Cardiovascular Systems Inc
Form 10-K
September 28, 2010

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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, 2010

or

o **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 **St. Paul, Minnesota** *(Address of principal executive offices)*	**55112-3495** *(Zip Code)*

Registrant s telephone number, including area code:
(651) 259-1600

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, One-tenth of One Cent ($0.001) Par Value Per Share	NASDAQ Global Market

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 o 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 o 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 o

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 o No o

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. o

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. (Check one):

Large accelerated filer o Accelerated filer o Non-accelerated filer o Smaller reporting company þ
(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 o No þ

As of December 31, 2009, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was $49,227,511 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 September 23, 2010 was 15,694,291.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the registrant s 2010 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 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, pr potential and similar expressions 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 an CSI following the completion of the merger and the name change, and all references to Replidyne refer to Replidyne prior to the completion of the merger and the name change.

Replidyne was a biopharmaceutical company focused on discovering, developing, in-licensing and commercializing anti-infective products.

CSI-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 Diamondback Systems 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) 259-2800, and our website is www.csi360.com. The information contained in or connected to 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 of certain marks including Diamondback 360° , CSI , CSI logo, Lumen Library ViperWire , ViperWire Advance , ViperSlide , and ViperTrack. We have applied for federal registration of certain marks, including ViperCaddy , Predator 360° , and Stealth 360°. 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, was 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°) and the Diamondback Predator 360°™ PAD System (Predator 360°), are catheter-based platforms capable of treating a broad range of plaque types in leg arteries both above and below the knee and address many of the limitations associated with existing treatment alternatives. We refer to the Diamondback 360° and the Predator 360° collectively in this report as the Diamondback Systems. 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 commenced commercial launch of the Predator 360° in April 2009. As of June 30, 2010, the Diamondback Systems have been utilized in an estimated 29,000 procedures. We intend to leverage the capabilities of the Diamondback Systems to expand into the interventional coronary market.

In addition to the Diamondback Systems, we are expanding our product portfolio through internal product development and establishment of business relationships. We now offer multiple accessory products designed to complement the use of the Diamondback Systems, and we have entered into distribution agreements with Medtronic, Inc. and Asahi-Intecc, Ltd.

Market Overview

PAD is a circulatory problem in which plaque deposits build up on the walls of 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 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 (moderate) or calcified (hardened) plaque deposits that have not been successfully treated with existing non-invasive treatment techniques. PAD may involve arteries either above or below the knee. 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.

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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 over 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.

Our Solution

The Diamondback Systems represent a new 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 Diamondback 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 causing the crown to orbit against it, creating a smooth lumen, or channel, in the vessel. The Diamondback Systems are designed to differentiate between hard plaque and soft, compliant arterial tissue, a concept that we refer to as differential sanding.

Normal arteries are compliant; 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 Diamondback Systems sand plaque into small particles and restore both blood flow and vessel compliance. The particles created by the Diamondback 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 Diamondback 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 Diamondback Systems offer the following key benefits:

Strong Safety Profile

Differential Sanding Reduces Risk of Adverse Events. The Diamondback 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 Diamondback 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 Diamondback 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 Diamondback 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.

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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° 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 the Predator 360°.

Treats Difficult, Fibrotic and Calcified Lesions. The Diamondback 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 Diamondback 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 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 Diamondback 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 Diamondback 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 Diamondback 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 Diamondback Systems do not require a collection reservoir that needs to be repeatedly emptied or cleaned during the procedure. Rather, the Diamondback 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.

Cost and Time Efficient Procedure

Short Procedure Time. The Diamondback Systems have a short treatment time. Treatment with the Diamondback 360° typically ranges from three to six minutes, while treatment time with the Predator 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 Diamondback 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 Diamondback 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.

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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 Diamondback Systems through our direct sales force, which targets interventional cardiologists, vascular surgeons and interventional radiologists. As a key element of our strategy, we focus on educating and training physicians on the Diamondback 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 Diamondback 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 Diamondback Systems and drive physician acceptance. We have conducted four clinical trials to demonstrate the safety and efficacy of the Diamondback 360° in treating PAD, involving 935 patients, including PAD I and PAD II pilot trials, our pivotal OASIS trial and our CONFIRM DIAMONDBACK Registry. In addition, we have completed enrollment in two clinically rigorous, randomized post-market feasibility trials to further differentiate the performance of the Diamondback 360° from conventional balloon angioplasty. In both of these studies, the CALCIUM 360° and COMPLIANCE 360°, acute procedural success and device safety will be verified by an independent core lab, and the long-term durability of the procedure will be evaluated. Finally, we are currently enrolling up to 1,200 patients in the CONFIRM PREDATOR Registry. In this registry, we will collect acute clinical data to further demonstrate the ability of the Predator 360° to rapidly and effectively treat lesions above and below the knee.

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

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

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

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

Leverage Technology Platform into Coronary Market. Based on the excellent clinical performance of the Diamondback 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

investigational device exemption, or 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. Patient enrollment in ORBIT II is currently underway.

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Pursue Strategic Acquisitions and Partnerships. We have ongoing agreements with both Medtronic, Inc. and Asahi-Intecc, Ltd. In April 2009, we signed a sales agency agreement with Invatec, Inc. to distribute the Invatec balloon catheter line, including the SubMarine Plus™ PTA Balloon Catheter, the Admiral Xtreme™ PTA Balloon Catheter and the Amphirion Deep™ PTA Balloon Catheter. These balloons are typically used at low pressure, if needed, following the restoration of vessel compliance with the Diamondback Systems. Medtronic, Inc. recently acquired Invatec, Inc, and we continue to market these balloons under a new agreement with Medtronic, Inc. that expires on September 30, 2010 unless renewed. In August 2009, we signed an exclusive distribution agreement with Asahi-Intecc, Ltd. to market its peripheral guide wire 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 Diamondback Systems internationally.

Our Product

Components of the Diamondback Systems

The Diamondback Systems each use a single-use, low-profile catheter that travels over our proprietary ViperWire Advance™ Guide Wire. The system is used in conjunction with a reusable external control unit.

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 Diamondback Systems travel over this wire to the lesion and operate on this wire. The ViperWire is available in two levels of firmness.

Control Unit. 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.

Technology Overview

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

Plaque Modification through Differential Sanding. The Diamondback 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 Diamondback Systems. The diamond preferentially engages and sands harder material. The Diamondback 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 Diamondback 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 Diamondback Systems as they rotate. As the crown moves outward, the centrifugal force is offset by the counterforce exerted by the arterial

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wall. If the tissue is compliant, it flexes away, rather than generating an opposing force that would allow the Diamondback Systems to engage and sand the wall. Diseased tissue provides resistance and is able to generate an opposing force that allows the Diamondback 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. 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 Diamondback 360° crown is available in two configurations classic and solid. The classic crown addresses treatment needs in arteries typically below the knee and in more tortuous anatomy, while the solid crown addresses treatment needs in larger arteries typically above the knee. The Predator 360° crown is available in the solid configuration and is constructed to allow the crown to engage and treat the lesion more rapidly when shorter procedure times are desired. Both the Diamondback 360° and Predator 360° crowns are available in multiple sizes, including 1.25, 1.50, 1.75, 2.00 and 2.25 millimeter diameters. For both devices, the catheter length is 135 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. We are developing a new drive shaft that may enhance the ability to advance the device more smoothly and effectively through tortuous anatomy and challenging lesion morphologies and potentially enhance the devices performance.

We view the Diamondback 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 Diamondback Systems can be used to treat plaque in multiple anatomic locations.

