$ 23,717
<b>Noncash investing and financing activities</b>			
Issuance and expiration of common stock warrants	497	216	97
Beneficial conversion feature on convertible debt	28	236	97
Equipment included in accounts payable	160		

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Conversion of convertible debt	600	5,531		
Net exercise of common stock warrants	335	1,505		
Premium on convertible debt	267	1,263		
Amendment of restricted stock units				517
Other		250		
<b>Supplemental cash flow information</b>				
Interest paid	\$ 1,383	\$ 1,447	\$ 1,161	

The accompanying notes are an integral part of these consolidated financial statements.

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**CARDIOVASCULAR SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(dollars in thousands, except per share and share amounts)**

**1. Summary of Significant Accounting Policies**

***Company Description***

Cardiovascular Systems, Inc. was incorporated as Replidyne, Inc. in Delaware in 2000. On February 25, 2009, Replidyne, Inc. completed its reverse merger with Cardiovascular Systems, Inc., a Minnesota corporation incorporated in 1989 ( CSI-MN ), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of November 3, 2008 (the Merger Agreement ). Pursuant to the Merger Agreement, CSI-MN continued after the merger as the surviving corporation and a wholly-owned subsidiary of Replidyne. At the effective time of the merger, Replidyne, Inc. changed its name to Cardiovascular Systems, Inc. ( CSI ) and CSI-MN merged with and into CSI, with CSI continuing after the merger as the surviving corporation. These transactions are referred to herein as the merger.

The Company develops, manufactures and markets devices for the treatment of vascular diseases. The Company's primary products, the Diamondback 360° PAD System, the Diamondback Predator 360° PAD System, and the Stealth 360° PAD System, are catheter-based platforms capable of treating a broad range of plaque types in leg arteries both above and below the knee and address many of the limitations associated with existing treatment alternatives.

***Principles of Consolidation***

The consolidated balance sheets, statements of operations, changes in stockholders' equity (deficiency) and comprehensive loss, and cash flows include the accounts of the Company and its wholly-owned inactive Netherlands subsidiary, SCS B.V., after elimination of all intercompany transactions and accounts. SCS B.V. was formed for the purpose of conducting human trials and the development of production facilities. Operations of the subsidiary ceased in fiscal 2002; accordingly, there are no assets or liabilities included in the consolidated financial statements related to SCS B.V.

***Cash and Cash Equivalents***

The Company considers all money market funds and other investments purchased with an original maturity of three months or less to be cash and cash equivalents.

**Table of Contents****CARDIOVASCULAR SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Accounts Receivable and Allowance for Doubtful Accounts***

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. Customer credit terms are established prior to shipment with the general standard being net 30 days. Collateral or any other security to support payment of these receivables generally is not required. The Company maintains an allowance for doubtful accounts. This allowance is an estimate and is regularly evaluated by the Company for adequacy by taking into consideration factors such as past experience, credit quality of the customer base, age of the receivable balances, both individually and in the aggregate, and current economic conditions that may affect a customer's ability to pay. Provisions for the allowance for doubtful accounts attributed to bad debt are recorded in general and administrative expenses. The following table shows allowance for doubtful accounts activity for the fiscal years ended June 30, 2012 and 2011:

	<b>Amount</b>
Balance at June 30, 2010	\$ 403
Provision for doubtful accounts	51
Write-offs	(103)
Balance at June 30, 2011	\$ 351
Provision for doubtful accounts	60
Write-offs	(19)
Balance at June 30, 2012	\$ 392

***Inventories***

Inventories are stated at the lower of cost or market with cost determined on a first-in, first-out ( FIFO ) method of valuation. The establishment of inventory allowances for excess and obsolete inventories is based on estimated exposure on specific inventory items.

***Property and Equipment***

Property and equipment is carried at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over estimated useful lives of five years for production equipment and furniture and fixtures; three years for computer equipment and software; and the shorter of their estimated useful lives or the lease term for leasehold improvements. Expenditures for maintenance and repairs and minor renewals and betterments which do not extend or improve the life of the respective assets are expensed as incurred. All other expenditures for renewals and betterments are capitalized. The assets and related depreciation accounts are adjusted for property retirements and disposals with the resulting gains or losses included in the consolidated statement of operations.

***Patents***

The capitalized costs incurred to obtain patents are amortized using the straight-line method over their remaining estimated lives. Patent amortization begins at the time of patent application approval, and does not exceed 20 years. The recoverability of capitalized patent costs is dependent upon the Company's ability to derive revenue-producing products from such patents or the ultimate sale or licensing of such patent rights. Patents that are abandoned are written off at the time of abandonment.

***Long-Lived Assets***

The Company regularly evaluates the carrying value of long-lived assets for events or changes in circumstances that indicate that the carrying amount may not be recoverable or that the remaining estimated





**Table of Contents****CARDIOVASCULAR SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

useful life should be changed. An impairment loss is recognized when the carrying amount of an asset exceeds the anticipated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition. The amount of the impairment loss to be recorded, if any, is calculated by the excess of the asset's carrying value over its fair value.

***Operating Leases***

The Company leases manufacturing and office space under operating lease agreements. The leases contain rent escalation clauses for which the lease expense is recognized on a straight-line basis over the terms of the leases. Rent expense that is recognized but not yet paid is included in other liabilities on the consolidated balance sheets.

***Revenue Recognition***

The Company sells the majority of its products via direct shipment to hospitals or clinics. The Company recognizes revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sales price is fixed or determinable; and collectability is reasonably assured. These criteria are generally met at the time of delivery when the risk of loss and title passes to the customer. The Company records estimated sales returns, discounts and rebates as a reduction of net sales in the same period revenue is recognized.

Costs related to products delivered are recognized in the period revenue is recognized. Cost of goods sold consists primarily of raw materials, direct labor, and manufacturing overhead.

***Warranty Costs***

The Company provides its customers with the right to receive a replacement if a product is determined to be defective at the time of shipment. Warranty reserve provisions are estimated based on Company experience, volume, and expected warranty claims. Warranty reserve, provisions and claims for the fiscal years ended June 30, 2012 and 2011 were as follows:

	<b>Amount</b>
Balance at June 30, 2010	\$ 116
Provision	159
Claims	(205)
Balance at June 30, 2011	\$ 70
Provision	297
Claims	(264)
Balance at June 30, 2012	\$ 103

***Income Taxes***

Deferred income taxes are recorded to reflect the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts based on enacted tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

Developing a provision for income taxes, including the effective tax rate and the analysis of potential tax exposure items, if any, requires significant judgment and expertise in federal and state income tax laws,



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**CARDIOVASCULAR SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

regulations and strategies, including the determination of deferred tax assets. The Company's judgment and tax strategies are subject to audit by various taxing authorities.

Existing accounting guidance requires that accounting for uncertainty in income taxes is recognized in the financial statements. The guidance provides that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized. The guidance also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

***Research and Development Expenses***

Research and development expenses include costs associated with the design, development, testing, enhancement and regulatory approval of the Company's products. Research and development expenses include employee compensation, including stock-based compensation, supplies and materials, consulting expenses, travel and facilities overhead. The Company also incurs significant expenses to operate clinical trials, including trial design, third-party fees, clinical site reimbursement, data management and travel expenses. Research and development expenses are expensed as incurred. Approved patent applications are capitalized and amortized using the straight-line method over their remaining estimated lives. Patent amortization begins at the time of patent application approval, and does not exceed 20 years.

***Concentration of Credit Risk***

Financial instruments that potentially expose the Company to concentration of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company maintains its cash balances primarily with one financial institution. At times, these balances exceed federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk in cash and cash equivalents.

