Cardiovascular Systems Inc
Form 10-K
September 12, 2011
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended June 30, 2011

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	**41-1698056**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
651 Campus Drive	**55112-3495**
St. Paul, Minnesota	*(Zip Code)*
(Address of principal executive offices)	

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**

Common Stock, One-tenth of One Cent ($0.001) Par Value Per Share	The NASDAQ Stock Market LLC

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 þ

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 þ

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 þ 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 þ	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 þ

As of December 31, 2010, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was $154,270,452 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 30, 2011 was 17,696,121.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the registrant s 2011 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, potenti 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 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. (CSI) and CSI-MN changed its name to CSI Minnesota, Inc. As of immediately following the effective time of the merger, former CSI-MN stockholders owned approximately 80.2% of the outstanding common stock of the combined company, and Replidyne stockholders owned approximately 19.8% of the outstanding common stock of the combined company. 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. 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 prior to the completion of the merger and to CSI following the completion of the merger an 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-MN 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 (as hereafter defined) and our Viper line of ancillary products.

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.

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We have received federal registration in the U.S. Patent and Trademark Office, or USPTO, of certain marks including Diamondback 360° , CSI , a first CSI logo, a second CSI logo, Lumen Library , ViperWire , ViperWire Advance , Viperslide , ViperTrack , and ViperC applied for federal registration with the USPTO of certain marks, including Predator 360° , Stealth 360° , Attack the Plaque. Preserve the Media and Change Compliance First. 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.

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 leg arteries both above and below the knee and address many of the limitations associated with existing treatment alternatives. We refer to the Diamondback 360°, the Predator 360° and the Stealth 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 limited market release that same month. We expect to continue this limited release through the first quarter of fiscal 2012, ending September 30, 2011, after which we plan to begin a broader commercial launch. As of June 30, 2011, the PAD Systems had been utilized in more than 50,000 procedures.

We intend to leverage the capabilities of the PAD Systems 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 addition to the PAD Systems, we are expanding our product portfolio through internal product development and establishment of business relationships with other medical device companies. We now offer multiple accessory products designed to complement the use of the PAD Systems, and we have entered into a 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 do not heal. If untreated, 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.

PAD affects approximately eight to 12 million people in the United States, as cited by the authors of the PARTNERS study published in the Journal of the American Medical Association in 2001. According to 2007 statistics from the American Heart Association, PAD becomes more common with age and affects approximately

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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 existing 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 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 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. As a result of these challenges, many medically managed patients develop more severe symptoms that require procedural intervention.

Coronary Artery Disease

Based on data from the U.S. Agency for Healthcare Research and Quality, or AHRQ, and the U.S. Centers for Medicare and Medicaid Services, we estimate that approximately 924,000 percutaneous coronary interventions, or PCI, procedures occurred in the United States in 2009. Based on various studies, we believe that more than 25% of PCI procedures involve moderate to severe levels of calcified coronary arteries and could benefit from the use of our device. In addition, based on AHRQ data, we estimate that in 2009 approximately 478,000 coronary artery bypass graft surgeries were performed in the United States. These patients generally have higher rates of calcification and we believe they could benefit from the use of our device.

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 an external control unit (Diamondback 360° or Predator 360°) or a saline infusion pump (Stealth 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.

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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 (Fresenius), pursuant to which Fresenius will manufacture and serve as a single-source supplier of the ViperSlide lubricant through March 2016.

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, lightweight 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.

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

Technology Overview

The two technologies used in the PAD Systems are plaque modification through differential sanding and plaque removal.

Plaque Modification through Differential Sanding. The PAD Systems were designed to allow the devices to differentiate between soft compliant and harder diseased arterial tissue. This property is consistent with sanding material such as the diamond grit used in the PAD Systems. The diamond preferentially engages and sands harder material. The PAD Systems also treat soft plaque, which is still harder than a normal vessel wall. Arterial lesions tend to be harder and stiffer than compliant, undiseased tissue, and they often are fibrotic or calcified. The PAD Systems sand the lesion but are designed not to damage more compliant parts of the artery. The mechanism 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. Of 36 consecutive experiments that we performed in carbon blocks, animal and cadaver models:

- 93.1% of particles were smaller than a red blood cell, with a 99% confidence interval; and
- 99.3% of particles were smaller than the lumen of the capillaries (which provide the connection between the arterial and venous system), with a 99% confidence interval.

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. We believe that the small size of the particles also 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.

Plaque Removal. 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. Normal arteries are compliant; they have the ability to expand and contract as needed to supply blood flow to the legs and feet. Arteries burdened with fibrotic (moderately hard) and/or calcified (extremely hard) plaque often lose their compliance, which makes other therapies such as angioplasty, stenting, surgical bypass and atherectomy problematic. 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 lumen. Our current systems allow the user to choose between three rotational speeds.
- *Crown Characteristics.* The crown can be designed with various weights (as determined by different materials and density) and coated with diamond grit of various width, height and configurations. The

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Diamondback 360° crown is available in two configurations classic and solid. Crown sizes and configurations are selected based on several case criteria, including reference vessel size, length and degree of stenosis, and anatomy tortuosity. The Predator 360° crown is available in the solid configuration and is constructed to allow the crown to engage and treat the lesion more efficiently, which can result in shorter procedure times. Both the classic and Predator 360° crowns are available in multiple sizes, including 1.25, 1.50, 1.75, 2.00 millimeter. There is also a 2.25 millimeter diameter in the Predator 360° crown configuration. Currently, the Stealth 360° device is available with a 1.50 millimeter classic crown, and 1.25 millimeter and 2.00 millimeter Predator 360° crown configuration. For both configurations, the catheter length is 145 centimeters, which addresses procedural approach and target lesion locations both above and below the knee.

Drive Shaft Characteristics. The drive shaft can be designed with various shapes and degrees of rigidity. The drive shaft on the Stealth 360° device with a Predator 360° crown configuration is newly-developed, enhancing the ability to advance the device more smoothly and effectively through tortuous anatomy and challenging lesion morphologies, thereby improving the overall efficiency of the device.

We view the PAD Systems as platforms that can be used to develop additional products by adjusting one or more of the speed, crown and shaft variables.

Applications

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

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 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. Plaque in arteries above the knee may also be diffuse, fibrotic and calcific; however, these arteries are longer, straighter and wider than below-the-knee vessels. While effective in difficult-to-treat below-the-knee vessels, and indicated for vessels up to four millimeters in diameter, our products are also being used to treat lesions above the knee.

Coronary Artery Disease. Given the many similarities between peripheral and 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 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 (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.

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 positioning the crown to orbit against it, 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.

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Normal arteries are compliant; they have the ability to expand and contract as needed to supply blood flow to the legs and feet. Arteries burdened with fibrotic (moderately hard) and/or calcified (extremely hard) 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 to three minutes of sanding time, potentially reducing the overall procedure time.

We believe that 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 even the middle or outer layers of the artery s wall. The Diamondback 360° s perforation rate was 2.4% 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 often considered the safest of interventional methods. This was demonstrated in our OASIS trial, which had a low 4.8% rate of device-related serious adverse events, or SAEs.

Reduces the Risk of Distal Embolization. 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 and 48% of the lesions having a length greater than three centimeters, the performance of 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. Other PAD devices have demonstrated limited effectiveness in treating these challenging lesions.

Orbital Motion Improves Device-to-Lumen Ratio. The orbiting action of the PAD Systems can create a lumen of approximately 2.0 times the diameter of the crown. The variable device-to-lumen ratio allows the continuous removal of plaque as the opening of the lumen increases during the operation of the

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devices. Non-orbiting rotational atherectomy catheters remove plaque by abrading the lesion with a spinning, abrasive burr, which 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.

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 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. The devices ability to differentiate between diseased and compliant tissue reduces the risk of complications associated with user error and potentially broadens the user population.

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 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.

Limited Use of Fluoroscopy. The relative simplicity of our process and predictable crown location allows physicians to significantly reduce fluoroscopy use, thus limiting radiation exposure.

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. Treatment with the Diamondback 360° typically ranges from three to four minutes, while treatment time with the Predator 360° and Stealth 360° is typically shorter ranging from 90 seconds to three minutes.

Single Crown Can Create Various Lumen Sizes Limiting Hospital Inventory Costs. The orbital mechanism of action with the PAD Systems allows a single-sized 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. The PAD Systems can create a lumen that is 100% larger than the actual diameter of the device, for a device-to-lumen ratio of approximately 1.0 to 2.0.

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

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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 are expanding our product portfolio. We now 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.

Leverage Technology Platform into Coronary Market. Based on the clinical performance of the PAD Systems in treating lower extremity PAD, we intend to leverage the devices capabilities 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 360º 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 429 patient trial in the United States to evaluate the safety and effectiveness of the Diamondback 360º in treating severely calcified coronary lesions. In May 2011, we received approval from the FDA to complete enrolment of the 429 patients in our ORBIT II clinical trial, which followed the FDA s review of data from the first 50 cases in the ORBIT II trial.

Pursue Strategic Acquisitions and Partnerships. In August 2009, we signed an exclusive distribution agreement with Asahi-Intecc, Ltd. (Asahi) to market its peripheral guidewire line in the United States. We offer two Asahi 0.18 wire platforms: the Astato 30 and Treasure 12. The Astato 30 is a high-penetration guide wire specially designed to break through fibrous caps and calcium deposits, and treat long, complex lesions. The Treasure 12 has a one-piece core to provide control, torque performance and tactile feedback to the physician.

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 twelve clinical trials to demonstrate the safety and efficacy of the PAD Systems in treating PAD, enrolling a total of 3,746 patients in our PAD I and PAD II pilot trials, OASIS pivotal trial, OASIS LT study demonstrating long term durability of the Diamondback 360º and the CONFIRM DIAMONDBACK, CONFIRM PREDATOR and CONFIRM OUTFLOW Post-Market Registries. In

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addition, we have also completed enrollment in the CALCIUM 360° and COMPLIANCE 360° post-market, randomized feasibility studies that further differentiate the performance of the Diamondback 360° and Predator 360° from conventional balloon angioplasty.

To demonstrate the safety and effectiveness of the Diamondback 360° for use in coronary arteries we also completed the ORBIT I coronary clinical trial 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.

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 £ 30% residual stenosis with orbital atherectomy followed by a low-pressure balloon inflation of £ 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 at follow-up who have undergone another peripheral intervention in the same lesion due to their worsening symptoms. Treatments such as an angioplasty, stenting or surgery 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 nonserious or serious (referred to as an SAE) depending on the treatment required to repair the perforation.

Inclusion criteria for trials often limit size of lesion and severity of disease, as measured by the Rutherford Class, which utilizes a scale of I to VI, with I being mild and VI being most severe, and the ABI.

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

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arteries between 1.5 mm and 6.0 mm in diameter, with Rutherford Class scores of IV or lower. Patients were 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 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%
SAEs at 30 days	8%, with an upper bound of 16%	4.8%, device-related; 9.7%, overall
TLR	20% or less	2.4%

Perforations	N/A	1 serious perforation
ABI at baseline	N/A	0.68 ± 0.2*
ABI at 30 days	N/A	0.9 ± 0.18*
ABI at 6 months	N/A	0.83 ± 0.23*

* Mean ± Standard Deviation

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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.

OASIS Long-Term Study

In 2009 we completed a retrospective study evaluating the long-term results of 64 patients from the pivotal OASIS trial. Outcomes were analyzed out to a mean of 29 months and include limb salvage rate, TLR rate and ABI. TLR, or reintervention in the originally treated lesion, was 13.6%. A 100% limb salvage rate was maintained. ABI scores remained significantly improved. This 29 month data of OASIS patients adds to our confidence in the safety and efficacy of the Diamondback 360°.

Post-Market Feasibility Studies

In May 2010, enrollment was completed in the COMPLIANCE 360° clinical trial, the first of two PAD post-market studies initiated in calendar 2009. This 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 inflation, if desired, with that of high-pressure balloon inflation alone. Fifty patients were enrolled at nine U.S. medical centers. The results of this trial showed that the Diamondback 360° or Predator 360° can achieve superior results in treating calcified plaque by improving lesion compliance through differential sanding, without the need for stent placement. Trial results with a p-value of less than 0.0001 statistically demonstrated the success rate in the Diamondback 360° or Predator 360° arm of the trial had a procedural success rate of 360% greater than in the balloon arm of the trial and required 91% less bailout stenting. The six month study results will be presented as an oral presentation at the Transcatheter Cardiovascular Therapeutics, or TCT, conference in November 2011 in San Francisco, CA. Patients will complete their 12 month follow up by the end of September 2011. Twenty four months of data will continue to be collected.