Below-the-Knee Peripheral Artery Disease. Arteries below the knee have small diameters and may be diffusely diseased, calcified or both, limiting the effectiveness of traditional devices. The Diamondback Systems are effective in both diffuse 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. The Millennium Research Group estimates that there will be

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approximately 258,600 endovascular procedures to treat above-the-knee PAD in 2011 and that there will be approximately 71,220 endovascular procedures to treat below-the-knee PAD in 2011.

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, four pre-clinical animal studies, and our ORBIT I 50-patient human clinical study to evaluate the Diamondback 360° in coronary artery disease. In the bench studies, we evaluated the system for conformity to specifications and patient safety, and, under conditions of expected clinical use, no safety issues were observed. In three of the animal studies, the system was used to treat a large number of stented and non-stented arterial lesions. The system was able to safely debulk lesions without evidence or observations of significant distal embolization, and the treated vessels in the animal studies showed only minimal to no damage. The fourth animal study evaluated the safety of the system for the treatment of coronary stenosis. There were no device-related adverse events associated with system treatment during this study, with some evidence of injury observed in 17% of the tissue sections analyzed, although 75% of these injuries were minimal or mild. A coronary application would require us to conduct a clinical trial and receive PMA from the FDA. We participated in three pre-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. The pivotal trial will initially enroll up to 100 patients at as many as 50 U.S. sites, with the potential to enroll up to 429 patients.

Clinical Trials and Studies for Our Products

CSI is committed to providing relevant clinical evidence to allow physicians to select and utilize the best treatment options for their patients. We have conducted four clinical trials to demonstrate the safety and efficacy of the Diamondback 360° in treating PAD, enrolling a total of 935 patients in our PAD I and PAD II pilot trials, our pivotal OASIS trial, and our recently completed CONFIRM DIAMONDBACK Post-Market Registry. We have completed a retrospective study evaluating the long-term results of 64 patients from the OASIS Trial in order to determine durability of procedure results. In addition, we have also completed enrollment in two post-market, randomized feasibility studies to further differentiate the performance of the Diamondback 360° from conventional balloon angioplasty. Last, we are currently enrolling up to 1,200 patients in our CONFIRM PREDATOR Post-Market Registry.

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

Metric	Description
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 another peripheral intervention precipitated by their worsening symptoms, such as an angioplasty, stenting or surgery 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.

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

Metric	Description
Serious Adverse Events	Serious adverse events, or 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 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 Ankle Brachial Index.

PAD I Feasibility Trial

Our first trial was a two-site, 17-patient feasibility clinical trial in Europe, which we refer to as PAD I, that began in March 2005. Patients enrolled in the trial had lesions that were less than 10 cm in length in arteries between 1.5 mm and 6.0 mm in diameter, with Rutherford Class scores of IV or lower. Patients were 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 were presented at the Transcatheter Therapeutics conference, or TCT, in 2005 and published in American Journal of Cardiology. Results 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).

PAD II Feasibility Trial

After being granted the CE Mark in May 2005, we began a 66-patient European clinical trial at seven sites, which we refer to as PAD II, 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

We received an IDE to begin our pivotal United States trial, OASIS, in September 2005. 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.

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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. We believe physicians using other plaque removal devices require approximately ten to 20 minutes of treatment time to achieve desired results, although treatment times may vary depending upon the nature of the procedure, the condition of the patient and other factors. 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% mean, with an upper bound of 16%	4.8% mean, device-related; 9.7% mean, 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

We submitted our OASIS data and received 510(k) clearance from the FDA for use of the Diamondback 360°, including the initial version of the control unit, with a hollow crown as a therapy for patients with PAD in August 2007. The FDA s labeling requirements reflected the inclusion criteria for the OASIS trial listed above. We received 510(k) clearances in October 2007 for the updated control unit used with the Diamondback 360° and in November 2007 for the Diamondback 360° with a solid crown. In May 2005, we received the CE mark, allowing for the commercial use of the Diamondback 360° within the European Union; however, our current plans are to focus sales in the United States.

OASIS Long-Term Study

A retrospective study evaluating the long-term results of 64 patients from the pivotal OASIS trial has been completed. Outcomes were analyzed out to a mean of 29 months and include limb salvage rate, target lesion revascularization rate (TLR) and ankle-brachial index (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 we initiated in calendar 2009. This prospective, randomized, multi-center study evaluates the clinical benefits of modifying plaque to change large vessel compliance above the knee with the Diamondback 360º. The study compares the performance of the Diamondback 360º, 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 study is based on a six-month clinical endpoint; results will be reported subsequent to completion of six-month follow-up and data analysis.

In April 2010, enrollment was completed in the CALCIUM 360º study, a prospective, randomized, multi-center study, which compares the effectiveness of the Diamondback 360º to balloon dilation in treating heavily 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. Acute clinical results are being analyzed, and the first report of results

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occurred at the Transcatheter Cardiovascular Therapeutics Meeting in September 2010 in Washington, DC. This study will follow patients out to 12 months and results will be reported at six and 12 month intervals.

CONFIRM Post-Market Clinical Study Series

CSI is conducting the CONFIRM Post-Market Clinical Study Series, which will further evaluate acute, long-term, and economic parameters related to the use of the Diamondback Systems. The CONFIRM I Registry currently consists of two arms: CONFIRM DIAMONDBACK and CONFIRM PREDATOR.

Enrollment of 728 patients in the CONFIRM DIAMONDBACK Post-Market Registry was completed in March 2010. In this prospective registry, 1,138 lesions were treated by 84 investigators at 57 institutions 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 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. Final results were reported at the Transcatheter Cardiovascular Therapeutics Meeting in September 2010 in Washington, DC.

Enrollment of up to 1,200 patients in the prospective CONFIRM PREDATOR Post-Market Registry commenced in August 2010. CONFIRM PREDATOR will evaluate clinical performance of the Predator 360°. Consecutive patients will be enrolled at up to 200 sites in the United States. Data on acute clinical performance and short-term economic parameters will be collected during this study. We anticipate enrollment will be complete by about March 31, 2010.

Data from CONFIRM I will be used to design future studies in the CONFIRM series to further evaluate long-term durability and economic parameters associated with use of the Diamondback Systems.

Sales and Marketing

We market and sell the Diamondback Systems through a direct sales force in the United States. While we sell directly to hospitals, 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 Diamondback Systems;
- developing relationships with key opinion leaders; and
- facilitating regional referral marketing programs.

We are not marketing our products internationally and do not expect to do so in the near future; however, we will continue to evaluate international opportunities.

Research and Development

Our research and development efforts are focused in the development of products to penetrate our three key target markets: below-the-knee, above-the-knee and coronary vessels. Research and development expenses for fiscal 2010, fiscal 2009 and fiscal 2008 were $10.3 million, $14.7 million and $16.1 million, respectively.

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Manufacturing

We use internally-manufactured and externally-sourced components to manufacture the Diamondback Systems. Most of the externally-sourced components are available from multiple suppliers; however, a few key components, including the diamond grit coated crown, 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. The sterilization facility sends samples to an independent laboratory to test for sterility. Upon return from the sterilizer, product is held in inventory prior to shipping to our customers.

The current floor plan at our principal manufacturing facility in Minnesota allows for finished goods of approximately 8,000 devices and for approximately 50 control units. The manufacturing areas, including the shaft manufacturing and the controlled-environment assembly areas, are equipped to accommodate approximately 30,000 units per shift annually.

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 units per shift annually. This facility has finished goods storage capacity of greater than 15,000 units of the Diamondback Systems and other accessory products.

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 treated with the Diamondback 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 Diamondback 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.

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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 Diamondback 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, 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. 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. 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 and coronary market opportunities, competitors and potential competitors have historically dedicated significant resources to aggressively promote their products. We believe that the Diamondback Systems compete primarily on the basis of:

safety and efficacy;

predictable clinical performance;

ease of use;

price;

physician relationships;

customer service and support; and

adequate third-party reimbursement.