***Fair Value of Financial Instruments***

Under the authoritative guidance for fair value measurements, fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. The authoritative guidance also establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors market participants would use in valuing the asset or liability developed based upon the best information available in the circumstances. The categorization of financial assets and financial liabilities within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The hierarchy is broken down into three levels defined as follows:

*Level 1 Inputs* quoted prices in active markets for identical assets and liabilities

*Level 2 Inputs* observable inputs other than quoted prices in active markets for identical assets and liabilities

*Level 3 Inputs* unobservable inputs

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The following table sets forth the fair value of the Company's financial instruments that were measured on a recurring basis as of June 30, 2012. Assets are measured on a recurring basis if they are remeasured at least annually:

	<b>Conversion Option</b>
Balance at June 30, 2010	\$ 388
Issuance of convertible notes	1,715
Conversion of convertible notes	(1,669)
Change in conversion option valuation	491
<b>Balance at June 30, 2011</b>	<b>\$ 925</b>
Issuance of convertible notes	295
Conversion of convertible notes	(182)
Change in conversion option valuation	(554)
<b>Balance at June 30, 2012</b>	<b>\$ 484</b>

The fair value of the conversion option is related to the loan and security agreement with Partners for Growth (described in Note 3) and has been included as a component of debt conversion option and other assets on the accompanying balance sheet. The Monte Carlo option pricing model used to determine the value of the conversion option included various inputs including historical volatility, stock price simulations, and assessed behavior of the Company and Partners for Growth based on those simulations. Based upon these inputs, the Company considers the conversion option to be a Level 3 investment.

As of June 30, 2012, the Company believes that the carrying amounts of its other financial instruments, including accounts receivable, accounts payable and accrued liabilities, approximate their fair value due to the short-term maturities of these instruments. The carrying amount of long-term debt approximates fair value based on interest rates currently available for debt with similar terms and maturities.

***Use of Estimates***

The preparation of the Company's consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

***Stock-Based Compensation***

The Company recognizes stock-based compensation expense in an amount equal to the fair value of share-based payments computed at the date of grant. The fair value of all stock option and restricted stock awards are expensed in the consolidated statements of operations ratably over the related vesting period.

***Recent Accounting Pronouncements***

In May 2011, the FASB issued guidance to amend the accounting and disclosure requirements on fair value measurements. The new guidance limits the highest-and-best-use measure to nonfinancial assets, permits certain financial assets and liabilities with offsetting positions in market or counterparty credit risks to be measured at a net basis, and provides guidance on the applicability of premiums and discounts. Additionally, the new guidance expands the disclosures on Level 3 inputs by requiring quantitative disclosure of the unobservable inputs and



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assumptions, as well as description of the valuation processes and the sensitivity of the fair value to changes in unobservable inputs. The new guidance became effective for the Company beginning January 1, 2012. Other than requiring additional disclosures, there was no material impact on the Company's consolidated financial statements upon adoption.

In June 2011, the FASB issued guidance requiring that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In the two-statement approach, the first statement should present total net income and its components followed consecutively by a second statement that should present total other comprehensive income, the components of other comprehensive income, and the total of comprehensive income. The new guidance will be effective for the Company beginning July 1, 2012. Other than requiring additional disclosures, the Company does not anticipate material impacts on its consolidated financial statements upon adoption as the Company has no other comprehensive income.

**2. Selected Consolidated Financial Statement Information**

	June 30,	
	2012	2011
<b>Accounts Receivable</b>		
Accounts receivable	\$ 14,036	\$ 13,605
Less: Allowance for doubtful accounts	(392)	(351)
	\$ 13,644	\$ 13,254
<b>Inventories</b>		
Raw materials	\$ 2,558	\$ 2,705
Work in process	1,022	640
Finished goods	3,481	2,473
	\$ 7,061	\$ 5,818
<b>Property and equipment</b>		
Equipment	\$ 4,564	\$ 3,968
Furniture	318	318
Leasehold improvements	180	180
	5,062	4,466
Less: Accumulated depreciation and amortization	(2,899)	(2,083)
	\$ 2,163	\$ 2,383
<b>Patents</b>		
Patents	\$ 3,145	\$ 2,770
Less: Accumulated amortization	(510)	(456)
	\$ 2,635	\$ 2,314



**Table of Contents****CARDIOVASCULAR SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of June 30, 2012, future estimated amortization of patents and patent licenses will be:

2013	\$ 65
2014	65
2015	65
2016	60
2017	54
Thereafter	2,326
	<b>\$ 2,635</b>

This future amortization expense is an estimate. Actual amounts may vary from these estimated amounts due to additional intangible asset acquisitions, potential impairment, accelerated amortization or other events.

	June 30,	
	2012	2011
<b>Accrued expenses</b>		
Salaries and bonus	\$ 1,034	\$ 938
Commissions	4,087	2,111
Accrued vacation	1,592	1,648
Merger related lease obligation		293
Other	549	555
	<b>\$ 7,262</b>	<b>\$ 5,545</b>

**3. Debt*****Loan and Security Agreement with Silicon Valley Bank***

On March 29, 2010, the Company entered into an amended and restated loan and security agreement with Silicon Valley Bank. The agreement was amended on December 27, 2011 to increase outstanding borrowings, and subsequently amended on June 29, 2012 to modify financial covenants and reduce the interest rate and other fees. The agreement, as amended, includes a \$12,000 term loan and a \$15,000 line of credit. The terms of each of these loans are as follows:

The \$12,000 term loan has an initial interest rate of 8.0%, which can be reduced to 7.0% based on the achievement of positive EBITDA for the trailing six month period. The term loan has a 36 month maturity, with repayment terms that include interest only payments during the first six months, followed by 30 equal principal payments of \$400 plus interest, and a final payment of \$100 due at maturity. This term loan also includes an acceleration provision that requires the Company to pay the entire outstanding balance, plus a penalty ranging from 1.0% to 3.0% of the commitment amount, upon prepayment or the occurrence and continuance of an event of default. The balance outstanding on the term loan at June 30, 2012 and 2011 was \$11,694 and \$7,286, respectively, net of the unamortized discount associated with warrants issued to Silicon Valley Bank in connection with the loan. The unamortized discount associated with warrants and other fees paid to the lender will be amortized over the 36 month maturity period. See Note 6 for additional information.



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The \$15,000 line of credit expires on June 30, 2014 and has a floating interest rate equal to the Wall Street Journal's prime rate, plus 1.25%, with an interest rate floor of 4.5%. Interest on borrowings is due monthly and the principal balance is due at maturity. Borrowings on the line of credit are based on 85% of eligible accounts. Accounts receivable receipts are deposited into a lockbox account in the name of

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**CARDIOVASCULAR SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Silicon Valley Bank. The line of credit is subject to non-use fees, annual fees, and cancellation fees. There was not an outstanding balance on the line of credit at June 30, 2012.

Borrowings from Silicon Valley Bank are secured by all of the Company's assets. The borrowings are subject to prepayment penalties and financial covenants, including maintaining certain liquidity and fixed charge coverage ratios, and certain three-month EBITDA targets. The Company was in compliance with all financial covenants as of June 30, 2012. The agreement also includes subjective acceleration clauses that permit Silicon Valley Bank to accelerate the due date under certain circumstances, including, but not limited to, material adverse effects on the Company's financial status or otherwise. Any non-compliance by the Company under the terms of debt arrangements could result in an event of default under the Silicon Valley Bank loan, which, if not cured, could result in the acceleration of this debt.

In connection with and as additional consideration for entering into the amendment to the amended and restated loan agreement with Silicon Valley Bank on December 27, 2011, the Company issued a warrant to purchase 12,760 shares of its common stock to Silicon Valley Bank, which Silicon Valley Bank immediately transferred to its parent company, SVB Financial Group. The warrant's exercise price was set at \$9.796 per share, which price was based on the five-day average closing share price of the Company's common stock prior to the date of the amendment. The warrant expires on the tenth anniversary of the issue date, subject to earlier expiration in accordance with its terms.