In April 2010, enrollment was completed in the CALCIUM 360° study, a prospective, randomized, multi-center study comparing the effectiveness of the Diamondback 360° and 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. Six-month results showed orbital treatment outperformed balloon angioplasty. A key finding was that by modifying calcified lesions first, the Diamondback 360° and Predator 360° allow use of a lower-pressure adjunctive balloon therapy, reducing the need for bailout stenting with anticipated improved longer-term patient outcomes. Orbital treatment outperformed balloon angioplasty on the primary endpoint of device success (less than or equal to 30% restenosis with no dissection C-F) with 92.6% in the Diamondback 360° and Predator 360° arm of the trial versus 78.8% in the balloon arm of the trial. These results will be reported as an abstract at the San Francisco TCT conference. Patients will complete their 12 month follow up by the end of September 2011. Twenty four months of data will continue to be collected.

CONFIRM Post-Market Clinical Registry Series

We are conducting the CONFIRM Post-Market Clinical Registry Series, which will further evaluate acute and economic parameters related to the use of the PAD Systems. The CONFIRM Series currently consists of three registries: CONFIRM I DIAMONDBACK, CONFIRM II PREDATOR, and CONFIRM III OUTFLOW.

Enrollment of 728 patients in the CONFIRM I DIAMONDBACK Post-Market Registry was completed in March 2010. In this prospective registry, 1,138 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%). Lesions were long and calcified. Lesions were treated with the Diamondback 360° followed by

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low pressure balloon angioplasty, if desired. An average residual stenosis of 10.5% 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 2.2% of lesions, which is also consistent with the 2.5% reported in OASIS. 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.

Enrollment of 1,145 patients in the prospective CONFIRM II PREDATOR Post-Market Registry was completed December 2010. The CONFIRM II PREDATOR evaluated clinical performance of the Predator 360°. Data on acute clinical performance and short-term economic parameters were collected during this study. An abstract will be presented at the San Francisco TCT conference.

Data from CONFIRM DIAMONDBACK and PREDATOR registries were used to design the CONFIRM III OUTFLOW registry. This is the third study in the CONFIRM series to further evaluate acute procedural outcomes and economic parameters associated with use of the PAD Systems. Enrollment of 1,275 patients in the CONFIRM III OUTFLOW Post-Market Registry was completed June 2011. Data will be reported at future scientific conferences.

ORBIT I Coronary Feasibly Safety Study

The ORBIT I trial, a 50-patient study in India, was completed in 2009. This feasibility trial investigated the safety of the Diamondback 360° in treating calcified coronary artery lesions. The safety was evaluated by six-months MACE rate. Study results showed the device success for the study was 100%. Six months MACE rate was 8%. The ORBIT I trial confirmed that the OAS is safe in treating subjects with de novo calcified coronary artery disease. The 6 month results will be presented at the TCT conference in 2011.

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 IDE was FDA approved and we began the ORBIT II pivotal clinical trial. This trial plans to enroll 429 patients in up to 50 U.S. investigational centers to evaluate the safety and effectiveness of the Diamondback 360° 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.

Sales and Marketing

We market and sell the PAD Systems through a direct sales force in the United States. 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
- developing relationships with key opinion leaders; and
- facilitating regional referral marketing programs.

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

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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 2011, fiscal 2010 and fiscal 2009 were $8.9 million, $10.3 million and $14.7 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, and printed circuit board assemblies, are single sourced. 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, 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. During the time of commercialization, we have had two minor instances of recall, involving one single lot of Diamondback 360° devices (eight units), and two boxes of ViperWires (ten wires), related to Use By date labeling issues. While these recalls were reported to the FDA, according to regulations, they did not provide a risk to patient safety. A third 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 Thomas Medical Products. All of the unused ViperSheaths were captured and subsequently destroyed by Thomas Medical Products, with FDA observance.

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

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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, and many private insurers follow these policies. 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.

The continued availability of insurance coverage and reimbursement for newly approved medical devices is uncertain. The commercial success of our products in both domestic and international markets will be dependent on whether third-party coverage and reimbursement is available for patients that use our products. 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 of new medical devices, and, as a result, they may not continue to provide adequate payment for our products. To position our device for acceptance by third-party payors, we may have to agree to a lower net sales price than we might otherwise charge. The continuing efforts of governmental and commercial third-party payors to contain or reduce the costs of healthcare may limit our revenue.

In some foreign markets, pricing and profitability of medical devices are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. Also, the trends toward managed healthcare in the United States and legislation intended to reduce the cost of government insurance programs could significantly influence the purchase of healthcare services and products and may result in lower prices for our products or the exclusion of our products from reimbursement programs.

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 Pathway Medical Technologies, 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.

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Patents and Intellectual Property

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, 2011, we held 21 issued U.S. patents and have 31 U.S. patent applications pending, as well as 63 issued or granted foreign patents and 98 foreign patent applications, each of which corresponds to aspects of our U.S. patents and applications. Our issued U.S. patents expire between 2011 and 2027, 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 ten registered U.S. trademarks, six registered marks in Europe, five registered marks in Canada, and three 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

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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.

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.

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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 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 Investigational Device Exemption (IDE) trial to support a PMA to use the Diamondback 360° as a therapy in treating patients with 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 allows 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. The FDA granted us approval to move to Phase II in May of 2011.

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.

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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 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;

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;

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

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

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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.

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, 2011, we had 286 employees, including 66 employees in manufacturing, 166 employees in sales, six employees in marketing, seven employees in clinical, 23 employees in general and administrative, and 18 employees in research and development, all of which are full-time employees. None of our employees are represented by a labor union or 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 may 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 $11.1 million in fiscal 2011, $23.9 million in fiscal 2010, and $31.9 million in fiscal 2009. As of June 30, 2011, we had an accumulated deficit of approximately $162.4 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 and other products. Additionally, we expect that our general and administrative expenses will increase as our business grows. As a result, our operating losses could continue.

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We may be unable to sustain our revenue growth.

Our revenue has grown in each of the three complete 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. 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. For example, our customers ability to borrow money from their existing lenders or to obtain credit from other sources to fund operations may be impaired resulting in a decrease in sales. Although we review our customers financial condition and ability to pay on an ongoing basis and we maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments, we cannot guarantee that we will continue to experience the same loss rates that we have in the past. 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. In addition, uncertainty about current global economic conditions could increase the volatility of our stock price.

We have a limited history selling the PAD Systems, which are currently our primary products, and our inability to market these products successfully would have a material adverse effect on our business and financial condition.

Although we also sell a variety of ancillary products, the PAD Systems are our primary products and we are largely dependent on them. We have limited experience in the commercial manufacturing and marketing of these products. Our ability to generate revenue will depend upon our ability to further successfully commercialize the PAD Systems and to develop, manufacture and receive required regulatory clearances and approvals and patient reimbursement for treatment with future versions of the PAD Systems. As we continue to commercialize the PAD Systems, we may need to expand our sales force to reach our target market. Developing a sales force is expensive and time consuming and could delay or limit the success of any product launch. Thus, we may not be able to expand our sales and marketing capabilities on a timely basis or at all. If we are unable to adequately increase these capabilities, we will need to contract with third parties to market and sell the PAD Systems and any other products that we may develop. To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services on our behalf, our product revenues could be lower than if we marketed and sold our products on a direct basis. Furthermore, any revenues resulting from co-promotion or other marketing and sales arrangements with other companies will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. If we fail to successfully develop, commercialize and market the PAD Systems or any future versions of these products that we develop, our business will be materially adversely affected.

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;

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- the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for conditions treated by our systems;
- the degree to which treatments using our products are approved for reimbursement by public and private insurers;
- 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.

If longer-term or more extensive clinical trials performed by us or others indicate that procedures using the PAD Systems or any future products are not safe, effective and long lasting, physicians may choose not to use our products. Furthermore, unsatisfactory patient outcomes or injuries could cause negative publicity for our products. Physicians may be slow to adopt our products if they perceive liability risks arising from the use of these products. It is also possible that as our products become more widely used, latent defects could be identified, creating negative publicity and liability problems for us, thereby adversely affecting demand for our products. If the PAD Systems and our future products do not achieve an adequate level of acceptance by physicians, patients and the medical community, our overall business and profitability would be harmed.

Our future growth depends on physician adoption of the PAD Systems, which requires physicians to change their screening and referral practices.

We believe that we must educate physicians to change their screening and referral practices. For example, although there is a significant correlation between PAD and coronary artery disease, many physicians do not routinely screen for PAD while screening for coronary artery disease. We target our sales efforts to interventional cardiologists, vascular surgeons and interventional radiologists because they are often the primary care physicians diagnosing and treating both coronary artery disease and PAD. However, the initial point of contact for many patients may be general practitioners, podiatrists, nephrologists and endocrinologists, each of whom commonly treats patients experiencing complications resulting from PAD. If referring physicians are not educated about PAD in general and the existence of the PAD Systems in particular, they may not refer patients to interventional cardiologists, vascular surgeons or interventional radiologists for the procedure using the PAD Systems, and those patients may instead be surgically treated or treated with an alternative interventional procedure. If we are not successful in educating physicians about screening for PAD or referral opportunities, our ability to increase our revenue may be impaired.

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.

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.

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.

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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. Certain of these proposals 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 adoption of some or all of these proposals, including the recent federal legislation, could adversely affect our revenue and financial condition.

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act, or the Patient Act. The impact on the healthcare industry of the Patient Act is extensive and includes, among other things, having the federal government assume a larger role in the healthcare system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits. Elements of this legislation, such as comparative effectiveness research, an independent payment advisory board, payment system reforms, including shared savings programs and other provisions, could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business. These changes may impact reimbursement for health care services, including reimbursement to hospitals and physicians. States may also enact further legislation that impacts Medicaid payments to hospitals and physicians. In addition, the Centers for Medicare & Medicaid Services, the Federal agency responsible for administering the Medicare program, may establish new payment levels for hospitals and physicians in line with the new legislation, which could increase or decrease payment to such entities. The healthcare reform legislation and any future legislative and regulatory initiatives could adversely affect demand for our products and have a material adverse impact on our operating results. Any healthcare reforms enacted in the future may, like the Patient Act, be phased in over a number of years but, if enacted, could reduce our revenues, increase our costs, or require us to revise the ways in which we conduct business or put us at risk for loss of business. Our results of operations, financial position and cash flows could be materially adversely affected by changes under the Patient Act and changes under any federal or state legislation adopted in the future.

The Patient Act also imposes significant new taxes on medical device makers. These taxes will result in a significant increase in the tax burden on our industry, which could have a material, negative impact on our results of operations, financial position and cash flows. As rules and regulations are developed under the new law, there may be exemptions created for certain types or classes of products. We may find, however, that there are no exemptions applicable to our products. This tax will impact our cost of doing business and may ultimately lower our profit margins. Additionally, the increased cost of business caused by this tax may hinder our ability to spend money on research and development of our products. We may be required to increase the prices of our devices to offset the additional cost of the tax. Medicaid and health insurance providers may place a cap on the reimbursement for purchases of our devices that will not allow us to offset the cost of the tax. We may ultimately lose customers who are unwilling or unable to pay the increased costs, which could adversely affect our business and operating results.

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.

Our success depends on the acceptance of the PAD Systems by the medical community as safe and effective. Because our technology is relatively new in the treatment of PAD, we have performed clinical trials

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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. If the results obtained from any future clinical trials or clinical or commercial experience indicate that the PAD Systems are not as safe or effective as other treatment options or as current short-term data would suggest, adoption of these products may suffer and our business would be harmed.

Even if we believe that the data collected from clinical trials or clinical experience indicate positive results, each physician s actual experience with our device will vary. 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 and may be unable to sell the PAD Systems at profitable levels.

We compete against very large and well-known stent and balloon angioplasty device manufacturers, including Abbott Laboratories, Boston Scientific, Cook Medical, Johnson & Johnson and Medtronic. 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. We also compete against manufacturers of atherectomy catheters including, among others, Covidien, Spectranetics, Boston Scientific and Pathway Medical Technologies, as well as other manufacturers that may enter the market due to the increasing demand for treatment of vascular disease. Several other companies provide products used by surgeons in peripheral bypass procedures. 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.