Patents and Intellectual Property

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, 2010, we held 26 issued U.S. patents and have 43 U.S. patent applications pending, as well as 59 issued or granted foreign patents and 51 foreign patent applications, each of which corresponds to aspects of our U.S. patents and applications. Our issued U.S. patents expire between 2010 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 Diamondback 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 nine registered U.S. trademarks, five registered marks in Europe, and have three U.S. and five Canadian 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

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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 Diamondback Systems.

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

United States

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

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

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.

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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.

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

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

- the systems may not be safe or effective to the FDA s satisfaction;
- the data from preclinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities used may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

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

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We are currently seeking PMA to use the Diamondback 360° as a therapy in treating patients with coronary artery disease and have submitted an IDE to the FDA. The FDA granted unconditional approval in April 2010 to begin the ORBIT II coronary study in the United States. The pivotal trial will initially enroll up to 100 patients at as many as 50 U.S. sites, with the potential to enroll up to 429 patients.

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

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

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

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

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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;
- 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.

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Fraud and Abuse

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

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

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

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

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

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 European Union, although actual implementation of the 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.

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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.

Employees

As of June 30, 2010, we had 287 employees, 246 of which are full-time employees, including 42 employees in manufacturing, 146 employees in sales, 11 employees in marketing, five employees in clinical, 21 employees in general and administrative, and 21 employees in research and development. 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 $23.9 million in fiscal 2010, $31.9 million in fiscal 2009, and $39.2 million in fiscal 2008. As of June 30, 2010, we had an accumulated deficit of approximately $151.3 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 Diamondback Systems and additional expenses as we seek to develop and commercialize future versions of the Diamondback Systems and other products. Additionally, we expect that our general and administrative expenses will increase as our business grows and we incur the legal and regulatory costs associated with being a public company. As a result, our operating losses could continue.

We may be unable to sustain our revenue growth.

Our revenue has grown in each of the two 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 Diamondback Systems and new and improved products we introduce, including growing our customer base and reorders of the Diamondback 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 and such losses have historically been within our expectations and the provisions established, 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.

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We have a limited history selling the Diamondback 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 Diamondback Systems are our primary products and we are largely dependent on them. We have limited experience in the commercial manufacture and marketing of these products. Our ability to generate revenue will depend upon our ability to further successfully commercialize the Diamondback Systems and to develop, manufacture and receive required regulatory clearances and approvals and patient reimbursement for treatment with future versions of the Diamondback Systems. As we continue to commercialize the Diamondback 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 Diamondback 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 Diamondback Systems or any future versions of these products that we develop, our business will be materially adversely affected.

The Diamondback Systems and future products may never achieve broad market acceptance.

The Diamondback 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 long-term clinical trials relating to use of our products;
- the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for conditions treated by our 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 Diamondback 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 Diamondback 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 Diamondback 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.

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Our future growth depends on physician adoption of the Diamondback 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 Diamondback Systems in particular, they may not refer patients to interventional cardiologists, vascular surgeons or interventional radiologists for the procedure using the Diamondback 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 Diamondback 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 Diamondback 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 Diamondback Systems to permit hospitals and doctors to consider the products cost-effective for patients requiring PAD treatment, or that current reimbursement levels for the Diamondback 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 Diamondback Systems. In order to position the Diamondback Systems for acceptance by third-party payors, we may have to agree to lower prices than we might otherwise charge.

Governmental and private sector payors have instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. It is uncertain whether the Diamondback 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 Diamondback Systems is limited or not available, the acceptance of the Diamondback Systems and, consequently, our business will be substantially harmed.

Healthcare reform legislation could adversely affect our revenue 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.

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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 pilots 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 revenues. 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, our 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 and our 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 Diamondback 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 Diamondback 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 only with limited patient populations. The long-term effects of using the Diamondback Systems in a large number of patients are not known and the results of short-term clinical use of the Diamondback 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 Diamondback 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 Diamondback 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 Diamondback Systems.

We face significant competition and may be unable to sell the Diamondback Systems at profitable levels.

We compete against very large and well-known stent and balloon angioplasty device manufacturers, including Abbott Laboratories, Boston Scientific, Cook, 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,

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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 Diamondback 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 Diamondback Systems could become obsolete and our revenue would decline as our customers purchase competitor products.

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

We have limited experience in commercially manufacturing the Diamondback 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 Diamondback 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 Diamondback 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.

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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 Diamondback 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 Diamondback 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. We depend on these suppliers to provide us and our customers with materials in a timely manner that meet ours 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;
- 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 ours 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.

Other than existing, unfulfilled purchase orders or obligations we have met, our suppliers have no contractual obligations to supply us with, and we are not contractually obligated to purchase from them, any of our supplies. 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

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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.

Manufacturing operations are often 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 has increased from six full-time employees on January 1, 2007 to 157 full-time employees on June 30, 2010, 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. Although we expect to achieve our first profitable quarter during fiscal year 2011, our plans for expansion may still require additional financing. In particular, 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.

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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 Diamondback 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 have not fully recovered since then. To date, our loan arrangements with Silicon Valley Bank and Partners for Growth remain available to us. 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 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 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.

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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 Diamondback 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 Diamondback Systems internationally, we currently do not intend to market the Diamondback 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 Diamondback 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. In that regard, ev3 Inc., ev3 Endovascular, Inc., and FoxHollow Technologies, Inc. have brought an action against us that, if successful, could limit our ability to retain the services of certain sales personnel that were formerly employed by those companies and make it more difficult to recruit and hire such sales and other personnel in the future. We do not carry key person life insurance on any of our employees.

We may be subject to damages or other remedies as a result of pending litigation.

On December 28, 2007, ev3 Inc., ev3 Endovascular, Inc. and FoxHollow Technologies, Inc. filed a complaint against us and certain of our employees alleging, among other things, misappropriation and use of their confidential information by us and certain of our employees who were formerly employees of FoxHollow. The complaint also alleges that certain of our employees violated their employment agreements with FoxHollow requiring them to refrain from soliciting FoxHollow employees. There can be no assurance as to the outcome of this litigation. We are defending this litigation vigorously. If we are not successful in defending it, we could be required to pay substantial damages and be subject to equitable relief that could include a requirement that we terminate the employment of certain employees, including certain key sales personnel who were formerly employed by FoxHollow. In any event, the defense of this litigation, regardless of the outcome, could result in substantial legal costs and diversion of our

management s time and efforts from the operation of our business. If the plaintiffs in this litigation are successful, it could have a material adverse effect on our business, operations and financial condition.

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Risks Related to Government Regulation

Our ability to market the Diamondback 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 Diamondback 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 Diamondback 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 will not actively promote or advertise the Diamondback Systems for off-label uses. In addition, we cannot make comparative claims regarding the use of the Diamondback 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 Diamondback 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 360º in treating calcified coronary artery lesions, and results successfully met both safety and efficacy endpoints. We recently submitted an investigational device exemption, or IDE, application to the FDA for ORBIT II, a pivotal trial in the United States to evaluate the safety and effectiveness of the Diamondback 360º in treating severely calcified coronary lesions, which application the FDA approved. 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 a multi-year study. 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 cause our stock price to decline and 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 Diamondback 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 Diamondback 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 one 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 Diamondback 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 manufacture, requires a new clearance or approval from the FDA. If the FDA disagrees with any determination by us that new

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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 Diamondback 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 Diamondback Systems may result in injuries that lead to product liability suits, which could be costly to our business. The Diamondback 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 Diamondback Systems for off-label applications. The off-label use of the Diamondback Systems may be more likely to result in complications that have serious consequences, including, in certain circumstances, in death.

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

If the Diamondback 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.

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.

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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, some of these physicians own our stock, which they purchased 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.