In connection with and as additional consideration for entering into the subsequent amendment to the amended and restated loan agreement with Silicon Valley Bank on June 29, 2012, the Company issued a warrant to purchase 18,649 shares of its common stock to Silicon Valley Bank, which Silicon Valley Bank immediately transferred to its parent company, SVB Financial Group. The warrant's exercise price was set at \$9.652 per share, which price was based on the five-day average closing share price of the Company's common stock prior to the date of the amendment. The warrant expires on the tenth anniversary of the issue date, subject to earlier expiration in accordance with its terms.

***Loan and Security Agreement with Partners for Growth***

On April 14, 2010, the Company entered into a loan and security agreement with Partners for Growth III, L.P. (PFG). The agreement was amended on August 23, 2011 to provide that PFG will make loans to the Company up to \$5,000, December 27, 2011 to raise the total amount of indebtedness that the Company may accrue under the term loan portion of the amended and restated loan and security agreement with Silicon Valley Bank from \$10,000 to \$12,000, and June 30, 2012 to modify financial covenants. The amended agreement provides that PFG will make loans to the Company up to \$5,000. The agreement has a maturity date of April 14, 2015. The loans bear interest at a floating per annum rate equal to 2.75% above Silicon Valley Bank's prime rate, and such interest is payable monthly. The principal balance of and any accrued and unpaid interest on any notes are due on the maturity date and may not be prepaid by the Company at any time in whole or in part.

As of June 30, 2012, PFG has provided the Company with the following three loans totaling \$5,000 that are outstanding: (i) a \$3,500 loan dated June 30, 2011 with a conversion price of \$13.64, (ii) a \$500 loan dated August 4, 2011, as amended and restated August 24, 2011, with a conversion price of \$15.30, and (iii) a \$1,000 loan dated August 24, 2011 with a conversion price of \$13.42. At any time prior to the maturity date, PFG may at its option convert any of the outstanding loans into shares of the Company's common stock at the applicable conversion price, which in each case equaled the ten-day volume weighted average price per share of the Company's common stock prior to the issuance date of each note. The Company may also effect at any time a mandatory conversion of amounts, subject to certain terms, conditions and limitations provided in the agreement, including a requirement that the ten-day volume weighted average price of the Company's common stock prior to the date of conversion is at least 15% greater than the conversion price. The Company may reduce the conversion price to a price that represents a 15% discount to the ten-day volume weighted average price of its common stock to satisfy this condition and effect a mandatory conversion. During the year ended June 30, 2012, PFG, at its option, converted a \$500 loan (at par) into 40,323 shares of the Company's common stock in accordance with the conversion terms set forth in the agreement. The Company has reflected a net expense of

**Table of Contents****CARDIOVASCULAR SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

\$736 and \$859 for the years ended June 30, 2012 and 2011 as a component of interest and other, net on the accompanying statement of operations, which represents the net effect of (i) the write-off of the conversion option on the converted loan, (ii) the write-off of the unamortized debt premium on the converted loan and (iii) the change in fair value of the conversion options on all outstanding loans. The balance outstanding under the loan and security agreement at June 30, 2012 and 2011 was \$5,575 and \$4,607, respectively, including the net unamortized premium associated with the warrants. The net unamortized premium associated with warrants issued to PFG in connection with the loan, a beneficial conversion feature, and other fees paid to the lender will be amortized over the remaining maturity period.

The loans are secured by certain of the Company's assets, and the agreement contains customary covenants limiting the Company's ability to, among other things, incur debt or liens, make certain investments and loans, effect certain redemptions of and declare and pay certain dividends on its stock, permit or suffer certain change of control transactions, dispose of collateral, or change the nature of its business. In addition, the PFG loan and security agreement contains financial covenants requiring the Company to maintain certain liquidity and fixed charge coverage ratios and certain three-month EBITDA targets. The Company was in compliance with all financial covenants at June 30, 2012. If the Company does not comply with the various covenants, PFG may, subject to various customary cure rights, decline to provide additional loans, require amortization of the loan over its remaining term, or require the immediate payment of all amounts outstanding under the loan and foreclose on any or all collateral, depending on which financial covenants are not maintained.

In connection with the initial agreement in April 2010, the Company issued PFG a warrant to purchase 66,299 shares of the Company's common stock at an exercise price of \$5.43 per share. In connection with the same agreement, PFG Equity Investors, LLC and Silicon Valley Bank were also issued warrants to purchase 9,724 and 71,307 shares of the Company's common stock, respectively, at an exercise price of \$5.43 per share. One-half of each warrant was immediately exercisable, and the remaining half became exercisable as additional funds were drawn during the year ended June 30, 2011. The warrants were exercised in June 2011. In connection with and as additional consideration for entering into the amendment to the loan and security agreement with PFG, as amended, on December 27, 2011, the Company issued one warrant to purchase 23,151 shares of the Company's common stock to PFG, one warrant to purchase 3,396 shares of the Company's common stock to PFG Equity Investors, LLC, an affiliate of PFG, and one warrant to purchase 24,900 shares of the Company's common stock to Silicon Valley Bank. Each warrant expires on the fifth anniversary of the issue date, subject to earlier expiration in accordance with its terms, and the exercise price for each of the warrants was set at \$9.33 per share, which was based on the ten-day average closing share price of the Company's common stock prior to the date of the amendment.

As of June 30, 2012, debt maturities (including debt discount and premium) were as follows:

2013	\$ 4,800
2014	5,050
2015	7,400
2016	0
<b>Total</b>	<b>\$ 17,250</b>
Less: Current Maturities	(4,678)
<b>Long-Term Debt (excluding net unamortized premium)</b>	<b>\$ 12,572</b>
Add: Net Unamortized Premium and Discounts	270
<b>Long-term debt</b>	<b>\$ 12,842</b>

**Table of Contents****CARDIOVASCULAR SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. Interest and Other, Net**

Interest and other, net, includes the following:

	Year Ended June 30,		
	2012	2011	2010
Interest expense, including premium and discount amortization	\$ (1,356)	\$ (1,417)	\$ (1,435)
Interest income	5	12	402
Change in fair value of conversion option	(554)	491	
Net write-offs upon conversion (option and unamortized premium)	(182)	(1,350)	
Gain on investments			150
Other	(237)	(52)	(122)
<b>Total</b>	<b>\$ (2,324)</b>	<b>\$ (2,316)</b>	<b>\$ (1,005)</b>

**5. Equity Offering**

On May 22, 2012, the Company, in a registered underwritten public offering, sold 1,780,000 shares of its common stock at \$9.00 per share. Net proceeds to the Company, after deducting underwriting discounts, commissions, and estimated expenses, were \$14,889.

**6. Common Stock Warrants**

In connection with, and as additional consideration for, the December 27, 2011 amendment to the amended and restated loan agreement with Silicon Valley Bank, the Company issued Silicon Valley Bank a warrant to purchase 12,760 shares of the Company's common stock at an exercise price of \$9.796 per share. The fair value of this warrant was \$91. Additionally, in connection with an amendment to the loan and security agreement with PFG, on December 27, 2011, the Company issued Silicon Valley Bank a warrant to purchase 24,900 shares of the Company's common stock at an exercise price of \$9.33 per share. This fair value of this warrant was \$136. In connection with the amendment to the loan and security agreement with PFG on December 27, 2011, the Company issued PFG a warrant to purchase 23,151 shares of Company common stock and issued PFG Equity Investors, LLC a warrant to purchase 3,396 shares of Company common stock, all at an exercise price of \$9.33 per share. The fair value of this warrant was \$145. On June 29, 2012, in connection with and as additional consideration for entering into a subsequent amendment to the amended and restated loan agreement with Silicon Valley Bank, the company issued a warrant to purchase 18,649 shares of the Company's common stock to Silicon Valley Bank at an exercise price of \$9.652 per share. The fair value of this warrant was \$125.