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;

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.

Our ability to compete depends on our ability to innovate successfully. If our competitors demonstrate the increased safety or efficacy of their products as compared to ours, our revenue may decline.

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 there are few barriers that would prevent new entrants or existing competitors from developing products that compete directly with our products. Demand for the PAD Systems could be diminished by equivalent or superior products and technologies offered by competitors. Our competitors may produce more advanced products than ours or demonstrate superior safety and efficacy of their products. If we are unable to innovate successfully, the PAD Systems could become obsolete and our revenue would decline as our customers purchase competitor products.

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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. If we fail to develop and implement these manufacturing capabilities and processes, we may be unable to profitably commercialize the PAD Systems and any future products we may develop because the per unit cost of our products is highly dependent upon production volumes and the level of automation in our manufacturing processes. There are technical challenges to increasing manufacturing capacity, including equipment design and automation capabilities, material procurement, problems with production yields and quality control and assurance. Increasing our manufacturing capacity may require that we invest substantial additional funds and hire and retain additional management and technical personnel who have the necessary manufacturing experience. We may not successfully complete any required increase in manufacturing capacity in a timely manner or at all. If we are unable to manufacture a sufficient supply of our products, maintain control over expenses or otherwise adapt to anticipated growth, or if we underestimate growth, we may not have the capability to satisfy market demand and our business will suffer.

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. We also cannot assure you that any third-party contract manufacturers will have the ability to produce the quantities of our products needed for development or commercial sales or will be willing to do so at prices that allow the products to compete successfully in the market. Additionally, we can give no assurance that even if we do contract with third-party manufacturers for production that these manufacturers will not experience manufacturing difficulties or experience quality or regulatory issues. 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 the components of the PAD Systems. We purchase components from these suppliers on a purchase order basis and carry only limited levels of inventory for these components. If we underestimate our requirements, we may not have an adequate supply, which could interrupt manufacturing of our products and result in delays in shipments and loss of revenue. Conversely, an overestimation of our requirements will reduce our cash available for operations and may result in excess or obsolete materials.

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 demand. Our reliance on these outside suppliers also subjects us to other risks that could harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier s operations;
- delays in product shipments;
- price fluctuations;
- our suppliers may make errors in manufacturing components;

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- our suppliers may discontinue production of components;
- we and our customers may not be able to obtain adequate supplies in a timely manner or on commercially acceptable terms;
- we and our customers may have difficulty locating and qualifying alternative suppliers for our and their sole-source supplies;
- switching components may require product redesign and new regulatory submissions;
- we may experience production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us or our customers in a timely manner; and
- our suppliers may encounter financial hardships unrelated to us or our customers demand for components or other products.

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. If we lost one of these suppliers and were unable to obtain an alternate source on a timely basis or on terms acceptable to us, our production schedules could be delayed, our margins could be negatively impacted, and we could fail to meet our customers demand. Our customers rely upon our ability to meet committed delivery dates and any disruption in the supply of key components would adversely affect our ability to meet these dates and could result in legal action by our customers, cause us to lose customers or harm our ability to attract new customers, any of which could decrease our revenue and negatively impact our growth. In addition, to the extent that our suppliers use technology or manufacturing processes that are proprietary, we may be unable to obtain comparable materials or components from alternative sources.

We may be faced with a supplier s decision to discontinue manufacturing a component, which may force us or our customers to make last time purchases, qualify a substitute part, or make a design change which may divert engineering time away from the development of new products.

Consolidation in the healthcare industry could lead to demands for price concessions or the exclusion of some suppliers from our market segment, which could have an adverse effect on our business, financial condition or results of operations.

The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry. This in turn has resulted in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to consolidate purchasing decisions for some of our hospital customers. We expect that market demand, government regulation, third-party reimbursement policies, government contracting requirements, and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers and competitors, which may reduce competition, exert downward pressure on the prices of our products and adversely impact our business, financial condition or 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. Our sales and marketing force

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has increased from six full-time employees on January 1, 2007 to 172 full-time employees on June 30, 2011, and we expect to continue to grow our sales and marketing force in the future. We also expect to significantly expand our manufacturing operations to meet anticipated growth in demand for our products. Rapid expansion in personnel may result in less experienced people producing and selling our product, 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. We may require additional capital in order to continue to conduct the research and development and obtain regulatory clearances and approvals necessary to bring any future products to market and to establish effective marketing and sales capabilities for existing and future products. Our operating plan may change, and we may need additional funds sooner than anticipated to meet our operational needs and capital requirements for product development, clinical trials and commercialization. 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 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.

Our future capital requirements will depend on many factors, including:

- the costs of expanding our sales and marketing infrastructure and our manufacturing operations;
- the degree of success we experience in commercializing the PAD Systems;
- the number and types of future products we develop and commercialize;
- the costs, timing and outcomes of regulatory reviews associated with our future product candidates;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent and scope of our general and administrative expenses.

Disruptions in the global financial markets, including the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States and other governments and the related liquidity crisis, considerably disrupted the credit and capital markets at the end of 2008 and markets have not fully recovered since then. 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. We were not in compliance with some of the financial covenants contained in our prior loan agreement with Silicon Valley Bank during certain months in the year ended June 30, 2010, which Silicon Valley Bank waived and these covenants were subsequently changed in our amended and restated loan and security agreement with Silicon Valley Bank. 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

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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 in our loan and security agreements could limit our ability to conduct our business and respond to changing economic and business conditions and may place us at a competitive disadvantage relative to other companies that are subject to fewer restrictions.

Our loan and security agreements with Silicon Valley Bank and Partners for Growth limit our ability to, among other things:

- transfer all or any part of our business or properties;
- permit or suffer a change in control;
- merge or consolidate, or acquire any entity;
- incur additional indebtedness or liens with respect to any of their properties;
- pay dividends or make any other distribution on or purchase of, any of our capital stock;
- make investments in other companies; or
- engage in related party transactions.

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 do not intend to market the PAD Systems internationally in the near future, which will limit our potential revenue from these products.

While we plan to continue to evaluate the financial viability of marketing the PAD Systems internationally, we currently do not intend to market the PAD Systems internationally in the near future in order to focus our resources and efforts on the U.S. market, as international efforts would require substantial additional sales and marketing, regulatory and personnel expenses. Our decision to market these products only in the United States will limit our ability to reach all of our potential markets and will limit our potential sources of revenue. In addition, our competitors will have an opportunity to further penetrate and achieve market share abroad until such time, if ever, that we market the PAD Systems or other products internationally.

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, especially David L. Martin, our President and Chief Executive Officer. 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. Competition for senior management personnel, as well as scientists, clinical and regulatory specialists, engineers and sales personnel, is intense and we may not be able to retain our personnel. 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. The loss of a member of our senior management

or professional staff would require the remaining senior executive officers to divert immediate and substantial attention to seeking a replacement. In particular, we expect to substantially increase the size of our sales force, which will require management s attention. We do not carry key person life insurance on any of our employees.

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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. While off-label uses of medical devices are common and the FDA does not regulate physicians choice of treatments, the FDA does restrict a manufacturer s communications regarding such off-label use. We are not permitted to promote or advertise the PAD Systems for off-label uses. In addition, we cannot make comparative claims regarding the use of the PAD Systems against any alternative treatments without conducting head-to-head comparative clinical trials, which would be expensive and time consuming. If our promotional activities fail to comply with the FDA s regulations or guidelines, we may be subject to FDA warnings or enforcement action.

If we determine to market the PAD Systems 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. In 2008, we completed the ORBIT I trial, a 50-patient study in India which investigated the safety of the Diamondback 360° in treating calcified coronary artery lesions, and results successfully met both safety and efficacy endpoints. 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. Clinical trials are complex, expensive, time consuming, uncertain and subject to substantial and unanticipated delays. Clinical trials generally involve a substantial number of patients in one or more multi-year studies. We may encounter problems with our clinical trials, and any of those problems could cause us or the FDA to suspend those trials, or delay the analysis of the data derived from them.

A number of events or factors, including any of the following, could delay the completion of our clinical trials in the future and negatively impact our ability to obtain FDA clearance or approval for, and to introduce, a particular future product:

- delays in obtaining or maintaining required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply of our future product candidates or other materials necessary to conduct our clinical trials;
- difficulties in enrolling patients in our clinical trials;
- negative or inconclusive results from clinical trials, results that are inconsistent with earlier results, or the likelihood that the part of the human anatomy involved is more prone to serious adverse events, necessitating additional clinical trials;
- serious or unexpected side effects experienced by patients who use our future product candidates; or
- failure by any of our third-party contractors or investigators to comply with regulatory requirements or meet other contractual obligations in a timely manner.

Our clinical trials may not begin as planned, may need to be redesigned, and may not be completed on schedule, if at all. Delays in our clinical trials may result in increased development costs for our future product candidates, which could limit our ability to obtain additional financing. In addition, if one or more of our clinical trials is delayed, competitors may be able to bring products to market before we do, and the commercial viability of our future product candidates could be significantly reduced.

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We may become subject to regulatory actions if we are found to have promoted the PAD Systems for unapproved uses.

If the FDA determines that our promotional materials, training or other activities constitute promotion of our products for unapproved uses, it could request that we cease use of or modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of an untitled or warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional, training or other materials to constitute promotion of our products for an unapproved or uncleared use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

The PAD Systems may in the future be subject to product recalls that could harm our reputation.

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. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. During the time of commercialization, we have had two minor instances of recall, involving a single lot of Diamondback 360° devices (eight units), and two boxes of ViperWires (ten wires), related to Use By date labeling issues. In addition, a third 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 Thomas Medical Products. Any additional 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.

If we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems, our products could be subject to restrictions or withdrawal from the market.

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;
- fines, 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.

Furthermore, any modification to a device that has received FDA clearance or approval that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, design or

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manufacture, requires a new clearance or approval from the FDA. If the FDA disagrees with any determination by us that new clearance or approval is not required, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval. In addition, we could be subject to significant regulatory fines or penalties.

Regulatory clearance or approval of a product may also require costly post-marketing testing or surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as the QSR, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

The use, misuse or off-label use of the PAD Systems may increase the risk of injury, which could result in product liability claims and damage to our business.

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. The PAD Systems are not FDA-cleared or approved for treatment of the carotid arteries, the coronary arteries, within bypass grafts or stents, of thrombus or where the lesion cannot be crossed with a guidewire or a significant dissection is present at the lesion site. We cannot prevent a physician from using the PAD Systems for off-label applications. The off-label use of the PAD Systems may be more likely to result in complications that have serious consequences, including, in certain circumstances, death.

We may face risks related to product liability claims, which could exceed the limits of available insurance coverage.

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 medical device industry is subject to substantial litigation, and we face an inherent risk of exposure to product liability claims in the event that the use of our products results or is alleged to have resulted in adverse effects to a patient. In most jurisdictions, producers of medical products are strictly liable for personal injuries caused by medical devices. We may be subject in the future to claims for personal injuries arising out of the use of our products. Product liability claims could divert management s attention from our core business, be expensive to defend and result in sizable damage awards against us. A product liability claim against us, even if ultimately unsuccessful, could have a material adverse effect on our financial condition, results of operations, and reputation. 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.

Compliance with environmental laws and regulations could be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability.

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. Although we are currently classified as a Very Small Quantity Hazardous Waste Generator within Ramsey County, Minnesota, we cannot ensure that we will maintain our licensed status as such, nor can we ensure that we will not incur material costs or liability in connection with our operations, or that our past or future operations will not result in claims or injury by employees or the public. Environmental laws and regulations could also become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations.

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We and our distributors must comply with various federal and state anti-kickback, self-referral, false claims and similar laws, any breach of which could cause a material adverse effect on our business, financial condition and results of operations.

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.

Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can give rise to claims that the relevant law has been violated. 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. Individual employees may need to defend such suits on behalf of us or themselves, which could lead to significant disruption in our present and future operations. Certain states in which we intend to market our products have similar fraud and abuse laws, imposing substantial penalties for violations. Any government investigation or a finding of a violation of these laws would likely have a material adverse effect on our business, financial condition and results of operations.

Anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for the referral of an individual or the ordering or recommending of the use of a product or service for which payment may be made by Medicare, Medicaid or other government-sponsored healthcare programs. In addition, the cost of non-compliance with these laws could be substantial, since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from federally funded healthcare programs for non-compliance.