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 Securities and Exchange Commission and the Nasdaq Global Market, have imposed various requirements on public companies, including requiring 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 financial compliance costs and made some activities more time consuming and costly. We cannot ensure that our corporate compliance program is or will be in compliance with all potentially applicable regulations.

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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, at certain times, 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, when and if required, 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, 2010, we had a portfolio of 26 issued U.S. patents and 59 issued or granted non-U.S. patents covering aspects of our core technology, which expire between 2010 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 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 USPTO has adopted new rules of practice (the application of which has been enjoined as a result of litigation) that limit the number of claims that may be filed in a patent application and the number of continuation or

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continuation-in-part applications that may be filed. These new rules may result in patent applicants being unable to secure all of the rights that they would otherwise have been entitled to in the absence of the new rules and, therefore, may negatively affect our ability to obtain comprehensive patent coverage. 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.

To protect our proprietary rights, 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 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. 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.

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.

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

The medical technology industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. The likelihood that patent infringement or misappropriation claims may be brought against us increases as we achieve more visibility in the marketplace and introduce products to market. 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

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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 its 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

Until recently there has not been a public market for our common stock and our stock price is expected to be 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. Some of the factors that may cause the market price of our common stock to fluctuate include:

- our ability to develop, obtain regulatory clearances or approvals for and market new and enhanced products on a timely basis;
- changes in governmental regulations or in the status of our regulatory approvals, clearances or future applications;
- our announcements or our competitors announcements regarding new products, product enhancements, significant contracts, number of hospitals and physicians using our products, acquisitions or strategic investments;
- announcements of technological or medical innovations for the treatment of vascular disease;
- delays or other problems with the manufacturing of the Diamondback Systems;

volume and timing of orders for the Diamondback Systems and any future products, if and when commercialized;

changes in the availability of third-party reimbursement in the United States and other countries;

quarterly variations in our or our competitors results of operations;

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changes in earnings estimates or recommendations by securities analysts who cover our common stock;

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

changes in healthcare policy;

product liability claims or other litigation;

product recalls;

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;

disputes or other developments with respect to intellectual property rights;

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, 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 in the 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 do not 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 may look to reports of equity research analysts for additional information regarding our industry and operations. Therefore, any trading market for our common stock will 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 not to provide research coverage of our common stock, which may adversely affect the market price of our common stock. If equity research analysts do provide research coverage 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. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

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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:

authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

limiting the removal of directors by the stockholders;

prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of stockholders;

eliminating the ability of stockholders to call a special meeting of stockholders; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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 that began April 1, 2010. We have leased this facility through March 2020. This facility will primarily accommodate additional manufacturing activities.

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

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

We are 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 us and former employees of FoxHollow currently employed by us, which complaint was subsequently amended. In July 2010, ev3 Inc. was acquired and became an indirect wholly-owned subsidiary of Covidien plc.

The complaint, as amended, alleges the following:

That certain of our employees (i) violated provisions in their employment agreements with their former employer FoxHollow, barring them from misusing FoxHollow confidential information and from soliciting or encouraging employees of FoxHollow to join us, and (ii) breached a duty of loyalty owed to FoxHollow.

That we and certain of our employees misappropriated confidential information and trade secrets of one or more of the Plaintiffs.

That all defendants engaged in unfair competition and conspired to gain an unfair competitive and economic advantage for us to the detriment of the Plaintiffs.

That (i) we tortiously interfered with the contracts between FoxHollow and certain of our employees by allegedly procuring breaches of the non-solicitation encouragement provision in those agreements and that we aided and abetted FoxHollow employees breach their duty of loyalty, and (ii) one of our employees tortiously interfered with the contracts between certain of our employees and FoxHollow by allegedly procuring breaches of the confidential information provision in those agreements.

The Plaintiffs seek, among other forms of relief, an award of damages in an amount greater than $50,000, a variety of forms of injunctive relief, exemplary damages under the Minnesota Trade Secrets Act, and recovery of their attorney fees and litigation costs. Although we have requested the information, the Plaintiffs have not yet disclosed what specific amount of damages they claim.

We are defending this litigation vigorously, and believe that the outcome of this litigation will 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. If we are not successful in this litigation, we could be required to pay substantial damages and could be subject to equitable relief that could include a requirement that we terminate or otherwise alter the terms or conditions of employment of certain employees, including certain key sales personnel who were formerly employed by FoxHollow. In any event, the defense of this litigation, regardless of the outcome, could result in substantial legal costs and diversion of management s time and efforts from the operation of business.

Executive Officers of the Registrant.

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

Name	Age	Position

David L. Martin	46	President and Chief Executive Officer
Laurence L. Betterley	56	Chief Financial Officer
James E. Flaherty	56	Chief Administrative Officer and Secretary
Brian Doughty	47	Vice President of Commercial Operations
Scott Kraus	40	Vice President of Sales
Paul Koehn	47	Vice President of Manufacturing
Robert J. Thatcher	56	Executive Vice President
Paul Tyska	52	Vice President of Business Development

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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 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.

Brian Doughty, Vice President of Commercial Operations. Mr. Doughty joined us in December 2006 as Director of Marketing, was named Vice President of Marketing in August 2007 and became Vice President of Commercial Operations in April 2009. Prior to joining us, Mr. Doughty was Director of Marketing at EKOS Corporation from February 2005 to December 2006, National Sales Initiatives Manager of FoxHollow Technologies, Inc. from September 2004 to February 2005, National Sales Operations Director at Medtronic from August 2000 to September 2004, and Sales Team Leader for Johnson and Johnson from December 1998 to August 2000. Mr. Doughty has also held sales and sales management positions for Ameritech Information Systems.

Scott Kraus, Vice President of Sales. Mr. Kraus has been with us since September 2006, acting as a senior sales director, until becoming Vice President of Sales in April 2009. Previously, Mr. Kraus was at Boston Scientific Corporation where he served as Account Manager/Regional Sales Manager from April 2006 to September 2006. He held the same position with Guidant Corporation from December 2000 to April 2006, before Boston Scientific s acquisition of Guidant in April 2006. Earlier, he gained sales experience at C.R. Bard, Bristol-Myers Squibb and Surgical Specialties Corporation.

Paul Koehn, Vice President of Manufacturing. Mr. Koehn joined us in March 2007 as Director of Manufacturing and was promoted to Vice President of Manufacturing in October 2007. 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

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management positions at Medtronic, Inc., Schneider USA, Inc. (a former division of Pfizer Inc.), Boston Scientific Corporation and several startup companies.

Paul Tyska, Vice President of Business Development. Mr. Tyska joined us in August 2006 as Vice President of Business Development. Previously, Mr. Tyska was employed at FoxHollow Technologies, Inc. since July 2003 where he most recently served as National Sales Director from February 2006 to August 2006. Mr. Tyska has held various positions with Guidant Corporation, CardioThoracic Systems, Inc., W. L. Gore & Associates and ATI Medical Inc.

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, as adjusted to reflect a 1-for-10 reverse stock split that occurred on February 25, 2009:

	Common Stock	
	High	**Low**
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	5.53	4.37
Fiscal Year Ended June 30, 2009		
First quarter	$ 14.30	$ 11.60
Second quarter	12.70	2.80
Third quarter (through February 25, 2009)	10.30	6.60
Third quarter (from February 26, 2009 through March 31, 2009)	10.15	4.78
Fourth quarter	7.97	5.60

The number of record holders of our common stock on September 23, 2010 was approximately 518. No cash dividends have been previously paid on our common stock and none are anticipated during fiscal year 2011. 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

During the fiscal year ended June 30, 2010, we issued and sold 879 unregistered shares of our common stock pursuant to warrant exercises with exercise price of $8.83 per share. The shares were sold in private transactions exempt from registration pursuant to Section 4(2) of the Securities Act. No underwriters were involved in the transactions or received any commissions or other compensation. Proceeds of the sales were used to fund our working capital requirements.