During the year ended June 30, 2010, the Company entered into a loan and security agreement with Partners for Growth III, L.P. In connection with this agreement the Company issued PFG a warrant to purchase 66,299 shares of the Company's common stock at an exercise price of \$5.43 per share. In connection with the same agreement, PFG Equity Investors, LLC and Silicon Valley Bank were also issued warrants to purchase 9,724 and 71,307 shares of Company common stock, respectively, at an exercise price of \$5.43 per share. One-half of each warrant was immediately exercisable, and the remaining half became exercisable as additional funds were drawn during the year ended June 30, 2011. The fair value of the immediately exercisable warrants was \$97, while the fair value of the warrants that vested during the year ended June 30, 2011 was \$216. The warrants were exercised in June 2011.

**Table of Contents****CARDIOVASCULAR SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following summarizes common stock warrant activity:

	<b>Warrants Outstanding</b>	<b>Price Range per Share</b>
Warrants outstanding at June 30, 2009	3,121,421	\$1.55-61.30
Issued	147,330	\$5.43
Exercised	(879)	\$1.55
Expired	(25,880)	\$1.55-14.16
Warrants outstanding at June 30, 2010	3,241,992	\$5.43-61.30
Exercised	(548,366)	\$ 5.43-8.83
Expired	(3,202)	\$9.28
Warrants outstanding at June 30, 2011	2,690,424	\$8.78-61.30
Issued	82,856	\$9.33-9.80
Exercised	(313,239)	\$8.78-8.83
Expired	(2,608)	\$8.79-8.83
Warrants outstanding at June 30, 2012	2,457,433	\$8.83-61.30

The following assumptions were utilized in determining the fair value of warrants issued during the year ended June 30, 2012 under the Black-Scholes model:

	<b>Year Ended June 30, 2012</b>
Risk-free interest rates	1.0% to 2.16%
Expected life	5 to 10 years
Expected volatility	58.5% to 63.4%
Expected dividends	None

The weighted average fair value of warrants issued during the year ended June 30, 2012, was \$6.00. There were no warrants issued during the year ending June 30, 2011.

The aggregate intrinsic value of a warrant is the amount by which the market value of the underlying stock exceeds the exercise price of the warrant. The aggregate intrinsic value for warrants at June 30, 2012, 2011 and 2010 was \$2,167, \$15,267, and \$0, respectively.

**7. Stock Options and Restricted Stock Awards**

The Company has a 2007 Equity Incentive Plan (the "2007 Plan"), which was assumed from CSI-MN, under which options to purchase common stock and restricted stock awards have been granted to employees, directors and consultants at exercise prices determined by the board of directors; and also in connection with the merger the Company assumed options and restricted stock awards granted by CSI-MN under its 1991 Stock Option Plan (the "1991 Plan") and 2003 Stock Option Plan (the "2003 Plan") (the 2007 Plan, the 1991 Plan and the 2003 Plan collectively, the "Plans"). The 1991 Plan and 2003 Plan permitted the granting of incentive stock options and nonqualified options. A total of 485,250 shares of

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common stock were originally reserved for issuance under the 1991 Plan, but with the approval of the 2003 Plan no additional options were granted under it. A total of 2,458,600 shares of common stock were originally reserved for issuance under the 2003 Plan, but with the approval of the 2007 Plan no additional options will be granted under it.

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**Table of Contents****CARDIOVASCULAR SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The 2007 Plan originally allowed for the granting of up to 1,941,000 shares of common stock as approved by the board of directors in the form of nonqualified or incentive stock options, restricted stock awards, restricted stock unit awards, performance share awards, performance unit awards or stock appreciation rights to officers, directors, consultants and employees of the Company. The Plan was amended in February 2009 to increase the number of authorized shares to 2,509,969. Generally, options or shares granted under the 2007 Plan expire ten years from the date of grant and vest over three years. The amended 2007 Plan includes a renewal provision whereby the number of shares shall automatically be increased on the first day of each fiscal year ending on July 1, 2017, by the lesser of (i) 970,500 shares, (ii) 5% of the outstanding common shares on such date, or (iii) a lesser amount determined by the board of directors. On July 1, 2012, the number of shares available for grant was increased by 450,000 under the 2007 Plan renewal provision, which was 2.2% of shares outstanding at June 30, 2012.

The Company also maintains the 2006 Equity Incentive Plan (the 2006 Plan), relating to Replidyne activity prior to the merger in February 2009. A total of 794,641 shares were originally reserved under the 2006 Plan, but effective with the merger no additional options will be granted under it. Generally, options granted under the 2006 Plan expire ten years from the date of grant and vested over four years. Vested options granted to employees terminated 90 days after termination.

All options granted under the Plans become exercisable over periods established at the date of grant. The option exercise price is generally not less than the estimated fair market value of the Company's common stock at the date of grant, as determined by the Company's management and board of directors. In addition, the Company has granted nonqualified stock options to a director outside of the Plans.

Stock option activity is as follows:

	Number of Options(a)	Weighted Average Exercise Price
Options outstanding at June 30, 2009	3,707,882	\$ 10.43
Granted	58,551	\$ 7.70
Exercised	(37,313)	\$ 8.36
Forfeited or expired	(372,127)	\$ 9.34
Options outstanding at June 30, 2010	3,356,993	\$ 10.49
Exercised	(180,702)	\$ 8.60
Forfeited or expired	(105,292)	\$ 12.32
Options outstanding at June 30, 2011	3,070,999	\$ 10.54
Exercised	(311,814)	\$ 9.12
Forfeited or expired	(387,987)	\$ 13.11
Options outstanding at June 30, 2012	2,371,198	\$ 10.31

(a) Includes the effect of options granted, exercised, forfeited or expired from the 1991 Plan, 2003 Plan, 2007 Plan, 2006 Plan and options granted outside the stock option plans described above.

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Options outstanding and exercisable at June 30, 2012 were as follows:

Exercise Price	Options Outstanding		Options Exercisable	
	Number of Outstanding Shares	Remaining Weighted Average Contractual Life (Years)	Number of Exercisable Shares	Remaining Weighted Average Contractual Life (Years)
\$5.01	12,940	7.43	12,940	7.43
\$7.90	352,488	5.10	352,488	5.10
\$8.75	85,080	6.67	85,080	6.67
\$8.83	823,919	4.40	823,919	4.40
\$9.28	32,671	2.40	32,671	2.40
\$11.38	70,055	5.38	70,055	5.38
\$12.15	739,532	2.99	739,532	2.99
\$12.37	138,781	3.30	138,781	3.30
\$13.98	74,281	5.63	74,281	5.63
\$14.00	4,000	0.50	4,000	0.50
\$16.40	6,000	0.50	6,000	0.50
\$18.55	31,451	3.75	31,451	3.75
	2,371,198	4.11	2,371,198	4.11

As of June 30, 2012, all options were fully vested. An employee's vested options must be exercised at or within 90 days of termination to avoid forfeiture. The Company determined the fair value of options using the Black-Scholes option pricing model. The estimated fair value of options, including the effect of estimated forfeitures, was recognized as expense on a straight-line basis over the options' vesting periods. There were no options granted during the years ended June 30, 2012 or 2011.

The aggregate intrinsic value of a stock option award is the amount by which the market value of the underlying stock exceeds the exercise price of the award. The aggregate intrinsic value for vested and outstanding options at June 30, 2012, 2011 and 2010 was \$1,624, \$12,712 and \$0, respectively. The total aggregate intrinsic value of options exercised during the years ended June 30, 2012, 2011 and 2010 was \$770, \$736 and \$30, respectively. Shares supporting option exercises are sourced from new share issuances.