We have entered into consulting agreements with physicians, including some who may make referrals to us or order our products. One of these physicians was one of 20 principal investigators in our OASIS clinical trial at the same time he was acting as a paid consultant for us. In addition, prior to our merger with Replidyne, some of these physicians purchased our stock in arm s-length transactions on terms identical to those offered to non-physicians or received stock options from us as consideration for consulting services performed by them. We believe that these consulting agreements and equity investments by physicians are common practice in our industry, and while these transactions were structured with the intention of complying with all applicable laws, including the federal ban on physician self-referrals, commonly known as the Stark Law, state anti-referral laws and other applicable anti-kickback laws, it is possible that regulatory or enforcement agencies or courts may in the future view these transactions as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties, or prohibit us from accepting referrals from these physicians. Because our strategy relies on the involvement of physicians who consult with us on the design of our product, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with our physician advisors who refer or order our products to be in violation of applicable laws and determine that we would be unable to achieve compliance with such applicable laws. This could harm our reputation and the reputations of our clinical advisors.

The scope and enforcement of all of these laws is uncertain and subject to rapid change. There can be no assurance that federal or state regulatory or enforcement authorities will not investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a material adverse effect on our business, financial condition and results of operations. Any state or federal regulatory or enforcement review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in these laws, whether these changes are retroactive or will have effect on a going-forward basis only.

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We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the Nasdaq Global Market, have imposed various requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and compliance costs and made some activities more time consuming and costly. We cannot ensure that our corporate compliance program is in compliance with or will continue to comply with all potentially applicable regulations.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Moreover, if we are not able to comply with these requirements in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

These obligations divert management s time and attention away from our business. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that are applicable. If we fail to staff our accounting and finance function adequately or maintain internal controls adequate to meet the demands that are placed upon us a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to report our financial results accurately or in a timely manner, and our business and stock price may suffer. The costs of being a public company, as well as diversion of management s time and attention, may have a material adverse effect on our business, financial condition and results of operations.

Additionally, these laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, board committees or as executive officers.

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. As of July 31, 2011, we had a portfolio of 21 issued U.S. patents, 31 pending U.S. patent applications, 63 issued or granted non-U.S. patents, and 98 pending non-U.S. patent applications covering aspects of our core technology, which expire between 2011 and 2027. However, our issued patents and related intellectual property may not be adequate to protect us or permit us to gain or maintain a competitive advantage. The issuance of a patent is not conclusive as to its scope, validity or enforceability. The scope, validity or enforceability of our issued patents can be challenged in litigation or proceedings before the U.S. Patent and Trademark Office, or the USPTO. In addition, our pending patent applications include claims to numerous important aspects of our products under development that are not currently protected by any of our issued patents. We cannot assure you that any of our pending patent applications will result in the issuance of patents to us. The USPTO may deny or require significant narrowing of

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claims in our pending patent applications. Even if any patents are issued as a result of pending patent applications, they may not provide us with significant commercial protection or be issued in a form that is advantageous to us. Proceedings before the USPTO could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. 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. For instance, the U.S. Supreme Court has recently modified some tests used by the USPTO in granting patents during the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license. In addition, the U.S. Congress is now considering patent reform legislation that could transition the U.S. to a first to file system and alter the processes for challenging issued patents. These reforms could increase the uncertainties surrounding the prosecution of our patent applications and the enforcement of our issued patents. 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.

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. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, invalid or unenforceable, and could order us to pay third-party attorneys fees.

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 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. 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. However, trade secrets are difficult to protect. 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 securing necessary assignments from these third parties. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our products or obtain and use information that we regard as proprietary. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Finally, others may independently discover trade secrets and proprietary information, and this would prevent us from asserting any such trade secret rights against these 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

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products to market. All issued patents are entitled to a presumption of validity under the laws of the United States. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of such third parties or others. Our competitors may assert that our products are covered by U.S. or foreign patents held by them. 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. Because patent applications may take years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that we infringe. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings can be substantial, and it is possible that such efforts would be unsuccessful if unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. 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. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. 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. Further, any redesign may not receive FDA clearance or approval or may not receive such clearance or approval in a timely manner. Any such license could impair operating margins on future product revenue. A court could also order us to pay compensatory damages for such infringement, and potentially treble damages, plus prejudgment interest and third-party attorneys fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, selling, offering to sell or importing infringing products, or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, which would have a significant adverse impact on our business.

Risks Relating to Ownership of Our Common Stock

Our stock price is volatile and you may not be able to resell your shares.

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 $3.75 and as high as $15.72 per share during the twelve-month period ended June 30, 2011. In addition to the risk factors described in this section, 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;

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.

In addition, if securities class action litigation is initiated against us, we would incur substantial costs and our management s attention would be diverted from operations. All of these factors could cause the price of our stock to decline, and you may lose some or all of your investment.

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.

In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against such company. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

We do not expect to pay cash dividends for the foreseeable future, and accordingly, stockholders must rely on stock appreciation for any return on their investment in the company.

We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate that we will pay cash dividends for the foreseeable future. As a result, appreciation of the price of our common stock is the only potential source of return to stockholders. Investors seeking cash dividends should not invest in our common stock.

If equity research analysts cease to publish research or reports about our business or if they issue unfavorable research or downgrade our common stock, the price of our common stock could decline.

Investors look to reports of equity research analysts for additional information regarding our industry and operations and rely in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. Equity research analysts may elect to cease research coverage of our common stock, which may adversely affect the market price of our common stock. The price of our common stock could decline if one or more of these analysts downgrade the common stock or if they issue other unfavorable commentary about us or our business.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders.

Provisions in our restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions include:

providing that special meetings of stockholders may be called only by the Chairman of the Board, the Chief Executive Officer, or by a majority of our board of directors;

requiring a classified board of directors, with three separate classes of directors each serving a three-year term;

requiring that only business brought before an annual meeting by our board of directors or by a stockholder who complies with the procedures set forth in the bylaws may be transacted at an annual meeting of stockholders;

requiring advance notice of specified stockholder actions, such as the nomination of directors and stockholder proposals; and

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authorizing the issuance of, without stockholder approval, up to 5,000,000 shares of preferred stock that could adversely affect the rights and powers of the holders of our common stock.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by such corporation s board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of the common stock.

To the extent we raise additional capital by issuing equity securities, including in a debt financing where we issue convertible notes or notes with warrants, our stockholders may experience substantial dilution. We may sell common stock in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock in more than one transaction, existing stockholders may be materially diluted. In addition, new investors could gain rights superior to existing stockholders, such as liquidation and other preferences. We have stock options and warrants outstanding to purchase shares of our capital stock. Our stockholders will incur dilution upon exercise of any outstanding stock options or warrants.

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 2012 with an option to renew through November 2017. 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.

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

Dr. Leonid Shturman Claim

On October 27, 2009, Dr. Leonid Shturman, CSI-MN s founder, filed a complaint (the First Complaint) in the U.S. District Court in Minnesota (the Court) against us. The First Complaint 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, Leila Nadirashvili (Mrs. Shturman). We declined Mrs. Shturman s demands. Thereafter, there was no activity for approximately nine months.

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Earlier this year, the Court issued an order requesting counsel for Dr. Shturman to advise the Court regarding the status of the First Complaint. 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 intend to file an amended complaint in the U.S. District Court in Minnesota.

On August 24, 2011, instead of filing an amended complaint, Mrs. Shturman filed a second complaint in federal court seeking a declaration regarding ownership of the patent portfolio that she claims belongs to Dr. Shturman, slander by us of title to patent rights, tortious interference with prospective business relations, breach of settlement contract, and statutory unfair competition. Also, Mrs. Shturman filed a motion to be substituted in the First Complaint. We intend to file a motion in opposition to Mrs. Shturman s motion to be substituted to have the First Complaint dismissed.

In addition, Mrs. Shturman filed a writ to dismiss our Switzerland lawsuit based on res judicata and collateral estoppel, alleging that the claims in Switzerland are identical to the previously dismissed lawsuit in Minnesota. Our counsel in Switzerland has filed a response to the motion to dismiss stating that the claims in Switzerland are not subject to res judicata. In particular, we reserved the rights in the previously dismissed Minnesota lawsuit to assert claims to an invention included in the patents filed in Switzerland by Dr. Shturman.

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.

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.

Executive Officers of the Registrant.

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

Name	Age	Position
David L. Martin	47	President and Chief Executive Officer
Laurence L. Betterley	57	Chief Financial Officer
James E. Flaherty	57	Chief Administrative Officer and Secretary
Kevin Kenny	46	Executive Vice President of Sales and Marketing
Paul Koehn	48	Vice President of Quality and Manufacturing
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 CardioVention 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

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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.

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.

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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
Fiscal Year Ended June 30, 2011		
First quarter	$ 5.50	$ 3.75
Second quarter	12.00	5.03
Third quarter	13.40	8.75
Fourth quarter	15.72	10.32
Fiscal Year Ended June 30, 2010		
First quarter	$ 11.15	$ 6.77
Second quarter	7.39	3.78
Third quarter	5.65	4.10
Fourth quarter	5.60	4.34

The number of record holders of our common stock on August 30, 2011 was approximately 584. 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

None.

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.

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

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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.

At the closing of the merger, Replidyne s net assets, as calculated pursuant to the terms of the Merger Agreement, were approximately $36.6 million as adjusted. As of immediately following the effective time of the merger, former CSI stockholders owned approximately 80.2% of the outstanding common stock of the combined company, and Replidyne stockholders owned approximately 19.8% of the outstanding common stock of the combined company.

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, 2011, we had an accumulated deficit of $162.4 million. We expect our losses to continue but generally decline as revenue grows from continued commercialization activities, development of additional product enhancements, accumulation of clinical data on our products, and further regulatory submissions. To date, we have financed our operations primarily from the issuance of common and preferred stock, convertible promissory notes, and debt.

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 Diamondback 360° and Predator 360° PAD Systems use an external control unit that powers the system, while the 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-Intecc, Ltd. to market its peripheral guide wire line in the United States.

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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. 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.

Interest and Other Income (Expense). Interest and other income (expense) primarily includes interest expense (net of premium and discount amortization), interest income, change in the fair value of conversion option, net write-offs upon conversion (option and unamortized premium), decretion of redeemable convertible preferred stock warrants, and gain on investments.

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) is the result of the conversion of convertible debt, and includes the write-off of the related conversion option and any unamortized debt premium or discount.

Decretion of Redeemable Convertible Preferred Stock Warrants. Decretion of redeemable convertible preferred stock warrants reflected the change in the current estimated fair market value of the preferred stock warrants on a quarterly basis, as determined by management and the board of directors. Decretion was recorded as a decrease to redeemable convertible preferred stock warrants in the consolidated balance sheet and a decrease to net loss in the consolidated statement of operations. Concurrent with the merger, all preferred stock warrants were converted into warrants to purchase common stock and, accordingly, we stopped recording decretion as of the merger date.

Gain on Investments. Gain on investments reflects the change in the fair value of investments.

Decretion (Accretion) of Redeemable Convertible Preferred Stock. Decretion (accretion) of redeemable convertible preferred stock reflected the change in the current estimated fair market value of the redeemable preferred stock on a quarterly basis, as determined by management and the board of directors. Decretion (accretion) was recorded as a decrease (increase) to redeemable convertible preferred stock in the consolidated balance sheet and a decrease (increase) to the loss attributable to common stockholders in the consolidated statement of operations. The redeemable convertible preferred stock was converted into common stock immediately prior to the effective time of the merger with Replidyne. As such, the preferred stockholders forfeited their liquidation preferences and we stopped recording decretion (accretion) as of the merger date.

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

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Section 382 due to significant ownership changes (as defined in Section 382) resulting from our equity financings. At June 30, 2011, we had net operating loss carryforwards for federal and state income tax reporting purposes of approximately $146.2 million, which will expire at various dates through fiscal 2031.

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 clinics. 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 allowances 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 included 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 stock option and restricted stock awards and units are expensed in the consolidated statements of operations over the related vesting period. We calculate the fair value on the date of grant using a Black-Scholes model.

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To determine the inputs for the Black-Scholes option pricing model, we are required to develop several assumptions, which are highly subjective. These assumptions include:

- our common stock s volatility;
- the length of our options lives, which is based on future exercises and cancellations;
- the number of shares of common stock pursuant to which options will ultimately be forfeited;
- the risk-free rate of return; and
- future dividends.