As reported in our Form 8-K filed with the SEC on April 20, 2010, we issued a warrant to Partners for Growth III, L.P. (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. The Warrant was issued in a private transaction exempt from registration pursuant to Section 4(2) of the Securities Act. No underwriters were involved in the transactions or received any commissions or other compensation.

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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°) and the Diamondback Predator 360° (Predator 360°), are catheter-based platforms capable of treating a broad range of plaque types in leg arteries both above and below the knee and address many of the limitations associated with existing treatment alternatives. We also intend to pursue approval of our products for coronary use. We refer to the Diamondback 360° and the Predator 360° collectively in this report as the Diamondback 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 prior to 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-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.

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 Diamondback 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

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September 2007. We were granted 510(k) clearance of the Predator 360° in March 2009. We market the Diamondback 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 single-use catheter used in the Diamondback 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, 2010, we had an accumulated deficit of $151.3 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 through the private placement of equity securities and completion of the merger.

FINANCIAL OVERVIEW

Revenues. We derive substantially all of our revenues from the sale of Diamondback Systems and other ancillary products. The Diamondback Systems each use a disposable, single-use, low-profile catheter that travels over our proprietary ViperWire guidewire and an external control unit that powers the system. Our ancillary products include the ViperSlide™ Lubricant, ViperTrack™ Radiopaque Tape, and ViperCaddy™ Guide Wire Management. We also have ongoing agreements with both Medtronic, Inc. and Asahi-Intecc, Ltd. In April 2009, we signed a sales agency agreement with Invatec, Inc. to distribute the Invatec balloon catheter line. Medtronic, Inc. recently acquired Invatec, Inc, and we continue to market these balloons under a new agreement with Medtronic, Inc. that expires on September 30, 2010 unless renewed. In August 2009, we signed an exclusive distribution agreement with Asahi-Intecc, Ltd. to market its peripheral guide wire line in the United States.

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

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

Research and Development. 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 Income. Interest income is attributed to both interest earned on deposits in investments that consist of money market funds and auction rate securities and the initial fair value and changes in fair value of the auction rate securities put option discussed below.

Interest Expense. Interest expense results from outstanding debt balances, the issuance of convertible promissory notes, and debt discount amortization.

Decretion (Accretion) of Redeemable Convertible Preferred Stock Warrants. Decretion (accretion) 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 (accretion) was recorded as a decrease (increase) to redeemable convertible preferred stock warrants in the consolidated balance

sheet and a decrease (increase) 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 (accretion) as of the merger date.

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Gain (Impairment) on Investments. Gain (impairment) 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 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 Section 382 due to significant ownership changes (as defined in Section 382) resulting from our equity financings. At June 30, 2010, we had federal net operating loss carryforwards of $109.1 million. These net operating loss carryforwards are available to offset taxable income through 2030 and will begin to expire in 2011. We also had various state net operating loss carryforwards to offset future state taxable income. These net operating loss carryforwards typically will have the same expirations as our federal net operating loss carryforwards.

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, investments, stock-based compensation, preferred stock 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 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.

We also consider FASB guidance that addresses the timing and method of revenue recognition for revenue arrangements that include the delivery of more than one product or service. In these cases, we recognize revenue from each element of the arrangement as long as separate fair values for each element can be determined, we have completed our obligation to deliver or perform on that element, and collection of the resulting receivable is reasonably assured.

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.

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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.

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 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.

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 which 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 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

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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.

Preferred Stock. Prior to the merger, we recorded the current estimated fair value of our convertible preferred stock on a quarterly basis based on the fair market value of that stock as determined by our management and board of directors. The determination of fair market value included factors such as recent financing activity, preferred stock rights and preferences, clinical trials, revenues, and regulatory approval process. We recorded changes in the fair value of our redeemable convertible preferred stock in the consolidated statements of changes in stockholders equity (deficiency) and comprehensive (loss) income 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. In accordance with FASB guidance, the freestanding warrant that was related to our 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).

Legal Proceedings. In accordance with FASB guidance, we record a liability in our consolidated financial statements related to legal proceedings when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is possible, but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed in the notes to the consolidated financial statements. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded. Our significant legal proceedings are discussed in Note 12 to the consolidated financial statements. While it is not possible to predict the outcome for the matter discussed in Note 12 to the consolidated financial statements, we believe the defense of this litigation, regardless of the outcome, could result in substantial legal costs and diversion of management s time and efforts from the operation of business.

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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,		
	2010	2009	Percent Change	2009	2008	Percent Change
Revenues	$ 64,829	$ 56,461	14.8%	$ 56,461	$ 22,177	154.6%
Cost of goods sold	15,003	16,194	(7.4)	16,194	8,927	81.4
Gross profit	49,826	40,267	23.7	40,267	13,250	203.9
Expenses:						
Selling, general and administrative	62,447	59,822	4.4	59,822	35,326	69.3
Research and development	10,278	14,678	(30.0)	14,678	16,068	(8.7)
Total expenses	72,725	74,500	(2.4)	74,500	51,394	45.0
Loss from operations	(22,899)	(34,233)	(33.1)	(34,233)	(38,144)	(10.3)
Other income (expense):						
Interest expense	(1,435)	(2,350)	(38.9)	(2,350)	(7)	33,471.4
Interest income	402	3,380	(88.1)	3,380	1,167	189.6
Decretion (accretion) of redeemable convertible preferred stock warrants		2,991		2,991	(916)	426.5
Gain (impairment) on investments	150	(1,683)	(108.9)	(1,683)	(1,267)	32.8
Other	(122)					
Total other (expense) income	(1,005)	2,338	(143.0)	2,338	(1,023)	328.5
Net loss	(23,904)	(31,895)	(25.0)	(31,895)	(39,167)	(18.6)
Decretion (accretion) of redeemable convertible preferred stock		22,781		22,781	(19,422)	217.3
Net loss available to common stockholders	$ (23,904)	$ (9,114)	162.3%	$ (9,114)	$ (58,589)	(84.4)%

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 Diamondback 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. 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, increase the usage per physician, continue to focus on physician education programs, introduce new and improved products, and generate clinical data.

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 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

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the years ended June 30, 2010 and 2009 includes $548,000 and $475,000, respectively, for stock-based compensation. We expect that gross margin will stay fairly consistent in the future as sales volumes increase, 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. Our 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. 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 to further commercialize our products, but at a rate less than revenue growth.

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 Diamondback 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. 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 at or above amounts incurred for the year ended June 30, 2010, but lower as a percentage of revenue. Fluctuations could occur based on the number of projects and studies and the timing of expenditures.

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. 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 will be no gain (impairment) on investments related to these securities in future 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.

Comparison of Fiscal Year Ended June 30, 2009 with Fiscal Year Ended June 30, 2008

Revenues. Revenues increased by $34.3 million, or 154.6%, from $22.2 million for the year ended June 30, 2008 to $56.5 million for the year ended June 30, 2009. This increase was primarily attributable to increased sales of Diamondback Systems during the year ended June 30, 2009 compared to two quarters in the year ended June 30, 2008.

Cost of Goods Sold. Cost of goods sold increased by $7.3 million, or 81.4%, from $8.9 million for the year ended June 30, 2008 to $16.2 million for the year ended June 30, 2009. 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, 2008 to June 30, 2009 is primarily due to increased volume and manufacturing efficiencies. Cost of goods sold for the years ended June 30, 2009 and 2008 includes $475,000 and $232,000, respectively, for stock-based compensation.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses increased by $24.5 million, from $35.3 million for the year ended June 30, 2008 to $59.8 million for the year ended June 30, 2009. The primary reasons for the increase included the building of our sales and marketing organization, contributing $22.2 million; increased consulting and professional services, including $1.7 million in previously capitalized initial public offering costs, contributing $2.4 million; and payroll related expenses related to building our administrative organization, contributing $1.0 million. Selling, general, and administrative expenses for the years ended June 30, 2009 and 2008 includes $5.7 million and $6.9 million, respectively, for stock-based compensation.