**Table of Contents****CARDIOVASCULAR SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The fair value of each restricted stock award was equal to the fair market value of the Company's common stock at the date of grant. Vesting of restricted stock awards range from one to three years. The estimated fair value of restricted stock awards, including the effect of estimated forfeitures, is recognized on a straight-line basis over the restricted stock's vesting period. Restricted stock award activity is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Restricted stock awards outstanding at June 30, 2009	744,377	\$ 10.81
Granted	877,751	\$ 6.87
Forfeited	(187,441)	\$ 8.48
Vested	(328,804)	\$ 6.00
Restricted stock awards outstanding at June 30, 2010	1,105,883	\$ 7.69
Granted	804,159	\$ 6.08
Forfeited	(199,910)	\$ 6.91
Vested	(511,925)	\$ 7.68
Restricted stock awards outstanding at June 30, 2011	1,198,207	\$ 6.39
Granted	817,878	\$ 11.32
Forfeited	(253,810)	\$ 7.80
Vested	(517,445)	\$ 12.88
Restricted stock awards outstanding at June 30, 2012	1,244,830	\$ 9.08

Estimated pre-vesting forfeitures are considered in determining stock-based compensation expense. As of June 30, 2012, 2011 and 2010, the Company estimated its forfeiture rate at 11.6%, 10.7% and 9.4%, respectively. As of June 30, 2012, 2011 and 2010 the total compensation cost for non-vested awards not yet recognized in the consolidated statements of operations was \$7,767, \$5,128 and \$4,226, respectively, net of the effect of estimated forfeitures. These amounts are expected to be recognized over a weighted-average period of 2.44, 2.27 and 1.02 years, respectively.

**Table of Contents****CARDIOVASCULAR SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company grants restricted stock units to members of the Board of Directors. Restricted stock units represent the right to receive payment in the form of shares of the Company's common stock or in cash at the Company's option. Restricted stock unit payments would occur within 30 days following the six month anniversary of the date that the director ceases to serve on the Board. The estimated fair value of restricted stock awards is recognized on a straight-line basis over the vesting period. Restricted stock unit activity is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Restricted stock units outstanding at June 30, 2009	42,238	\$ 8.75
Granted	93,024	\$ 8.60
Forfeited	(5,814)	\$ 8.60
Restricted stock units outstanding at June 30, 2010	129,448	\$ 8.65
Granted	158,880	\$ 4.79
Converted to common stock	(28,212)	\$ 7.09
Forfeited	(22,397)	\$ 6.70
Restricted stock units outstanding at June 30, 2011	237,719	\$ 6.51
Granted	50,344	\$ 13.91
Forfeited	(3,596)	\$ 13.91
Restricted stock units outstanding at June 30, 2012	284,467	\$ 7.67

The following amounts were recognized as stock-based compensation expense in the consolidated statements of operations for the year ended June 30, 2012:

	Restricted Stock Awards	Employee Stock Purchase Plan	Restricted Stock Units	Total
Cost of goods sold	\$ 256	\$ 40	\$ 0	\$ 296
Selling, general and administrative	3,105	621	669	4,395
Research and development	439	35	0	474
Total	\$ 3,800	\$ 696	\$ 669	\$ 5,165

The following amounts were recognized as stock-based compensation expense in the consolidated statements of operations for the year ended June 30, 2011:

Stock Options	Restricted Stock Awards	Employee Stock Purchase Plan	Restricted Stock Units	Total
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Cost of goods sold	\$ 97	\$ 200	\$ 15	\$ 0	\$ 312
Selling, general and administrative	1,175	3,384	298	712	5,569
Research and development	34	518	35	0	587
Total	\$ 1,306	\$ 4,102	\$ 348	\$ 712	\$ 6,468

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**Table of Contents****CARDIOVASCULAR SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following amounts were recognized as stock-based compensation expense in the consolidated statements of operations for the year ended June 30, 2010:

	Stock Options	Restricted Stock Awards	Employee Stock Purchase Plan	Restricted Stock Units	Total
Cost of goods sold	\$ 323	\$ 205	\$ 20	\$ 0	\$ 548
Selling, general and administrative	3,405	3,382	378	107	7,272
Research and development	527	706	41	0	1,274
Total	\$ 4,255	\$ 4,293	\$ 439	\$ 107	\$ 9,094

The following summarizes shares available for grant under the Company's various equity incentive plans:

	Shares Available for Grant(a)
Shares available for grant at June 30, 2009	84,838
Reserved	705,695
Granted	(936,302)
Forfeited, expired or cancelled	255,942
Shares available for grant at June 30, 2010	110,173
Reserved	757,427
Granted	(1,092,500)
Forfeited, expired or cancelled	275,623
Shares available for grant at June 30, 2011	50,723
Reserved	849,353
Granted	(868,222)
Forfeited, expired or cancelled	581,447
Shares available for grant at June 30, 2012	613,301

(a) Excludes the effect of shares granted, exercised, forfeited or expired related to activity from shares granted outside the stock option plans described above. Excludes share forfeitures from grants not under the 2007 Plan.

**Employee Stock Purchase Plan**

The Company maintains an employee stock purchase plan (ESPP). The plan provides eligible employees the opportunity to acquire common stock in accordance with Section 423 of the Internal Revenue Code of 1986. Stock can be purchased each six-month period per year (twice per

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year). The purchase price is equal to 85% of the lower of the price at the beginning or the end of the respective period. The ESPP allows for an annual increase in reserved shares on each July 1 equal to the lesser of (i) one percent of the common shares outstanding, or (ii) 180,000 shares, provided that the Board of Directors may designate a smaller amount of shares to be reserved. On July 1, 2012, 180,000 shares were added to the plan. Employees purchased 170,000 shares at an average price of \$8.34 per share during the year ended June 30, 2012. Shares reserved under the plan for the year ending June 30, 2013 totaled 180,709.

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**Table of Contents****CARDIOVASCULAR SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. Income Taxes**

The components of the Company's overall deferred tax assets and liabilities are as follows:

	2012	June 30, 2011
Deferred tax assets		
Stock-based compensation	\$ 5,415	\$ 6,420
Accrued expenses	1,065	933
Inventories	1,049	448
Depreciation and amortization	175	109
Other	354	2,073
Research and development credit carryforwards	3,204	3,446
Net operating loss carryforwards	45,203	38,944
<b>Total deferred tax assets</b>	<b>56,465</b>	<b>52,373</b>
Valuation allowance	(56,465)	(52,373)
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

The Company has established valuation allowances to fully offset its deferred tax assets due to the uncertainty about the Company's ability to generate the future taxable income necessary to realize these deferred assets, particularly in light of the Company's historical losses. The future use of net operating loss carryforwards is dependent on the Company attaining profitable operations, and may be limited in any one year under Internal Revenue Code Section 382 due to significant ownership changes, as defined under such Section, as a result of the Company's equity financings. A summary of the valuation allowances are as follows:

	Amount
Balance at June 30, 2010	\$ 49,180
Additions	3,193
<b>Balance at June 30, 2011</b>	<b>52,373</b>
Additions	4,092
<b>Balance at June 30, 2012</b>	<b>\$ 56,465</b>

As of June 30, 2012 and 2011, the Company had federal tax NOL carryforwards of approximately \$128,273 and \$110,102, respectively. These NOL carryforwards are available to offset taxable income through 2032 and began to expire in 2011. The Company also had various state NOL carryforwards available to offset future state taxable income. These state NOL carryforwards typically will have the same expirations as the Company's federal tax NOL carryforwards.

As of June 30, 2012 and 2011, the Company had approximately \$3,065 and \$3,023 of federal research and development credit carryforwards, respectively. As of June 30, 2012 and 2011, the Company had approximately \$749 of state research and development credit carryforwards. The federal and state research and development credit carryforwards will begin to expire in 2024. As of June 30, 2012, the Company has recorded \$200 in anticipated refundable state research and development credits.