Prior to the consummation of the merger, we used comparable public company data to determine volatility for option grants. Expected volatility is now based on the historical volatility of our stock. We use a weighted average calculation to estimate the time our options will be outstanding. We estimated the number of options that are expected to be forfeited based on our historical experience. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the estimated life of the option. We use our judgment and expectations in setting future dividend rates, which is currently expected to be zero.

All options we have granted 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 our common stock at the date of grant, as determined by management and the board of directors.

The absence of an active market for our common stock prior to the merger required our management and board of directors to estimate the fair value of our common stock for purposes of granting options and for determining stock-based compensation expense. In response to these requirements, prior to the merger our management and board of directors estimated the fair market value of common stock at each date at which options are granted based upon stock valuations and other qualitative factors. Our management and board of directors conducted stock valuations using two different valuation methods: the option pricing method and the probability weighted expected return method. Both of these valuation methods took into consideration the following factors: financing activity, rights and preferences of our preferred stock, growth of the executive management team, clinical trial activity, the FDA process, the status of our commercial launch, our mergers and acquisitions and public offering processes, revenues, the valuations of comparable public companies, our cash and working capital amounts, and additional objective and subjective factors relating to our business. Our management and board of directors set the exercise prices for option grants based upon their best estimate of the fair market value of the common stock at the time they made such grants, taking into account all information available at those times. In some cases, management and the board of directors made retrospective assessments of the valuation of the common stock at later dates and determined that the fair market value of the common stock at the times the grants were made was different than the exercise prices established for those grants. In cases in which the fair market was higher than the exercise price, we recognized stock-based compensation expense for the excess of the fair market value of the common stock over the exercise price. Following the merger, our stock valuations are based upon the market price for our common stock.

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 11 to the consolidated financial statements.

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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,		
	2011	2010	Percent Change	2010	2009	Percent Change
Revenues	$ 78,780	$ 64,829	21.5%	$ 64,829	$ 56,461	14.8%
Cost of goods sold	16,277	15,003	8.5	15,003	16,194	(7.4)
Gross profit	62,503	49,826	25.4	49,826	40,267	23.7
Expenses:						
Selling, general and administrative	62,372	62,447	(0.1)	62,447	59,822	4.4
Research and development	8,940	10,278	(13.0)	10,278	14,678	(30.0)
Total expenses	71,312	72,725	(1.9)	72,725	74,500	(2.4)
Loss from operations	(8,809)	(22,899)	(61.5)	(22,899)	(34,233)	(33.1)
Interest and other income (expense)	(2,316)	(1,005)	130.4	(1,005)	2,338	(143.0)
Net loss	(11,125)	(23,904)	(53.5)	(23,904)	(31,895)	(25.0)
Decretion of redeemable convertible preferred stock					22,781	
Net loss available to common stockholders	$ (11,125)	$ (23,904)	(53.5)%	$ (23,904)	$ (9,114)	162.3%

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

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 20.1%, increase in sales of PAD Systems 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. 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 $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. We expect that gross margin will slightly decline in the first half of fiscal 2012 due to Stealth 360° becoming a higher percentage of revenue, as the Stealth 360° has higher unit costs compared to the Diamondback 360° or Predator 360° due to lower production volumes. In addition, we expect the ramp-up of our second manufacturing facility in Texas, with higher future production capacity, will temporarily increase production costs but enhance efficiencies over time. We expect that gross margin in the second half of fiscal 2012 will be fairly consistent with fiscal 2011, although 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 was $62.4 million for the years ended June 30, 2010 and June 30, 2011. Our selling, general and administrative expenses for

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the year ended June 30, 2011 have increased due to building our sales organization, along with increased professional fees 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. We expect our selling, general and administrative expenses to increase in the future due primarily to the costs associated with expanding our sales and marketing organization and programs to further commercialize our products, but at an annual rate less than revenue growth.

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. 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. 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, 2011; however, we expect these expenses to remain fairly consistent as a percentage of revenue. Fluctuations could occur based on the number of projects and studies and the timing of expenditures.

Interest and Other Income (Expense). Interest and other income (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 income (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. 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. 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. 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.

Comparison of Fiscal Year Ended June 30, 2010 with Fiscal Year Ended June 30, 2009

Revenues. Revenues increased by $8.4 million, or 14.8%, from $56.5 million for the year ended June 30, 2009 to $64.8 million for the year ended June 30, 2010. This increase was attributable to a $6.1 million, or 11.8%, increase in sales of PAD Systems and a $2.3 million, or 45.0%, increase in sales of supplemental and other revenue during the year ended June 30, 2010 compared to the year ended June 30, 2009. Supplemental products include our Viper product line and distribution partner products, some of which have been introduced over the last year. All of our revenues were in the United States.

Cost of Goods Sold. Cost of goods sold decreased by $1.2 million, or 7.4%, from $16.2 million for the year ended June 30, 2009 to $15.0 million for the year ended June 30, 2010. This decrease in cost of goods sold

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resulted in an increase to gross margin of six percentage points, from 71% for the year ended June 30, 2009 to 77% for the year ended June 30, 2010. These amounts represent the cost of materials, labor and overhead for single-use catheters, guidewires, control units, and other supplemental products. The increase in gross margin from the year ended June 30, 2009 to June 30, 2010 was primarily due to manufacturing 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, 2010 and 2009 includes $548,000 and $475,000, respectively, for stock-based compensation.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $2.6 million, or 4.4%, from $59.8 million for the year ended June 30, 2009 to $62.4 million for the year ended June 30, 2010. The primary reasons for the increase included increased sales and marketing expenses of $4.8 million from building our sales organization along with additional education programs, partially offset by reduced consulting and professional services, primarily from a $1.7 million write-off of previously capitalized initial public offering costs in fiscal 2009. Selling, general, and administrative expenses for the years ended June 30, 2010 and 2009 includes $7.3 million and $5.7 million, respectively, for stock-based compensation.

Research and Development Expenses. Research and development expenses decreased by $4.4 million, or 30.0%, from $14.7 million for the year ended June 30, 2009 to $10.3 million for the year ended June 30, 2010. 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 2010, as well as the timing of those projects. Research and development expenses for the year ended June 30, 2010 and 2009 includes $1.3 million and $612,000, respectively, for stock-based compensation.

Interest and Other Income (Expense). Interest and other income (expense) decreased by $3.3 million, or 143.0%, from income of $2.3 million for the year ended June 30, 2009 to expense of ($1.0) million for the year ended June 30, 2010. Significant changes in interest and other income (expense) during these periods included:

Interest Expense. Interest expense decreased by $1.0 million, from $2.4 million for the year ended June 30, 2009 to $1.4 million for the year ended June 30, 2010. The decrease was primarily due to significantly reduced amortization of the debt discount during the year ended June 30, 2010 from the refinancing of debt in April 2009.

Interest Income. Interest income decreased by $3.0 million, from $3.4 million for the year ended June 30, 2009 to $402,000 for the year ended June 30, 2010. The decrease was due to $2.8 million recorded during the year ended June 30, 2009 related to accepting the UBS offer to repurchase our auction rate securities, establishing an auction rate securities put option agreement.

Decretion of Redeemable Convertible Preferred Stock Warrants. Decretion of redeemable convertible preferred stock warrants reflects the change in estimated fair value of preferred stock warrants at the balance sheet dates. Decretion of redeemable convertible preferred stock warrants for the year ended June 30, 2009 was $3.0 million. There was no decretion of redeemable convertible preferred stock warrants during the year ended June 30, 2010 because all preferred stock was converted to common stock in conjunction with the merger.

Gain (Impairment) on Investments. *Gain (*impairment) on investments was $150,000 and ($1.7) million for the years ended June 30, 2010 and 2009, respectively. Gain (impairment) on investments was due to the change in the fair value of auction rate securities investments in both periods. On June 30, 2010, all the auction rate securities had been redeemed by the issuers at par value or repurchased by UBS at par value pursuant to an agreement reached with UBS in 2008. Due to the redemption and repurchase, there is no gain (impairment) on investments related to these securities in subsequent periods.

Decretion of Redeemable Convertible Preferred Stock. Decretion of redeemable convertible preferred stock reflected the change in estimated fair value of preferred stock at the balance sheet dates. Decretion of redeemable convertible preferred stock for the year ended June 30, 2009 was $22.8 million. There was no decretion of redeemable convertible preferred stock during the year ended June 30, 2010 because all preferred stock was converted to common stock in conjunction with the merger.

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Net Loss Available to Common Stockholders. Net loss available to common stockholders for year ended June 30, 2010 was $(23.9) million, or ($1.62) per basic and diluted share, compared to $(9.1) million, or ($1.13) per basic and diluted share for the year ended June 30, 2009.

NON-GAAP FINANCIAL INFORMATION

To supplement our consolidated condensed 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):

	Year Ended June 30,	
	2011	2010
Loss from operations	$ (8,809)	$ (22,899)
Add: Stock-based compensation	6,468	9,094
Add: Depreciation and amortization	716	599
Adjusted EBITDA	$ (1,625)	$ (13,206)

The improvement in Adjusted EBITDA of $11.6 million, or 87.7%, is primarily the result of the $14.1 million, or 61.5%, improvement in the loss from operations. The loss from operations was significantly impacted by increases in revenue and gross margin, and a decrease in operating expenses, as discussed above.

Adjusted EBITDA was also impacted by a decrease in stock-based compensation and increase in depreciation and amortization. Stock-based compensation decreased $2.6 million, or 28.9%, from $9.1 million for the year ended June 30, 2010 to $6.5 million for the year ended June 30, 2011. Stock-based compensation decreased as a result of prior year charges for extending the terms of certain expired stock options. 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.

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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 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 $21.2 million and $23.7 million at June 30, 2011 and 2010, respectively. During the year ended June 30, 2011, net cash used in operations amounted to $8.4 million. As of June 30, 2011, we had an accumulated deficit of $162.4 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 includes a $10.0 million term loan and a $15.0 million line of credit. The terms of each of these loans are as follows:

The $10.0 million term loan has a fixed interest rate of 9.0% and a final payment amount equal to 1.0% of the loan amount due at maturity. This 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 and interest payments. 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 principal amount, upon prepayment or the occurrence and continuance of an event of default. In connection with entering into the agreement, we amended a warrant previously granted to Silicon Valley Bank. The warrant provided an option to purchase 8,493 shares of common stock at an exercise price of $5.48 per share. The warrant was exercised in June 2011. The balance outstanding on the term loan at June 30, 2011 was $7.3 million, net of the unamortized discount associated with the warrant.

The $15.0 million line of credit has a two year maturity and a floating interest rate equal to Silicon Valley Bank s prime rate, plus 2.0%, with an interest rate floor of 6.0%. Interest on borrowings is due monthly and the principal balance is due at maturity. Borrowings on the line of credit are based on (a) 80% of eligible domestic receivables, plus (b) the lesser of 40% of eligible inventory or 25% of eligible domestic receivables or $2.5 million, minus (c) to the extent in effect, certain loan reserves as defined in the

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agreement. Accounts receivable receipts are deposited into a lockbox account in the name of Silicon Valley Bank. The accounts receivable line of credit is subject to non-use fees, annual fees, and cancellation fees. The agreement provides that initially 50% of the outstanding principal balance of the $10.0 million term loan reduces available borrowings under the line of credit. Upon the achievement of certain financial covenants, the amount reducing available borrowings will be reduced to zero. There was not an outstanding balance on the line of credit at June 30, 2011.

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, 2011. The agreement also includes subjective acceleration clauses which 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 our 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.

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 provides that PFG will make loans to us up to $4.0 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.