Research and Development Expenses. Research and development expenses decreased by $1.4 million, or 8.7%, from $16.1 million for the year ended June 30, 2008 to $14.7 million for the year ended June 30, 2009. Research and development expenses relate to specific projects to improve our product or expand into new markets, such as the development of a new control unit, shaft designs, crown designs, and PAD and coronary clinical trials. The reduction in expense related to timing of coronary clinical trial costs, along with fewer PAD development projects in 2009. Research and development for the years ended June 30, 2009 and 2008 includes $612,000 and $297,000, respectively, for stock-based compensation.

Interest Expense. Interest expense increased by $2.3 million, from $7,000 for the year ended June 30, 2008 to $2.4 million for the year ended June 30, 2009. Interest expense for the year ended June 30, 2009 consisted of amortization of the debt discount of $1.2 million and interest on outstanding debt facilities of $1.1 million. Interest on debt facilities was primarily the result of entering into a loan and security agreement with Silicon Valley Bank in September 2008.

Interest Income. Interest income increased by $2.2 million, from $1.2 million for the year ended June 30, 2008 to $3.4 million for the year ended June 30, 2009. The increase was primarily due to the impact of recording the put option asset of $2.8 million related to our auction rate securities. This was offset by lower average cash and cash equivalent balances along with reduced yields. Average cash and cash equivalent balances were $16.5 million and $20.4 million for the years ended June 30, 2009 and 2008, respectively.

Decretion (Accretion) of Redeemable Convertible Preferred Stock Warrants. Decretion of redeemable convertible preferred stock warrants for the year ended June 30, 2009 was $3.0 million. Accretion of redeemable convertible preferred stock warrants for the year ended June 30, 2008 was $916,000. Decretion (accretion) of redeemable

convertible preferred stock warrants reflects the change in estimated fair value of preferred stock warrants at the balance sheet dates. Due to the merger, decretion recognized during the year ended June 30, 2009 reflects a change in the estimated fair value of preferred stock warrants between July 1, 2008, and February 25, 2009 (date of merger) at which time the preferred stock warrants converted to common stock warrants. Due to the conversion no further decretion (accretion) has been recorded for these warrants since the merger.

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Impairment on Investments. Impairment on investments was $1.7 million and $1.3 million for the years ended June 30, 2009 and 2008, respectively. Impairment on investments was due to a decrease in the fair value of auction rate securities in both periods.

Decretion (Accretion) of Redeemable Convertible Preferred Stock. Decretion of redeemable convertible preferred stock for the year ended June 30, 2009 was $22.8 million. Accretion of redeemable convertible preferred stock for the year ended June 30, 2008 was $19.4 million. Decretion (accretion) of redeemable convertible preferred stock reflects the change in estimated fair value of preferred stock at the balance sheet dates. Due to the merger, decretion recognized during the year ended June 30, 2009 reflects a change in the estimated fair value of preferred stock between July 1, 2008, and February 25, 2009 (date of merger) at which time the preferred stock converted to common stock. Due to the conversion no further decretion (accretion) has been recorded for these shares since the merger.

Net Loss Available to Common Stockholders. Net loss available to common stockholders for year ended June 30, 2009 was $9.1 million, or ($1.13) per basic and diluted share, compared to $58.6 million, or ($13.25) per basic and diluted share for the year ended June 30, 2008.

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,	
	2010	**2009**
Loss from operations	$ (22,899)	$ (34,233)
Add: Stock-based compensation	9,094	6,771
Add: Depreciation and amortization	599	468
Adjusted EBITDA	$ (13,206)	$ (26,994)

The improvement in Adjusted EBITDA of $13.8 million, or 51.1%, is primarily the result of 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 an increase in stock-based compensation and depreciation and amortization. Stock-based compensation increased $2.3 million, or 34.3%, from $6.8 million for the year ended June 30, 2009 to $9.1 million for the year ended June 30, 2010. Stock-based compensation increased as a result of increased stock grants from headcount growth and 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

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understand our operating performance and evaluate the methodology used by our management to evaluate and measure such performance. Adjusted EBITDA is also used to measure performance in our financial covenants as required by Silicon Valley Bank and Partners for Growth.

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

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

Depreciation and amortization expense. We exclude depreciation and amortization expense from our non-GAAP financial measures primarily because such expenses, while constituting ongoing and recurring 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 $23.7 million and $33.4 million at June 30, 2010 and 2009, respectively. During the year ended June 30, 2010, net cash used in operations amounted to $13.6 million. As of June 30, 2010, we had an accumulated deficit of $151.3 million. We have historically funded our operating losses primarily from the issuance of common and preferred stock, convertible promissory notes, and debt.

On February 25, 2009, we completed the merger, in accordance with the terms of the Merger Agreement. At closing, Replidyne s net assets, as calculated pursuant to the terms of the Merger Agreement, were approximately $36.6 million.

At June 30, 2009, we had trading investments with a fair value of $20.0 million that consisted solely of AAA rated auction rate securities issued primarily by state agencies and backed by student loans substantially guaranteed by the Federal Family Education Loan Program, or FFELP. At June 30, 2009, the par value of the auction rate securities totaled $23.0 million. These securities were not liquid, as we had an inability to sell the securities due to continued failed auctions. We had previously obtained a margin loan from UBS Bank USA, which was secured by

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the $23.0 million par value of our auction rate securities. The outstanding balance on this loan at June 30, 2009 was $22.9 million. 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. Proceeds from the redemptions and repurchase were used to pay off the margin loan in full at June 30, 2010.

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.

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 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, 2010.

Prior to the amendment and restatement, our loan and security agreement with Silicon Valley Bank included a $3.0 million term loan, a $10.0 million accounts receivable line of credit, and a $5.5 million term loan that reduced the availability of funds on the accounts receivable line of credit.

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, 2010. 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 five-year maturity until 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 on April 15, 2010. In addition, for a period of one year until April 14, 2011, we may request up to $2.5 million of additional proceeds from time to time, in minimum increments of $250,000. After this period, we may only request additional proceeds (in increments of not less than $250,000) equal to the aggregate principal amount converted into our common stock through an optional conversion or mandatory conversion. At any time prior to the maturity date, PFG may at its option convert any amount into our common stock at the conversion price set forth in each note, which conversion price will be

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subject to adjustment upon certain events as provided in such note. The initial agreement has a conversion price of $5.43, which equaled the ten-day volume weighted average price per share of our common stock prior to the date of the agreement. 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 also may reduce the conversion price to a price that represents a 15% discount to the ten-day volume weighted average price of our common stock to satisfy this condition and effect a mandatory conversion. The balance outstanding on the convertible loan at June 30, 2010 was $1.5 million.

The loans are secured by certain of our assets, and the agreement contains customary covenants limiting our ability to, among other things, incur debt or liens, make certain investments and loans, effect certain redemptions of and declare and pay certain dividends on 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 as of June 30, 2010. 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 vests with respect to 50% on the issue date, and thereafter, vests pro rata from time to time according to a percentage equal to (a) the additional loans actually drawn until April 14, 2011, divided by (b) $2.5 million. The warrant expires on the fifth anniversary of the issue date, subject to earlier expiration in accordance with the terms.