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As required by FASB ASC Topic 740, Income Taxes, the Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more likely than not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being

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**Table of Contents****CARDIOVASCULAR SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

realized upon ultimate settlement with the relevant tax authority. The Company recorded a liability relating to unrecognized tax benefits of \$381 and \$383 at June 30, 2012 and 2011, respectively. Due to the Company having a full valuation allowance, this liability has been netted against the deferred tax asset. The Company recognizes interest and penalties related to uncertain tax provisions as part of the provision for income taxes. The Company has not currently reserved for any interest or penalties for such reserves due to the Company being in an NOL position. The Company does not expect to recognize any benefits from the unrecognized tax benefits within the next 12 months. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

Balance at July 1, 2010	\$ 347
Increases related to prior year tax positions	22
Increases related to current year tax positions	14
Balance at June 30, 2011	\$ 383
Increases related to prior year tax positions	(6)
Increases related to current year tax positions	4
Balance at June 30, 2012	\$ 381

The Company is subject to income taxes in the U.S. federal jurisdiction and various state jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company is potentially subject to income tax examinations by tax authorities for the tax years ended June 30, 2012, 2011, 2010, and 2009. The Company is not currently under examination by any taxing jurisdiction.

**9. Commitment and Contingencies*****Operating Leases***

The Company leases manufacturing and office space and equipment under various lease agreements which expire at various dates through March 2020. Rental expenses were \$1,200, \$1,188, and \$659 for the years ended June 30, 2012, 2011, and 2010, respectively.

Future minimum lease payments under the agreements as of June 30, 2012 are as follows:

2013	\$ 884
2014	855
2015	867
2016	641
2017	460
Thereafter	1,265
	\$ 4,972

Amounts payable under the Company's Texas production facility lease are included in the amounts above. A portion of those rent payments may reduce the deferred grant incentive liability rather than being recorded as expense. See Note 11 for additional information.



**10. Employee Benefits**

The Company offers a 401(k) plan to its employees. Eligible employees may authorize up to \$16 of their annual compensation as a contribution to the plan, subject to Internal Revenue Service limitations. The plan also allows eligible employees over 50 years old to contribute an additional \$6 subject to Internal Revenue Service

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**CARDIOVASCULAR SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

limitations. All employees must be at least 21 years of age to participate in the plan. The Company did not provide any employer matching contributions for the years ended June 30, 2012, 2011, and 2010.

**11. Texas Production Facility**

Effective on September 9, 2009, the Company entered into an agreement with the Pearland Economic Development Corporation (the PEDC ) for the construction and lease of an approximately 46,000 square foot production facility located in Pearland, Texas. The facility will primarily serve as an additional manufacturing location for the Company.

The lease agreement provides that the PEDC will lease the facility and the land immediately surrounding the facility to the Company for an initial term of ten years, beginning April 1, 2010. Monthly fixed rent payments are \$35 for each of the first five years of the initial term and \$38 for each of the last five years of the initial term. The Company will also be responsible for paying the taxes and operating expenses related to the facility. The lease has been classified as an operating lease for financial statement purposes. Upon an event of default under the agreement, the Company will be liable for the difference between the balance of the rent owed for the remainder of the term and the fair market rental value of the leased premises for such period.

The Company has the option to renew the lease for up to two additional periods of five years each. If the Company elects to exercise one or both of these options, the rent for such extended terms will be set at the prevailing market rental rates at such times, as determined in the agreement. After the commencement date and until shortly before the tenth anniversary of the commencement date, the Company will have the option to purchase all, but not less than all, of the leased premises at fair market value, as determined in the agreement. Further, within six years of the commencement date and subject to certain conditions, the Company has options to cause the PEDC to make two additions or expansions to the facility of a minimum of 34,000 and 45,000 square feet each.

The Company and the PEDC entered into a Corporate Job Creation Agreement dated June 17, 2009, which was subsequently amended July 2, 2012. The Job Creation Agreement, as amended, provided the Company with \$2,975 in net cash incentive funds. The Company believes it will be able to comply with the conditions specified in the amended agreement. The PEDC will provide the Company with an additional \$850 of net cash incentive funds in the following amounts and upon achievement of the following milestones:

\$425 upon the hiring of the 75<sup>th</sup> full-time employee at the facility on or before March 31, 2014, and maintaining 75 employees at the facility through March 31, 2015;

\$425 upon the hiring of the 125<sup>th</sup> full-time employee at the facility on or before June 30, 2015, and maintaining 125 employees at the facility through June 30, 2016.

In order to retain all of the cash incentives, the Company must create, fill and maintain no fewer than 25 jobs at the Texas facility by March 31, 2013 and must maintain at least that minimum number of jobs through June 30, 2015. Failure to meet this requirement will result in an obligation to make reimbursement payments to the PEDC as outlined in the amended agreement. The Company will not have any reimbursement requirements after June 30, 2015. As of June 30, 2012, the Company was in compliance with all minimum requirements under the amended agreement.

The Job Creation Agreement, as amended, also provided the Company with a net \$1,020 award, of which \$510 was received from the PEDC and the remainder is funded through the Texas Enterprise Fund program associated with the State of Texas. As of June 30, 2012, \$340 has been received and the remaining \$170 will be provided upon the hiring of the 75<sup>th</sup> full-time employee at the facility. The grant from the State of Texas is subject to reimbursement if the Company fails to meet certain job creation targets through 2014 and maintain these positions through 2020.



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**CARDIOVASCULAR SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company has presented the net cash incentive funds as a current and long-term liability on the balance sheet. The liabilities will be reduced through the remainder of the agreement and recorded as an offset to expenditures incurred using a systematic methodology. As of June 30, 2012, \$3,360 in cumulative expenses has reduced the deferred grant incentive liabilities, resulting in a remaining current liability of \$302 and long-term liability of \$163.

**12. Legal Matters**

***ev3 Legal Proceedings***

The Company was a party to a legal proceeding with ev3 Inc., ev3 Endovascular, Inc. and FoxHollow Technologies, Inc., together referred to as the Plaintiffs, which filed a complaint on December 28, 2007 in the Ramsey County District Court for the State of Minnesota against the Company and former employees of FoxHollow currently employed by the Company, which complaint was subsequently amended.

On October 27, 2010, the Company entered into a settlement agreement with the Plaintiffs. The agreement dismissed all claims and counterclaims in the legal proceeding between the two parties, with neither party admitting any liability or wrongdoing. Pursuant to the agreement, the Company paid ev3 \$1,000, in the form of \$750 cash and a \$250 promissory note. The promissory note bears interest at 3.5% per annum, with principal and cumulative interest due and payable on or before January 1, 2014. The Company received insurance proceeds of \$500 related to the settlement, and recorded a net expense of \$500 in selling, general, and administrative expenses related to the settlement during the year ended June 30, 2011. In addition, during the year ended June 30, 2011, the Company received an additional \$250 of insurance proceeds related to the reimbursement of out-of-pocket costs incurred related to this litigation.

***Michael Kallok Claim***

On July 18, 2011, the Company received a demand letter from legal counsel for Michael Kallok, a former officer, director and consultant to the Company, claiming that Mr. Kallok is entitled to 42,594 shares of the Company's common stock or, alternatively, the value of those shares as of July 15, 2011, which was \$610,798. Mr. Kallok asserts that the Company improperly deemed such shares forfeited under a restricted stock agreement with Mr. Kallok. This matter is proceeding to arbitration, which is scheduled to take place on September 10 and 11, 2012.

The Company is defending this claim vigorously, and believes that an adverse outcome of this dispute would not have a materially adverse effect on the Company's business, operations, cash flows or financial condition. The Company has not recognized any expense related to the settlement of this matter as it believes an adverse outcome of this action is not probable.