Under the agreement, PFG provided us with an initial loan of $1.5 million (the initial loan) on April 15, 2010. During the three months ended December 31, 2010, PFG, at its option, converted the entire $1.5 million (at par) into 276,243 shares of our common stock in accordance with the conversion terms set forth in the note for the initial loan. On December 3, 2010, and January 26, 2011, we issued PFG additional convertible notes under the agreement of $3.5 million and $500,000, respectively (subsequent loans). During the three months ended June 30, 2011, PFG, at its option, converted the $3.5 million subsequent loan (at par) into 362,320 shares of our common stock in accordance with the conversion terms set forth in the note for the subsequent loan. On June 30, 2011, we issued PFG an additional convertible note under the agreement of $3.5 million (the current loans). At any time prior to the maturity date, PFG may at its option convert the remaining $500,000 subsequent loan or the $3.5 million current loan into shares of our common stock at $12.40 or $13.64 per share, respectively, which 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 its common stock to satisfy this condition and effect a mandatory conversion. As a result of the various note issuances and conversions, we have reflected a net expense of $859,000 for the year ended June 30, 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 initial loan and subsequent loan, (ii) the write-off of the unamortized debt premium on the initial and subsequent loan and (iii) the change in fair value of the conversion options on all loans. The balance outstanding under the loan and security agreement at June 30, 2011 was $4.6 million, including the net unamortized premium associated with our conversion option and related beneficial conversion feature. The balance outstanding under the loan and security agreement at June 30, 2010 was $1.3 million, including the net unamortized discount associated with the warrant and our conversion option.

On July 26, 2011, PFG at its option converted the remaining subsequent loan of $500,000 (at par) into 40,323 shares of our common stock in accordance with the conversion terms set forth in the note for the subsequent loan. We then subsequently issued PFG a new convertible note of $500,000. At any time prior to the maturity date, PFG may at its option convert the $500,000 note into shares of our common stock at $15.30 per share, which equaled the ten-day volume weighted average price per share of our common stock prior to the issuance date of the note.

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On August 23, 2011, the loan and security agreement was amended. The amended agreement provides that PFG will make loans to us up to $5.0 million. All other terms of the original agreement remain the same. We then subsequently issued PFG a new convertible note of $1.0 million, which increased the aggregate amount drawn under the loan and security agreement, as amended, to the full available amount of $5.0 million. At any time prior to the maturity date, PFG may at its option convert the $1.0 million note into shares of our common stock at $13.42 per share, which equaled the ten-day volume weighted average price per share of our common stock prior to the issuance date of the note.

The loans are secured by certain assets, and the agreement contains customary covenants limiting the 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 our stock, permit or suffer certain change of control transactions, dispose of collateral, or change the nature of our 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, 2011. 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 execution of the PFG loan and security agreement, we issued a warrant to PFG on April 14, 2010, which allows PFG to purchase 147,330 shares of our common stock at a price per share of $5.43, which price was based on the ten-day volume weighted average price per share of our common stock prior to the date of the agreement. The warrant was exercised in June 2011.

Cash and Cash Equivalents. Cash and cash equivalents was $21.2 million and $23.7 million at June 30, 2011 and 2010, respectively. This decrease is primarily attributable net cash used in operations during the year ended June 30, 2011, partially offset by proceeds drawn on our convertible debt agreement.

Operating Activities. Net cash used in operating activities improved 38.4% to $8.4 million from $13.6 million for the years ended June 30, 2011 and 2010, respectively. For the years ended June 30, 2011 and 2010, we had a net loss of $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, 2011 and 2010. Significant changes in working capital during these periods included:

Cash used in accounts receivable of $(3.7) million and $(1.1) million during the years ended June 30, 2011and 2010, respectively. The increase in amount used between periods is due to higher revenue growth in fiscal year 2011.

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

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

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

Cash (used in) provided by accrued expenses and other liabilities of ($2.4) million and $3.8 million during the years ended June 30, 2011 and 2010, respectively. For the year ended June 30, 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.

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Investing Activities. Net cash (used in) provided by investing activities was ($1.7) million and $21.8 million for the years ended June 30, 2011 and 2010, respectively. For the year ended June 30, 2011, cash (used in) investing activities resulted from investment in property plant, 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 $7.5 million and ($17.9) million during the years ended June 30, 2011 and 2010, respectively. Cash provided by financing activities during these periods included:

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

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

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

Cash used in financing activities in these periods included:

payment of long-term debt of $2.4 million and $25.3 million during the years ended June 30, 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, 2011, 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, 2011 are summarized below:

	Payments Due by Period (in thousands)				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**3-5 Years**	**More Than 5 Years**
Operating leases(1)	$ 4,590	$ 920	$ 1,059	$ 886	$ 1,725
Purchase commitments(2)	6,149	6,149			
Debt maturities(3)	12,144	3,813	3,725	4,606	
Total	$ 22,883	$ 10,882	$ 4,784	$ 5,492	$ 1,725

(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.

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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 will be effective for us beginning January 1, 2012. Other than requiring additional disclosures, we do not anticipate material impacts 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.

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 commercial launch of the Stealth 360°; 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 future presentations of clinical trial results; 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; 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; an increase in revenues; a temporarily increase in production costs; gross margins in the second half of fiscal 2012 will be fairly consistent with fiscal 2011; an increase in selling, general and administrative expenses; research and development expenses being above amounts incurred in fiscal 2011; no payment of dividends in the foreseeable future; and the sufficiency of our current and anticipated financial resources to fund operating expenses for at least the next 12 months. In some cases, you can identify forward-looking statements by the following words: anticipate, believe, continue, could estimate, expect, intend, may, ongoing, plan, potential, predict, project, should, will, would, or the negative of these t terminology, although not all 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

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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, 2011 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 Stockholders of

Cardiovascular Systems, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of changes in stockholders 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, 2011 and 2010, and the results of their operations and cash flows for each of the three years in the period ended June 30, 2011 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, 2011, 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 included in item 9A. 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 was an integrated audit in 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 12, 2011

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Cardiovascular Systems, Inc.

Consolidated Balance Sheets

	June 30, 2011	June 30, 2010
	(Dollars in thousands, except per share and share amounts)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 21,159	$ 23,717
Accounts receivable, net	13,254	9,394
Inventories	5,818	4,319
Prepaid expenses and other current assets	797	1,048
Total current assets	41,028	38,478
Property and equipment, net	2,383	1,964
Patents, net	2,314	1,712
Debt conversion option and other assets	1,033	568
Total assets	$ 46,758	$ 42,722
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities		
Current maturities of long-term debt	$ 3,813	$ 2,302
Accounts payable	5,181	3,353
Deferred grant incentive	647	1,181
Accrued expenses	5,545	6,569
Total current liabilities	15,186	13,405
Long-term liabilities		
Long-term debt, net of current maturities	8,331	8,985
Deferred grant incentive	1,497	2,208
Other liabilities	109	409
Total long-term liabilities	9,937	11,602
Total liabilities	25,123	25,007
Commitments and contingencies		
Common stock, $0.001 par value at June 30, 2011 and 2010; authorized 100,000,000 common shares at June 30, 2011 and 2010; issued and outstanding 16,987,068 at June 30, 2011 and 15,148,549 at June 30, 2010, respectively	17	15
Additional paid in capital	174,157	157,718
Common stock warrants	9,909	11,305
Accumulated deficit	(162,448)	(151,323)
Total stockholders equity	21,635	17,715
Total liabilities and stockholders equity	$ 46,758	$ 42,722

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

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Cardiovascular Systems, Inc.

Consolidated Statements of Operations

	Year Ended June 30,		
	2011	2010	2009
	(Dollars in thousands, except per share and share amounts)		
Revenues	$ 78,780	$ 64,829	$ 56,461
Cost of goods sold	16,277	15,003	16,194
Gross profit	62,503	49,826	40,267
Expenses			
Selling, general and administrative	62,372	62,447	59,822
Research and development	8,940	10,278	14,678
Total expenses	71,312	72,725	74,500
Loss from operations	(8,809)	(22,899)	(34,233)
Interest and other, net	(2,316)	(1,005)	2,338
Net loss	(11,125)	(23,904)	(31,895)
Decretion of redeemable convertible preferred stock			22,781
Net loss available to common stockholders	$ (11,125)	$ (23,904)	$ (9,114)
Loss per common share Basic and diluted	$ (0.70)	$ (1.62)	$ (1.13)
Weighted average common shares used in computation Basic and diluted	15,915,800	14,748,293	8,068,689

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

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Cardiovascular Systems, Inc.

Consolidated Statements of Changes in Stockholders Equity (Deficiency) and Comprehensive Loss

	Common Stock		Additional Paid In		Accumulated		Comprehensive
	Shares	Amount	Capital	Warrants	Deficit	Total	Loss
	(Dollars in thousands, except per share and share amounts)						
Balances at June 30, 2008	4,900,984	$ 35,933	$	$ 680	$ (118,305)	$ (81,692)	$ (39,160)
Stock-based compensation related to restricted stock awards, net	425,359	2,464	2,003			4,467	
Stock-based compensation related to stock options		756	1,548			2,304	
Exercise of stock options and warrants at $1.55-$8.83 per share	100,333	640	307	(422)		525	
Issuance/expiration of common stock warrants		76	(8,217)	9,955		1,814	
Conversion of preferred warrants to common warrants				1,069		1,069	
Decretion of redeemable convertible preferred stock					22,781	22,781	
Conversion of preferred stock to common stock	5,954,389	6	75,456			75,462	
Merger with Replidyne, net of merger costs	2,732,839	3	35,494			35,497	
To adjust common stock to par value		(39,864)	39,864				
Net loss and comprehensive loss					(31,895)	(31,895)	(31,895)
Balances at June 30, 2009	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)
Balances at June 30, 2010	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)

Balances at June 30, 2011	16,987,068	$ 17	$ 174,157	$ 9,909	$ (162,448)	$ 21,635	$ (11,125)

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

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Cardiovascular Systems, Inc.

Consolidated Statements of Cash Flows

	Year Ended June 30,		
	2011	2010	2009
	(Dollars in thousands, except per share and share amounts)		
Cash flows from operating activities			
Net loss	$ (11,125)	$ (23,904)	$ (31,895)
Adjustments to reconcile net loss to net cash used in operations			
Depreciation and amortization of property and equipment	662	548	417
(Recoveries of) provision for doubtful accounts	(36)	137	95
Amortization of patents	54	51	53
Decretion of redeemable convertible preferred stock warrants			(2,991)
Amortization of debt discount	(25)	257	1,228
Debt conversion and valuation of conversion options, net	859		
Stock-based compensation	6,468	9,094	6,771
Other	250		
(Gain) impairment on investments		(150)	1,683
Gain on auction rate securities put option			(2,800)
Changes in assets and liabilities, net of merger			
Accounts receivable	(3,718)	(1,057)	(3,672)
Inventories	(1,499)	(950)	407
Prepaid expenses and other assets	323	6	2,362
Accounts payable	1,828	(1,398)	(1,100)
Accrued expenses and other liabilities	(2,402)	3,799	(268)
Net cash used in operations	(8,361)	(13,567)	(29,710)
Cash flows from investing activities			
Expenditures for property and equipment	(1,081)	(793)	(957)
Sales of investments		22,950	50
Costs incurred in connection with patents	(656)	(400)	(436)
Cash acquired in Replidyne merger, net of transaction costs paid			37,369
Net cash (used in) provided by investing activities	(1,737)	21,757	36,026
Cash flows from financing activities			
Issuance of common stock under employee stock purchase plan	965	1,197	
Issuance of convertible preferred stock warrants			75
Exercise of stock options and warrants	1,523	285	525
Proceeds from long-term debt	7,500	5,911	19,845
Payments on long-term debt	(2,448)	(25,277)	(945)
Net cash provided by (used in) financing activities	7,540	(17,884)	19,500
Net change in cash and cash equivalents	(2,558)	(9,694)	25,816
Cash and cash equivalents			
Beginning of period	23,717	33,411	7,595
End of period	$ 21,159	$ 23,717	$ 33,411
Noncash investing and financing activities			
Decretion (accretion) of redeemable convertible preferred stock	$	$	$ (22,781)
Conversion of Series A warrants to common warrants			1,069
Issuance of common stock warrants	216	97	1,814

Beneficial conversion feature on convertible debt	236	97	
Issuance of common stock warrants prior to merger			8,217
Conversion of redeemable convertible preferred stock to common stock			75,456
Expiration of common stock warrants		71	76
Adjustment of common stock to par value	2	1	39,864
Amendment of restricted stock units		517	
Conversion of convertible debt	5,531		
Net exercise of common stock warrants	1,505		
Premium on convertible debt	1,263		
Other	250		
Supplemental cash flow information			
Interest paid	$ 1,447	$ 1,161	$ 1,051

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. Prior to the merger, Replidyne was a biopharmaceutical company focused on discovering, developing, in-licensing and commercializing innovative anti-infective products.

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.