Cash and Cash Equivalents. Cash and cash equivalents was $23.7 million and $33.4 million at June 30, 2010 and 2009, respectively. This decrease is primarily attributable net cash used in operations during the year ended June 30, 2010.

Investments. Investments totaled $20.0 million at June 30, 2009, and consisted solely of AAA rated auction rate securities issued primarily by state agencies and backed by student loans substantially guaranteed by the Federal Family Education Loan Program, or FFELP. The auction rate securities were all redeemed or repurchased as of June 30, 2010.

Operating Activities. Net cash used in operating activities improved 54% to $13.6 million from $29.7 million for the years ended June 30, 2010 and 2009, respectively. For the years ended June 30, 2010 and 2009, we had a net loss of $23.9 million and $31.9 million, respectively. Changes in working capital accounts also contributed to the net cash used in the years ended June 30, 2010 and 2009. Significant changes in working capital during these periods included:

Cash (used in) accounts receivable of $(1.1) million and $(3.7) million during the years ended June 30, 2010 and 2009, respectively. The reduction in amount used between periods is due to lower revenue growth in fiscal year 2010.

Cash (used in) provided by inventories of $(1.0) million and $407,000 during the years ended June 30, 2010 and 2009, respectively. For the year ended June 30, 2010, cash (used in) inventories was primarily due to the timing of inventory purchases and sales. For the year ended June 30, 2009, cash provided by inventories was due to improved inventory management.

Cash provided by prepaid expenses and other current assets of $6,000 and $2.4 million during the years ended June 30, 2010 and 2009, respectively. For the year ended June 30, 2010, cash provided by prepaid expenses and other current assets was primarily due to payment timing of vendor deposits and other expenditures. For the year ended June 30, 2009, cash provided by prepaid expenses and other current assets was primarily due to payment timing of vendor deposits and assets acquired in the merger with Replidyne.

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Cash (used in) accounts payable of $(1.4) million and $(1.1) million during the years ended June 30, 2010 and 2009, respectively. For the year ended June 30, 2010 and 2009, cash (used in) accounts payable was primarily due to timing of purchases, vendor payments, and accounts payable acquired in the merger with Replidyne.

Cash provided by (used in) accrued expenses and other liabilities of $3.8 million and $(268,000) during the years ended June 30, 2010 and 2009, respectively. 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. For the year ended June 30, 2009, cash (used in) accrued expenses and other liabilities was primarily due to timing of payments and accruals acquired in the merger with Replidyne.

Investing Activities. Net cash provided by investing activities was $21.8 million and $36.0 million for the years ended June 30, 2010 and 2009, respectively. For the year ended June 30, 2009, cash acquired in the merger with Replidyne, net of transaction costs paid, was $37.0 million. For the years ended June 30, 2010 and 2009, we sold investments in the amount of $23.0 million and $50,000, respectively. The balance of cash provided by (used in) investing activities primarily related to the purchase of property and equipment and patents. Purchases of property and equipment and patents used cash of $1.2 million and $1.4 million for the years ended June 30, 2010 and 2009, respectively.

Financing Activities. Net cash (used in) provided by financing activities was $(17.9) million and $19.5 million in the years ended June 30, 2010 and 2009, respectively. Cash provided by financing activities during these periods included:

proceeds from long-term debt of $5.9 million and $19.8 million during the years ended June 30, 2010 and 2009, respectively;

employee stock purchase plan purchases of $1.2 million during the year ended June 30, 2010; and

exercise of stock options and warrants of $285,000 and $525,000 during the years ended June 30, 2010 and 2009, respectively.

Cash used in financing activities in these periods included:

payment of long-term debt of $25.3 million and $945,000 during the years ended June 30, 2010 and 2009, 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, 2010, 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.

Contractual Cash Obligations. Our contractual obligations and commercial commitments as of June 30, 2010 are summarized below:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**3-5 Years**	**More Than 5 Years**
			(In thousands)		
Operating leases(1)	$ 5,503	$ 913	$ 1,565	$ 840	$ 2,185
Purchase commitments(2)	6,546	6,546			
Debt maturities(3)	10,899	3,613	7,286		
Total	$ 22,948	$ 11,072	$ 8,851	$ 840	$ 2,185

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

(2) This amount reflects open purchase orders.

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

INFLATION

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

OFF-BALANCE SHEET ARRANGEMENTS

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

RECENT ACCOUNTING PRONOUNCEMENTS

In January 2010, the FASB issued further guidance regarding additional disclosures relating to fair value of transfers in and out of Levels 1 and 2 and for activity in Level 3 and clarifies certain other existing disclosure requirements. This guidance had no impact on our financial position, results of operations or cash flows.

In October 2009, the FASB issued guidance providing principles for allocation of consideration among multiple-elements, and accounting for separate deliverables under such an arrangement. The guidance introduces an estimated selling price method for valuing the elements of a bundled arrangement if vendor-specific objective evidence or third-party evidence of selling price is not available, and significantly expands related disclosure requirements. This standard is effective on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Alternatively, adoption may be on a retrospective basis, and early application is permitted. We do not expect the adoption of this standard will have a material impact on our consolidated financial position, results of operations or cash flows.

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 the use of the Diamondback Systems to treat coronary lesions and the potential market for this application; our clinical trials; our plan to continue to evaluate distribution agreements, licensing transactions and other strategic partnerships; the possibility that we may sell internationally in the future; our expectations that we will achieve our first profitable quarter during fiscal year 2011, our losses will continue but generally decline, our revenue will increase, gross margin will stay fairly consistent in the future, our selling, general and administrative expenses will increase, but at a rate less than revenue growth, and that we will incur research and development expenses at or above amounts incurred for the year ended June 30, 2010, but lower as a percentage of revenue; and the sufficiency of our current and anticipated financial resources. 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, proj

or the negative of these terms or other comparable 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

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developments in the U.S. and foreign countries; the experience of physicians regarding the effectiveness and reliability of the Diamondback Systems; the potential for unanticipated delays in enrolling medical centers and patients for clinical trials; dependence on market growth; the reluctance of physicians to accept new products; 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, 2010 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, changes in stockholders equity (deficiency) and comprehensive (loss) income and cash flows present fairly, in all material respects, the financial position of Cardiovascular Systems, Inc. (the Company) at June 30, 2010 and 2009, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2010, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes 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. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Minneapolis, Minnesota
September 28, 2010

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Cardiovascular Systems, Inc.

Consolidated Balance Sheets

	June 30, 2010	June 30, 2009
	(Dollars in thousands, except per share and share amounts)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 23,717	$ 33,411
Accounts receivable, net	9,394	8,474
Inventories	4,319	3,369
Prepaid expenses and other current assets	1,048	798
Total current assets	38,478	46,052
Auction rate securities put option		2,800
Investments, trading		20,000
Property and equipment, net	1,964	1,719
Patents, net	1,712	1,363
Other assets	180	436
Total assets	$ 42,334	$ 72,370
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities		
Current maturities of long-term debt	$ 3,613	$ 25,823
Accounts payable	3,353	4,751
Deferred grant incentive	1,181	
Accrued expenses	6,569	5,600
Total current liabilities	14,716	36,174
Long-term liabilities		
Long-term debt, net of current maturities	7,286	4,379
Deferred grant incentive	2,208	
Other liabilities	409	1,485
Total long-term liabilities	9,903	5,864
Total liabilities	24,619	42,038
Commitments and contingencies		
Common stock, $0.001 par value at June 30, 2010 and 2009; authorized 100,000,000 common shares at June 30, 2010 and 2009; issued and outstanding 15,148,549 at	15	14

June 30, 2010 and 14,113,904 at June 30, 2009, respectively		
Additional paid in capital	157,718	146,455
Common stock warrants	11,305	11,282
Accumulated deficit	(151,323)	(127,419)
Total stockholders equity	17,715	30,332
Total liabilities and stockholders equity	$ 42,334	$ 72,370