**Table of Contents****CARDIOVASCULAR SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****13. Earnings Per Share**

The following table presents a reconciliation of the numerators and denominators used in the basic and diluted earnings per common share computations:

	Year Ended June 30,		
	2012	2011	2010
<b>Numerator</b>			
Net loss	\$ 16,790	\$ 11,125	\$ 23,904
<b>Denominator</b>			
Weighted average common shares basic	18,035,635	15,915,800	14,748,293
Effect of dilutive stock options and warrants(a)(b)(c)			
Weighted average common shares outstanding diluted	18,035,635	15,915,800	14,748,293
Loss per common share basic and diluted	\$ (0.93)	\$ (0.70)	\$ (1.62)

- (a) At June 30, 2012, 2011, and 2010, 2,457,433, 2,690,424, and 3,241,992, warrants, respectively, were outstanding. The effect of the shares that would be issued upon exercise of these warrants has been excluded from the calculation of diluted loss per share, because those shares are anti-dilutive.
- (b) At June 30, 2012, 2011, and 2010, 2,371,198, 3,070,999, and 3,356,993 stock options, respectively, were outstanding. The effect of the shares that would be issued upon exercise of these options has been excluded from the calculation of diluted loss per share, because those shares are anti-dilutive.
- (c) At June 30, 2012 and 2011, 363,794 and 296,921 additional shares of common stock are issuable upon the conversion of outstanding convertible debt agreements. The effect of the shares that would be issued upon conversion of these debt agreements has been excluded from the calculation of diluted loss per share because those shares are anti-dilutive.

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### **Item 9. *Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.***

None.

### **Item 9A. *Controls and Procedures.***

#### **Evaluation of Disclosure Controls and Procedures**

Our Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, are responsible for establishing and maintaining our disclosure controls and procedures. The Certifying Officers have reviewed and evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 240.13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934 (the Exchange Act)) as of June 30, 2012. Based on that review and evaluation, which included inquiries made to certain other employees of the Company, the Certifying Officers have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, the Company's disclosure controls and procedures, as designed and implemented, are effective.

#### **Management's Annual Report on Internal Control Over Financial Reporting**

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) for the Company. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that the Company's internal control over financial reporting was effective as of June 30, 2012. PricewaterhouseCoopers LLP, the independent registered public accounting firm that audited the consolidated financial statements included in this Annual Report on Form 10-K, has also audited our internal control over financial reporting as of June 30, 2012, as stated in their attestation report included in Part IV, Item 15 of this Annual Report on Form 10-K.

#### **Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended June 30, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Item 9B. *Other Information.***

None.

## **PART III**

### **Item 10. *Directors, Executive Officers and Corporate Governance.***

Other than the information included in this Form 10-K under the heading Executive Officers of the Registrant, which is set forth at the end of Part I, the information required by Item 10 is incorporated by reference to the sections labeled Election of Directors, Information Regarding the Board of Directors and Corporate Governance and Section 16(a) Beneficial Ownership Reporting Compliance, all of which will appear in our definitive proxy statement for our 2012 Annual Meeting.

### **Item 11. *Executive Compensation.***

The information required by Item 11 is incorporated herein by reference to the sections entitled Executive Compensation, Director Compensation, Human Resources and Compensation Committee and Compensation Committee Interlocks and Insider Participation, all of which will appear in our definitive proxy statement for our 2012 Annual Meeting.



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**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by Item 12 is incorporated herein by reference to the sections entitled Security Ownership of Certain Beneficial Owners and Management and Equity Compensation Plan Information, which will appear in our definitive proxy statement for our 2012 Annual Meeting.

**Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by Item 13 is incorporated herein by reference to the sections entitled Information Regarding the Board of Directors and Corporate Governance Independence of the Board of Directors and Transactions With Related Persons, which will appear in our definitive proxy statement for our 2012 Annual Meeting.

**Item 14. Principal Accounting Fees and Services.**

The information required by Item 14 is incorporated herein by reference to the section entitled Principal Accountant Fees and Services, which will appear in our definitive proxy statement for our 2012 Annual Meeting.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules.**

(a) Documents filed as part of this report.

(1) Financial Statements. The following financial statements are included in Part II, Item 8 of this Annual Report on Form 10-K:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of June 30, 2012 and 2011

Consolidated Statements of Operations for the years ended June 30, 2012, 2011 and 2010

Consolidated Statements of Stockholders' Equity (Deficiency) and Comprehensive Loss for the years ended June 30, 2012, 2011 and 2010

Consolidated Statements of Cash Flows for the years ended June 30, 2012, 2011 and 2010

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules.

All financial statement schedules have been omitted, because they are not applicable, are not required, or the information is included in the Financial Statements or Notes thereto



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(3) Exhibits. See Exhibit Index immediately following the signature page of this Form 10-K

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CARDIOVASCULAR SYSTEMS, INC.

Date: September 10, 2012

By: /s/ David L. Martin  
David L. Martin  
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Each person whose signature appears below constitutes and appoints David L. Martin and Laurence L. Betterley as the undersigned's true and lawful attorneys-in fact and agents, each acting alone, with full power of substitution and resubstitution, for the undersigned and in the undersigned's name, place and stead, in any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granted unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all said attorneys-in-fact and agents, each acting alone, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Signature	Title	Date
/s/ David L. Martin David L. Martin	President, Chief Executive Officer and Director (principal executive officer)	September 10, 2012
/s/ Laurence L. Betterley Laurence L. Betterley	Chief Financial Officer (principal financial and accounting officer)	September 10, 2012
/s/ Edward Brown Edward Brown	Director	September 10, 2012
/s/ Brent G. Blackey Brent G. Blackey	Director	September 10, 2012
/s/ John H. Friedman John H. Friedman	Director	September 10, 2012
Leslie Trigg	Director	September 10, 2012
/s/ Augustine Lawlor Augustine Lawlor	Director	September 10, 2012

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/s/ Glen D. Nelson

Director

September 10, 2012

Glen D. Nelson

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**EXHIBIT INDEX**

**CARDIOVASCULAR SYSTEMS, INC.**

**FORM 10-K**

**Exhibit**

No.	Description
3.1	Restated Certificate of Incorporation, as amended.(7)
3.2	Amended and Restated Bylaws.(2)
4.1	Specimen Common Stock Certificate.(2)
4.2	Form of Cardiovascular Systems, Inc. common stock warrant issued to former preferred stockholders.(2)
4.3	Registration Rights Agreement by and among Cardiovascular Systems, Inc. and certain of its stockholders, dated as of March 16, 2009.(1)
4.4	Termination of Fourth Amended and Restated Stockholders Agreement by and among Cardiovascular Systems, Inc. and certain of its stockholders, dated as of March 16, 2009.(1)
10.1	Lease, dated September 26, 2005, by and between Cardiovascular Systems, Inc., a Minnesota corporation, and Industrial Equities Group LLC.(3)
10.2	First Amendment to the Lease, dated February 20, 2007, by and between Cardiovascular Systems, Inc., a Minnesota corporation, and Industrial Equities Group LLC.(3)
10.3	Second Amendment to the Lease, dated March 9, 2007, by and between Cardiovascular Systems, Inc., a Minnesota corporation, and Industrial Equities Group LLC.(3)
10.4	Third Amendment to the Lease, dated September 26, 2007, by and between Cardiovascular Systems, Inc., a Minnesota corporation, and Industrial Equities Group LLC.(3)
10.5	Lease Agreement, dated October 25, 2005, by and between Cardiovascular Systems, Inc., a Minnesota corporation, and Triumph 1450 LLC.(8)
10.6	Assumption of Lease, dated March 23, 2009 by Cardiovascular Systems, Inc.(7)
10.7	Employment Agreement, dated December 19, 2006, by and between Cardiovascular Systems, Inc., a Minnesota corporation, and David L. Martin.(3)
10.8	Employment Agreement, dated April 7, 2008, by and between Cardiovascular Systems, Inc., a Minnesota corporation, and Laurence L. Betterley.(3)
10.9	Employment Agreement, dated May 9, 2011, by and between Cardiovascular Systems, Inc. and Kevin J. Kenny.(13)
10.10	Form of Standard Employment Agreement.(3)
10.11 *	Summary of Fiscal Year 2013 Executive Officer Base Salaries.
10.12 *	Fiscal Year 2013 Director Compensation Arrangements.
10.13+	Purchasing Agreement between Cardiovascular Systems, Inc. and HealthTrust Purchasing Group, L.P., dated effective as of July 15, 2011, and amendment to Purchasing Agreement dated effective as of July 15, 2011.(13)
10.14	Form of Director and Officer Indemnification Agreement.(7)
10.15	Cardiovascular Systems, Inc. Amended and Restated 2007 Equity Incentive Plan.(5)
10.16	Form of Incentive Stock Option Agreement under the Amended and Restated 2007 Equity Incentive Plan.(7)
10.17	Form of Non-Qualified Stock Option Agreement under the Amended and Restated 2007 Equity Incentive Plan.(7)
10.18	Form of Restricted Stock Agreement under the Amended and Restated 2007 Equity Incentive Plan.(13)
10.19	Form of Restricted Stock Unit Agreement under the Amended and Restated 2007 Equity Incentive Plan.(13)