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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 allowances 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, 2011 and 2010:

	Amount
Balance at June 30, 2009	$ 253
Provision for doubtful accounts	279
Write-offs	(129)
Balance at June 30, 2010	$ 403
Provision for doubtful accounts	51
Write-offs	(103)
Balance at June 30, 2011	$ 351

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

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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, 2011 and 2010 were as follows:

	Amount
Balance at June 30, 2009	$ 65
Provision	257
Claims	(206)
Balance at June 30, 2010	$ 116
Provision	159
Claims	(205)
Balance at June 30, 2011	$ 70

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, 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.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentration of credit risk consist primarily of cash and cash equivalents, investments and accounts receivable. The Company maintains its cash and investment 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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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2011. Assets are measured on a recurring basis if they are remeasured at least annually:

		Level 3	
		Auction Rate Securities	
	Trading Securities	Put Option	Conversion Option
Balance at June 30, 2009	$ 20,000	$ 2,800	$
Sales of investments	(20,150)	(2,800)	
Gain on investments	150		
Issuance of conversion option			388
Balance at June 30, 2010	$	$	$ 388
Issuance of convertible notes			1,715
Conversion of convertible notes			(1,669)
Change in conversion option valuation			491
Balance at June 30, 2011	$	$	$ 925

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, 2011, 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. The Company calculates the fair value on the date of grant using a Black-Scholes model.

Preferred Stock

Prior to the merger, the Company recorded the current estimated fair value of its convertible preferred stock on a quarterly basis based on the fair market value of that stock as determined by management and the board of directors. The determination of fair market value included factors

such as recent financing activity, preferred

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

stock rights and preferences, clinical trials, revenues, and regulatory approval process. The Company recorded changes in the fair value of its redeemable convertible preferred stock in the consolidated statements of changes in stockholders equity (deficiency) and comprehensive loss and consolidated statements of operations as accretion of redeemable convertible preferred stock. Concurrent with the merger, all preferred stock was converted to common stock and, accordingly, was reclassified to stockholders equity (deficiency).

Preferred Stock Warrants

The freestanding warrant that was related to the Company s redeemable convertible preferred stock was classified as a liability on the balance sheet as of June 30, 2008. The warrant was subject to remeasurement at each balance sheet date and any change in fair value was recognized as a component of other income (expense). Fair value was measured using the Black-Scholes option pricing model. Concurrent with the merger, all preferred stock warrants were converted into warrants to purchase common stock and, accordingly, the liability was reclassified to stockholders equity (deficiency).

Reclassifications

Certain reclassifications have been made to the June 30, 2010 balance sheet to conform to June 30, 2011 presentation. These reclassifications had no effect on previously reported net loss, stockholders equity, or cash flows as previously reported.

Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board (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 will be effective for the Company beginning January 1, 2012. Other than requiring additional disclosures, the Company does not anticipate material impacts on its 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.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Selected Consolidated Financial Statement Information

	June 30, 2011	2010
Accounts Receivable		
Accounts receivable	$ 13,605	$ 9,797
Less: Allowance for doubtful accounts	(351)	(403)
	$ 13,254	$ 9,394
Inventories		
Raw materials	$ 2,705	$ 1,256
Work in process	640	282
Finished goods	2,473	2,781
	$ 5,818	$ 4,319
Property and equipment		
Equipment	$ 3,968	$ 3,085
Furniture	318	168
Leasehold improvements	180	131
	4,466	3,384
Less: Accumulated depreciation and amortization	(2,083)	(1,420)
	$ 2,383	$ 1,964
Patents		
Patents	$ 2,770	$ 2,114
Less: Accumulated amortization	(456)	(402)
	$ 2,314	$ 1,712

As of June 30, 2011, future estimated amortization of patents and patent licenses will be:

2012	$ 53
2013	53
2014	53
2015	53
2016	48
Thereafter	2,054
	$ 2,314

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2011	2010
Accrued expenses		
Salaries and bonus	$ 938	$ 1,620
Commissions	2,111	1,753
Accrued vacation	1,648	1,624
Merger related lease obligation	293	1,099
Other	555	473
	$ 5,545	$ 6,569

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 includes a $10,000 term loan and a $15,000 line of credit. The terms of each of these loans are as follows:

The $10,000 term loan has a fixed interest rate of 9.0% and a final payment amount equal to 1.0% of the loan amount due at maturity. This 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 and interest payments. 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 principal amount, upon prepayment or the occurrence and continuance of an event of default. In connection with entering into the agreement, the Company amended a warrant previously granted to Silicon Valley Bank. The warrant provided an option to purchase 8,493 shares of common stock at an exercise price of $5.48 per share. The warrant was exercised in June 2011. The balance outstanding on the term loan at June 30, 2011 and 2010 was $7,286 and $9,588, respectively, net of the unamortized discount associated with the warrant.

The $15,000 line of credit has a two year maturity and a floating interest rate equal to Silicon Valley Bank s prime rate, plus 2.0%, with an interest rate floor of 6.0%. Interest on borrowings is due monthly and the principal balance is due at maturity. Borrowings on the line of credit are based on (a) 80% of eligible domestic receivables, plus (b) the lesser of 40% of eligible inventory or 25% of eligible domestic receivables or $2,500, minus (c) to the extent in effect, certain loan reserves as defined in the agreement. Accounts receivable receipts are deposited into a lockbox account in the name of Silicon Valley Bank. The accounts receivable line of credit is subject to non-use fees, annual fees, and cancellation fees. The agreement provides that initially 50% of the outstanding principal balance of the $10,000 term loan reduces available borrowings under the line of credit. Upon the achievement of certain financial covenants, the amount reducing available borrowings will be reduced to zero. There was no outstanding balance on the line of credit at June 30, 2011 or 2010.

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, 2011. The agreement also includes subjective acceleration clauses which 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.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 provides that PFG will make loans to the Company up to $4,000. 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.

Under the agreement, PFG provided the Company with an initial loan of $1,500 (the initial loan) on April 15, 2010. During the three months ended December 31, 2010, PFG, at its option, converted the entire $1,500 (at par) into 276,243 shares of the Company s common stock in accordance with the conversion terms set forth in the note for the initial loan. On December 3, 2010, and January 26, 2011, the Company issued PFG additional convertible notes under the agreement of $3,500 and $500, respectively (subsequent loans). During the three months ended June 30, 2011, PFG, at its option, converted the $3,500 subsequent loan (at par) into 362,320 shares of the Company s common stock in accordance with the conversion terms set forth in the note for the subsequent loan. On June 30, 2011, the Company issued PFG an additional convertible note under the agreement of $3,500 (the current loans). At any time prior to the maturity date, PFG may at its option convert the remaining $500 subsequent loan or the $3,500 current loan into shares of the Company s common stock at $12.40 or $13.64 per share, respectively, which 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. As a result of the various note issuances and conversions, the Company has reflected a net expense of $859 for the year ended June 30, 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 initial loan and subsequent loan, (ii) the write-off of the unamortized debt premium on the initial and subsequent loan and (iii) the change in fair value of the conversion options on all loans. The balance outstanding under the loan and security agreement at June 30, 2011 was $4,607, including the net unamortized premium associated with Company s conversion option and related beneficial conversion feature. The balance outstanding under the loan and security agreement at June 30, 2010 was $1,311, including the net unamortized discount associated with the warrant and Company s conversion option.

On July 26, 2011, PFG at its option converted the remaining subsequent loan of $500 (at par) into 40,323 shares of the Company s common stock in accordance with the conversion terms set forth in the note for the subsequent loan. The Company then subsequently issued PFG a new convertible note of $500. At any time prior to the maturity date, PFG may at its option convert the $500 note into shares of the Company s common stock at $15.30 per share, which equaled the ten-day volume weighted average price per share of the Company s common stock prior to the issuance date of the note.

On August 23, 2011, the loan and security agreement was amended. The amended agreement provides that PFG will make loans to the Company up to $5,000. All other terms of the original agreement remain the same. The Company then subsequently issued PFG a new convertible note of $1,000, which increased the aggregate amount drawn under the loan and security agreement, as amended, to the full available amount of $5,000. At any time prior to the maturity date, PFG may at its option convert the $1,000 note into shares of the Company s common stock at $13.42 per share, which equaled the ten-day volume weighted average price per share of the Company s common stock prior to the issuance date of the note.

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,

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2011. 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 execution of the PFG loan and security agreement, the Company issued a warrant to PFG on April 14, 2010, which allows PFG to purchase 147,330 shares of the Company s common stock at a price per share of $5.43, which price was based on the ten-day volume weighted average price per share of the Company s common stock prior to the date of the agreement. The warrant was exercised in June 2011.

As of June 30, 2011, debt maturities (including debt discount and premium) were as follows:

2012	$ 3,962
2013	3,589
2014	250
2015	4,000
Total	$ 11,801
Less: Current Maturities	(3,813)
Long-Term Debt (excluding net unamortized premium)	$ 7,988
Add: Net Unamortized Premium	343
Long-term debt	$ 8,331

4. Interest and Other, Net

Interest and other, net, includes the following:

	Year Ended June 30,		
	2011	**2010**	**2009**
Interest expense, including premium and discount amortization	$ (1,417)	$ (1,435)	$ (2,350)
Interest income	12	402	3,380
Change in fair value of conversion option	491		
Net write-offs upon conversion (option and unamortized premium)	(1,350)		
Decretion of redeemable convertible preferred stock warrants			2,991
Gain on investments		150	(1,683)
Other	(52)	(122)	
Total	$ (2,316)	$ (1,005)	$ 2,338

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Common Stock Warrants

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 warrants to purchase 147,330 shares of the Company s common stock at an exercise price of $5.43 per share. Half of the warrants were immediately exercisable, and the remaining half became exercisable as additional funds were drawn during the year ended June 30, 2011. The immediately exercisable warrants were assigned a value of $97 for accounting purposes, while the warrants that vested during the year ended June 30, 2011 were assigned a value of $216. The warrants were exercised in June 2011. See Note 3 for additional information.

The following summarizes common stock warrant activity:

	Warrants Outstanding	Price Range per Share
Warrants outstanding at June 30, 2008	158,041	$1.55-12.37
Warrants issued	2,566,099	$8.83-61.30
Warrants converted	439,317	$8.83-14.16
Warrants exercised	(33,431)	$1.55-7.73
Warrants expired	(8,605)	$7.73
Warrants outstanding at June 30, 2009	3,121,421	$1.55-61.30
Warrants issued	147,330	$5.43
Warrants exercised	(879)	$1.55
Warrants expired	(25,880)	$1.55-14.16
Warrants outstanding at June 30, 2010	3,241,992	$5.43-61.30
Warrants exercised	(548,366)	$5.43-8.83
Warrants expired	(3,202)	$9.28
Warrants outstanding at June 30, 2011	2,690,424	$5.43-61.30

There were no warrants granted during the year ended June 30, 2011. The following assumptions were utilized in determining the fair value of warrants issued during the year ended June 30, 2010 under the Black-Scholes model:

	Year Ended June 30, 2010
Weighted average fair value of warrants granted	$1.95
Risk-free interest rates	1.39%
Expected life	2.5 years
Expected volatility	55.9%
Expected dividends	None

6. 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 common stock were originally reserved for

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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, 2011, the number of shares available for grant was increased by 849,353 under the 2007 Plan renewal provision.

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, 2008	3,803,124	$ 10.19
Options granted	99,314	$ 9.13
Options obtained through merger	239,716	$ 31.11
Options exercised	(66,903)	$ 7.90
Options forfeited or expired	(367,369)	$ 21.92
Options outstanding at June 30, 2009	3,707,882	$ 10.43
Options granted	58,551	$ 7.70
Options exercised	(37,313)	$ 8.36
Options forfeited or expired	(372,127)	$ 9.34
Options outstanding at June 30, 2010	3,356,993	$ 10.49
Options exercised	(180,702)	$ 8.60
Options forfeited or expired	(105,292)	$ 12.32
Options outstanding at June 30, 2011	3,070,999	$ 10.54

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

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Options outstanding and exercisable at June 30, 2011 were as follows:

	Options Outstanding		Options Exercisable	
Exercise Price	Number of Outstanding Shares	Remaining Weighted Average Contractual Life (Years)	Number of Exercisable Shares	Remaining Weighted Average Contractual Life (Years)
$5.01	12,940	8.43	12,940	8.43
$7.90	439,597	6.09	439,597	6.09
$8.75	88,962	7.68	88,962	7.68
$8.83	993,241	5.40	993,241	5.40
$9.28	32,671	3.41	32,671	3.41
$11.38	85,143	6.38	85,143	6.38
$12.15	1,103,932	3.39	1,103,932	3.39
$12.37	138,781	4.30	138,781	4.30
$13.98	74,281	6.63	74,281	6.63
$14.00	4,000	1.51	4,000	1.51
$16.40	6,000	1.51	6,000	1.51
$18.55	31,451	4.76	31,451	4.76
$18.60	60,000	0.66	60,000	0.66
	3,070,999	4.73	3,070,999	4.73

Options issued to employees and directors that are vested at June 30, 2011, were as follows:

	Number of Shares	Remaining Weighted Average Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
Options vested	2,741,788	4.73	$ 10.54	$ 11,350

As of June 30, 2011, all options were fully vested. An employee s unvested options are forfeited when employment is terminated; vested options must be exercised at or within 90 days of termination to avoid forfeiture. The Company determines the fair value of options using the Black-Scholes option pricing model. The estimated fair value of options, including the effect of estimated forfeitures, is recognized as expense on a straight-line basis over the options vesting periods. The following assumptions were used in determining the fair value of stock options granted under the Black-Scholes model:

	Year Ended June 30,	
	2010	2009

Weighted average fair value of options granted	$1.23	$4.66
Risk-free interest rates	1.32-2.07%	2.82%
Expected life	2.5-5 years	6 years
Expected volatility	46.7-55.9%	55.5%
Expected dividends	None	None

The risk-free interest rate for periods within the five and ten year contractual life of the options is based on the U.S. Treasury yield curve in effect at the grant date and the expected option life of 2.5 to 6 years. Expected volatility is based on the historical volatility of the Company s stock.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The aggregate intrinsic value of a stock 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, 2011, 2010 and 2009 was $12,712, $0, and $0, respectively. The total aggregate intrinsic value of options exercised during the years ended June 30, 2011, 2010 and 2009 was $736, $30 and $387, respectively. Shares supporting option exercises are sourced from new share issuances.

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, 2008	525,473	$ 14.68
Restricted stock awards granted	532,124	$ 9.08
Restricted stock awards forfeited	(106,765)	$ 14.06
Restricted stock awards vested	(206,455)	$ 14.52
Restricted stock awards outstanding at June 30, 2009	744,377	$ 10.81
Restricted stock awards granted	877,751	$ 6.87
Restricted stock awards forfeited	(187,441)	$ 8.48
Restricted stock awards vested	(328,804)	$ 6.00
Restricted stock awards outstanding at June 30, 2010	1,105,883	$ 7.69
Restricted stock awards granted	804,159	$ 6.08
Restricted stock awards forfeited	(199,910)	$ 6.91
Restricted stock awards vested	(511,925)	$ 7.68
Restricted stock awards outstanding at June 30, 2011	1,198,207	$ 6.39

Estimated pre-vesting forfeitures are considered in determining stock-based compensation expense. As of June 30, 2011, 2010 and 2009, the Company estimated its forfeiture rate at 10.7%, 9.4%, and 9.4%, respectively. As of June 30, 2011, 2010, and 2009 the total compensation cost for non-vested awards not yet recognized in the consolidated statements of operations was $5,128, $4,226 and $1,033, respectively, net of the effect of estimated forfeitures. These amounts are expected to be recognized over a weighted-average period of 2.27, 1.02 and 0.51 years, respectively.

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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, 2008		
Restricted stock units granted	42,238	$ 8.75
Restricted stock units outstanding at June 30, 2009	42,238	$ 8.75
Restricted stock units granted	93,024	$ 8.60
Restricted stock units forfeited	(5,814)	$ 8.60
Restricted stock units outstanding at June 30, 2010	129,448	$ 8.65
Restricted stock units granted	158,880	$ 4.79
Restricted stock units converted to common stock	(28,212)	$ 7.09
Restricted stock units forfeited	(22,397)	$ 6.70
Restricted stock units outstanding at June 30, 2011	237,719	$ 6.51

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
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

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

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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, 2009:

	Stock Options	Restricted Stock Awards	Employee Stock Purchase Plan	Total
Cost of goods sold	$ 199	$ 274	$ 2	$ 475
Selling, general and administrative	1,786	3,862	36	5,684
Research and development	276	331	5	612
Total	$ 2,261	$ 4,467	$ 43	$ 6,771

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, 2008	19,065
Shares reserved	575,444
Shares granted	(631,438)
Shares forfeited, expired or cancelled	121,767
Shares available for grant at June 30, 2009	84,838
Shares reserved	705,695
Shares granted	(936,302)
Shares forfeited, expired or cancelled	255,942
Shares available for grant at June 30, 2010	110,173
Shares reserved	757,427
Shares granted	(1,092,500)
Shares forfeited, expired or cancelled	275,623
Shares available for grant at June 30, 2011	50,723

(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

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 outstanding 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, 2011, 169,871 shares were added to the plan. Employees purchased 160,000 shares at an average price of $6.03 per share in the year ended June 30, 2011. Shares reserved under the plan for the year ended June 30, 2012 totaled 170,709.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Income Taxes

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

	June 30, 2011	2010
Deferred tax assets		
Stock-based compensation	$ 6,420	$ 5,568
Accrued expenses	933	749
Other	2,630	3,753
Research and development credit carryforwards	3,446	3,120
Net operating loss carryforwards	38,944	35,990
Total deferred tax assets	52,373	49,180
Valuation allowance	(52,373)	(49,180)
Net deferred tax assets	$	$

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, 2008	$ 29,353
Additions	11,764
Balance at June 30, 2009	$ 41,117
Additions	8,063
Balance at June 30, 2010	$ 49,180
Additions	3,193
Balance at June 30, 2011	$ 52,373

As of June 30, 2011 and 2010, the Company had federal tax NOL carryforwards of approximately $110,102 and $102,141, respectively. These NOL carryforwards are available to offset taxable income through 2031 and have started to expire. As of June 30, 2011 and 2010, the Company also had state NOL carryforwards of approximately $36,109 and $30,574, respectively, available to offset future state taxable income. These state NOL carryforwards typically will have the same expirations as our federal tax NOL carryforwards.

As of June 30, 2011 and 2010, the Company had approximately $3,080 and $2,783 of federal research and development credit carryforwards, respectively. As of June 30, 2011 and 2010, the Company had approximately $749 and $685 of state research and development credit carryforwards, respectively. The federal and state research and development credit carryforwards will begin to expire in 2024.

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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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

realized upon ultimate settlement with the relevant tax authority. The Company has recognized a liability relating to unrecognized tax benefits of $383 and $347 at June 30, 2011 and 2010, 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 twelve months. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	Amount
Balance at July 1, 2009	$
Increases related to prior year tax positions	317
Increases related to current year tax positions	30
Balance at June 30, 2010	$ 347
Increases related to prior year tax positions	22
Increases related to current year tax positions	14
Balance at June 30, 2011	$ 383

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, 2011, 2010, and 2009. The Company is not currently under examination by any taxing jurisdiction.

8. 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 $1,188, $659, and $658 for the years ended June 30, 2011, 2010, and 2009, respectively.

Future minimum lease payments under the agreements as of June 30, 2011 are as follows:

2012	$ 920
2013	645
2014	414
2015	426
2016	460
Thereafter	1,725
	$ 4,590

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 10 for additional information.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. 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 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, 2011, 2010, and 2009.

10. 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 previously entered into a Corporate Job Creation Agreement dated June 17, 2009. The Job Creation Agreement 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 grant agreement. The PEDC will provide the Company with an additional $1,700 of net cash incentive funds in the following amounts and upon achievement of the following milestones:

$1,020, upon the hiring of the 75th full-time employee at the facility; and

$680, upon the hiring of the 125th full-time employee at the facility.

In order to retain all of the cash incentives, beginning one year and 90 days after the commencement date, the Company must not have fewer than 25 full-time employees at the facility for more than 120 consecutive days. Failure to meet this requirement will result in an obligation to make reimbursement payments to the PEDC as outlined in the agreement. The Company will not have any reimbursement requirements after 60 months from the effective date of the agreement. As of June 30, 2011, the Company was in compliance with all minimum requirements under the agreement.

The Job Creation Agreement also provides the Company with a net $1,275 award, of which $510 will be funded by a grant from the State of Texas for which the Company has applied through the Texas Enterprise Fund program. As of June 30, 2011, $340 has been received and the remaining $170 will be provided upon the hiring of the 55th full-time employee at the facility. The PEDC has committed, by resolution, to guarantee the award and

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

will make payment to the Company for the remaining $765. As of June 30, 2011, $510 has been received. 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.

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 over a 60 month period and recorded as an offset to expenditures incurred using a systematic methodology that is intended to reduce the majority of the liabilities in the first 24 months of the agreement. As of June 30, 2011, $1,936 in cumulative expenses has reduced the deferred grant incentive liabilities, resulting in a remaining current liability of $647 and long-term liability of $1,497.

11. 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 dismisses 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 has received insurance proceeds of $500 related to the settlement, and has 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 $611. 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.

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.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. 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,		
	2011	2010	2009
Numerator			
Net loss	$ 11,125	$ 23,904	$ 31,895
Decretion of redeemable convertible preferred stock(a)			(22,781)
Net loss available to common stock- holders	$ 11,125	$ 23,904	$ 9,114
Denominator			
Weighted average common shares basic	15,915,800	14,748,293	8,068,689
Effect of dilutive stock options and warrants(b)(c)			
Weighted average common shares outstanding diluted	15,915,800	14,748,293	8,068,689
Loss per common share basic and diluted	$ (0.70)	$ (1.62)	$ (1.13)

(a) The calculation for accretion of redeemable convertible preferred stock adjusts the redeemable convertible preferred stock to fair value, which equals or exceeds the amount of any undeclared dividends on the redeemable convertible preferred stock.

(b) At June 30, 2011, 2010, and 2009, 2,690,424, 3,241,992, and 3,121,421 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.

(c) At June 30, 2011, 2010, and 2009, 3,070,999, 3,356,993 and 3,707,882 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.

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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, 2011. 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, 2011. 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, 2011, 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 controls 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, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

None.

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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 appear in our definitive proxy statement for our 2011 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, and Compensation Committee, all of which appear in our definitive proxy statement for our 2011 Annual Meeting.

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 appear in our definitive proxy statement for our 2011 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 appear in our definitive proxy statement for our 2011 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 appears in our definitive proxy statement for our 2011 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 Public Registered Accounting Firm

Consolidated Balance Sheets as of June 30, 2011 and 2010

Consolidated Statements of Operations for the years ended June 30, 2011, 2010 and 2009

Consolidated Statements of Stockholders Equity (Deficiency) and Comprehensive (Loss) Income for the years ended June 30, 2011, 2010 and 2009

Consolidated Statements of Cash Flows for the years ended June 30, 2011, 2010 and 2009

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

(3) Exhibits. See Exhibit Index to Form 10-K 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 12, 2011

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 12, 2011
/s/ Laurence L. Betterley Laurence L. Betterley	Chief Financial Officer (principal financial and accounting officer)	September 12, 2011
/s/ Edward Brown Edward Brown	Director	September 12, 2011
/s/ Brent G. Blackey Brent G. Blackey	Director	September 12, 2011
/s/ John H. Friedman John H. Friedman	Director	September 12, 2011
/s/ Geoffrey O. Hartzler Geoffrey O. Hartzler	Director	September 12, 2011
/s/ Leslie Trigg Leslie Trigg	Director	September 12, 2011

/s/ Augustine Lawlor Augustine Lawlor		Director	September 12, 2011
/s/ Glen D. Nelson Glen D. Nelson		Director	September 12, 2011

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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
10.10	Form of Standard Employment Agreement.(3)
10.11 *	Summary of Fiscal Year 2012 Executive Officer Base Salaries.
10.12 *	Fiscal Year 2012 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.
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.
10.19 *	Form of Restricted Stock Unit Agreement under the Amended and Restated 2007 Equity Incentive Plan.
10.20	Form of Performance Share Award under the Amended and Restated 2007 Equity Incentive Plan.(7)

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Exhibit

No.		Description
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.
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)
14.1*		Code of Ethics.
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).

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Exhibit No.	Description
32.1*	Section 1350 Certification of principal executive officer.
32.2*	Section 1350 Certification of principal financial officer.

* Filed 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.

(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.

(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.