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**Exhibit**

No.	Description
10.20	Form of Performance Share Award under the Amended and Restated 2007 Equity Incentive Plan.(7)
10.21	Form of Performance Unit Award under the Amended and Restated 2007 Equity Incentive Plan.(7)
10.22	Form of Stock Appreciation Rights Agreement under the Amended and Restated 2007 Equity Incentive Plan.(7)
10.23	2003 Stock Option Plan of Cardiovascular Systems, Inc., a Minnesota corporation, as amended.(3)
10.24	Form of Incentive Stock Option Agreement under the 2003 Stock Option Plan of Cardiovascular Systems, Inc., a Minnesota corporation.(3)
10.25	Form of Nonqualified Stock Option Agreement under the 2003 Stock Option Plan of Cardiovascular Systems, Inc., a Minnesota corporation.(3)
10.26	1991 Stock Option Plan of Cardiovascular Systems, Inc., a Minnesota corporation.(3)
10.27	Form of Non-Qualified Stock Option Agreement outside the 1991 Stock Option Plan of Cardiovascular Systems, Inc., a Minnesota corporation.(3)
10.28	Cardiovascular Systems, Inc. Amended and Restated 2006 Employee Stock Purchase Plan.(6)
10.29	Cardiovascular Systems, Inc. Executive Officer Severance Plan.(13)
10.30	Corporate Job Creation Agreement between Pearland Economic Development Corporation and Cardiovascular Systems, Inc., dated June 17, 2009.(4)
10.31	Build-To-Suit Lease Agreement between Pearland Economic Development Corporation and Cardiovascular Systems, Inc., dated September 9, 2009.(4)
10.32	Letter Agreement between Silicon Valley Bank and Cardiovascular Systems, Inc., dated September 9, 2009.(4)
10.33	Amended and Restated Loan and Security Agreement, dated March 29, 2010, by and between Cardiovascular Systems, Inc. and Silicon Valley Bank.(11)
10.34	Loan and Security Agreement, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P.(11)
10.35	Intellectual Property Security Agreement, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P.(11)
10.36	Copyright Collateral Agreement and Notice, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P.(11)
10.37	Domain Rights Collateral Agreement and Notice, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P.(11)
10.38	Patent Collateral Agreement and Notice, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P.(11)
10.39	Trademark Collateral Agreement and Notice, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P.(11)
10.40	Letter Agreement, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P.(11)
10.41	Settlement Agreement among ev3, Inc., ev3 Endovascular, Inc., FoxHollow Technologies, Inc., Tyco Healthcare Group LP d/b/a Covidien, Cardiovascular Systems, Inc., Aaron Lew, Paul Tyska, Sean Collins, David Gardner, Michael Micheli, Kevin Moore, Steve Pringle, Jason Proffitt, Thadd Taylor and Rene Treanor-Sarria, dated October 29, 2010.(9)
10.42+	Supply Agreement between Cardiovascular Systems, Inc. and Fresenius Kabi AB, dated April 4, 2011.(10)
10.43+	Amendment dated effective November 1, 2011 to Purchasing Agreement with Healthtrust Purchasing Group, L.P.(14)
10.44	Modification No.1 dated August 23, 2011 to Loan and Security Agreement with Partners for Growth III, L.P.(14)

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**Exhibit**

<b>No.</b>	<b>Description</b>
10.45	First Amendment to Loan and Security Agreement, dated as of December 27, 2011, by and between the Company and Silicon Valley Bank.(15)
10.46	Warrant to Purchase Stock, dated December 27, 2011, issued by the Company to Silicon Valley Bank.(15)
10.47	Warrant, dated December 27, 2011, issued by the Company to Silicon Valley Bank.(15)
10.48	Modification No. 2 to Loan and Security Agreement, dated as of December 27, 2011, by and between the Company and Partners for Growth III, L.P.(15)
10.49	Warrant, dated December 27, 2011, issued by the Company to PFG Equity Investors, LLC.(15)
10.50	Warrant, dated December 27, 2011, issued by the Company to Partners for Growth III, L.P.(15)
10.51 *	Fiscal 2013 Executive Officer Bonus Plan.
10.52	Fourth Amendment to Lease, dated March 23, 2012, by and between the Company and Industrial Equities Group LLC.(16)
10.53*	Second Amendment to Loan and Security Agreement, dated June 29, 2012, by and between the Company and Silicon Valley Bank.
10.54*	Modification No. 3 to Loan and Security Agreement, dated as of June 30, 2012, by and between the Company and Partners for Growth III, L.P.
10.55*	Amendment to Corporate Job Creation Agreement, dated effective July 2, 2012, by and between the Company and Pearland Economic Development Corporation.
10.56*	Warrant, dated June 29, 2012, issued by the Company to Silicon Valley Bank.
23.1*	Consent of PricewaterhouseCoopers LLP.
24.1*	Power of Attorney (included on the signature page).
31.1*	Certification of principal executive officer required by Rule 13a-14(a).
31.2*	Certification of principal financial officer required by Rule 13a-14(a).
32.1*	Section 1350 Certification of principal executive officer.
32.2*	Section 1350 Certification of principal financial officer.
101**	Financial statements from the annual report on Form 10-K of the Company for the year ended June 30, 2012, formatted, in XBRL: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Cash Flows, and (iv) the Notes to Financial Statements.

\* Filed herewith.

\*\* Furnished herewith.

Compensatory plan or agreement.

+ Confidential treatment has been granted for certain portions omitted from this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

@ Confidential treatment has been requested for certain portions omitted from this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

(1) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Current Report on Form 8-K filed on March 18, 2009.

(2) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Current Report on Form 8-K filed on March 3, 2009.

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- (3) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from CSI Minnesota, Inc.'s Registration Statement on Form S-1, File No. 333-148798.

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- (4) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Annual Report on Form 10-K filed on September 29, 2009.
- (5) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Registration Statement on Form S-8, File No. 333-158755.
- (6) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Registration Statement on Form S-8, File No. 333-158987.
- (7) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
- (8) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Registration Statement on Form S-1, File No. 333-133021.
- (9) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed on November 12, 2010.
- (10) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed on May 13, 2011.
- (11) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed on May 14, 2010.
- (12) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Annual Report on Form 10-K filed on September 28, 2010.
- (13) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Annual Report on Form 10-K filed on September 12, 2011.
- (14) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed on November 8, 2011.
- (15) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed on February 9, 2012.
- (16) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed on May 8, 2012.