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,		
	2010	**2009**	**2008**
	(Dollars in thousands, except per share and share amounts)		
Revenues	$ 64,829	$ 56,461	$ 22,177
Cost of goods sold	15,003	16,194	8,927
Gross profit	49,826	40,267	13,250
Expenses			
Selling, general and administrative	62,447	59,822	35,326
Research and development	10,278	14,678	16,068
Total expenses	72,725	74,500	51,394
Loss from operations	(22,899)	(34,233)	(38,144)
Other income (expense)			
Interest expense	(1,435)	(2,350)	(7)
Interest income	402	3,380	1,167
Decretion (accretion) of redeemable convertible preferred stock warrants		2,991	(916)
Gain (impairment) on investments	150	(1,683)	(1,267)
Other	(122)		
Total other (expense) income	(1,005)	2,338	(1,023)
Net loss	(23,904)	(31,895)	(39,167)
Decretion (accretion) of redeemable convertible preferred stock		22,781	(19,422)
Net loss available to common stockholders	$ (23,904)	$ (9,114)	$ (58,589)
Loss per common share			
Basic and diluted	$ (1.62)	$ (1.13)	$ (13.25)
Weighted average common shares used in computation			
Basic and diluted	14,748,293	8,068,689	4,422,326

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) Income

	Common Stock		Additional Paid in		Accumulated	Accumulated Other Comprehensive (Loss)		Comprehensive (Loss)
	Shares	Amount	Capital	Warrants	Deficit	Income	Total	Income
	(Dollars in thousands, except per share and share amounts)							
Balances at June 30, 2007	4,054,957	$ 26,054	$	$ 1,366	$ (59,716)	$ (7)	$ (32,303)	$ (15,603)
Issuance/forfeiture of restricted stock awards, net	525,473	1,152					1,152	
Stock-based compensation related to stock options		6,229					6,229	
Exercise of stock options and warrants at $1.55 - $12.37 per share	320,554	2,382		(570)			1,812	
Expiration of warrants		116		(116)				
Accretion of redeemable convertible preferred stock					(19,422)		(19,422)	
Unrealized gain on investments						7	7	$ 7
Net loss					(39,167)		(39,167)	(39,167)
Balances at June 30, 2008	4,900,984	$ 35,933	$	$ 680	$ (118,305)	$	$ (81,692)	$ (39,160)
Issuance/forfeiture of restricted stock awards, net	425,359	2,464	2,003				4,467	
Stock-based compensation related to stock options		756	1,548				2,304	
	100,333	640	307	(422)			525	

Exercise of stock options and warrants at $1.55-$8.83 per share								
Issuance of common stock warrants			(8,217)	10,031			1,814	
Conversion of preferred warrants to common warrants				1,069			1,069	
Expiration of warrants		76		(76)				
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					(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)
Issuance/forfeiture of restricted stock awards, net	686,509		5,015				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 of common stock warrants				97			97	
Expiration of warrants			71	(71)				
Employee Stock Purchase Plan Activity	309,944		1,635				1,635	

To adjust common stock to par value		1	(1)					
Net 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)

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,		
	2010	2009	2008
	(Dollars in thousands, except per share and share amounts)		
Cash flows from operating activities			
Net loss	$ (23,904)	$ (31,895)	$ (39,167)
Adjustments to reconcile net loss to net cash used in operations			
Depreciation and amortization of property and equipment	549	417	264
Provision for doubtful accounts	137	95	164
Amortization of patents	51	53	29
(Decretion) accretion of redeemable convertible preferred stock warrants		(2,991)	916
Amortization of debt discount	257	1,228	
Stock-based compensation	9,094	6,771	7,381
Amortization of discount on investments			(52)
(Gain) impairment on investments	(150)	1,683	1,267
Gain on auction rate securities put option		(2,800)	
Changes in assets and liabilities, net of merger			
Accounts receivable	(1,057)	(3,672)	(5,061)
Inventories	(950)	407	(2,726)
Prepaid expenses and other assets	6	2,362	(1,323)
Accounts payable	(1,398)	(1,100)	3,631
Accrued expenses and other liabilities	3,799	(268)	2,809
Net cash used in operations	(13,566)	(29,710)	(31,868)
Cash flows from investing activities			
Expenditures for property and equipment	(794)	(957)	(720)
Purchases of investments			(31,314)
Sales of investments	22,950	50	19,988
Costs incurred in connection with patents	(400)	(436)	(397)
Cash acquired in Replidyne merger, net of transaction costs paid		37,369	
Net cash provided by (used in) investing activities	21,756	36,026	(12,443)
Cash flows from financing activities			
Proceeds from sale of redeemable convertible preferred stock			30,296
Payment of offering costs			(51)
Issuance of common stock under employee stock purchase plan	1,197		
Issuance of convertible preferred stock warrants		75	
Exercise of stock options and warrants	285	525	1,865
Proceeds from long-term debt	5,911	19,845	16,398

Payments on long-term debt	(25,277)	(945)	(4,510)
Net cash (used in) provided by financing activities	(17,884)	19,500	43,998
Net change in cash and cash equivalents	(9,694)	25,816	(313)
Cash and cash equivalents			
Beginning of period	33,411	7,595	7,908
End of period	$ 23,717	$ 33,411	$ 7,595
Noncash investing and financing activities			
Decretion (accretion) of redeemable convertible preferred stock	$	$ (22,781)	$ 19,422
Conversion of Series A warrants to common warrants		1,069	
Issuance of common stock warrants	97	1,814	
Beneficial conversion feature on convertible debt	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 warrants	71	76	
Adjustment of common stock to par value	1	39,864	
Amendment of restricted stock units	517		
Capitalized financing costs included in accounts payable and accrued expenses			358
Net unrealized gain (loss) on investments			7
Supplemental cash flow information			
Interest paid	$ 1,161	$ 1,051	$ 7

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.

Unless the context otherwise requires, all references herein to the Company, CSI, we, us and our refer to CSI-M prior to 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. CSI is considered the accounting acquirer in the merger and financial results presented for all periods reflect historical CSI results.

The Company develops, manufactures and markets devices for the treatment of vascular diseases. The Company s primary products, the Diamondback 360° PAD System and the Diamondback Predator 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) income, and cash flows include the accounts of the Company and its wholly-owned inactive Netherlands subsidiary, SCS B.V., after elimination of all significant 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.

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

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

expenses. The following table shows allowance for doubtful accounts activity for the fiscal years ended June 30, 2010 and 2009:

	Amount
Balance at June 30, 2008	$ 164
Provision for doubtful accounts	95
Write-offs	(6)
Balance at June 30, 2009	$ 253
Provision for doubtful accounts	279
Write-offs	(129)
Balance at June 30, 2010	$ 403

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.

Investments

At June 30, 2009, we had investments with a fair value of $20,000 that consisted solely of AAA rated auction rate securities (ARS) issued primarily by state agencies and backed by student loans substantially guaranteed by the Federal Family Education Loan Program, or FFELP. These securities were not liquid, as we had an inability to sell the securities due to continued failed auctions.

At June 30, 2009, the Company had accepted an offer from UBS AG (UBS), providing rights related to the Company s ARS (the Rights). The Rights permitted the Company to require UBS to purchase the Company s ARS at par value at any time during the period of June 30, 2010 through July 2, 2012. At June 30, 2009, the Company had recorded $2,800 as the fair value of the auction rate securities put option asset. The Company considered the expected time until the Rights are exercised, carrying costs of the Rights, and the expected credit risk attributes of the Rights and UBS in their valuation of the put option asset. The put option did not meet the definition of a derivative instrument. Therefore, the Company elected to measure the put option at fair value for recognized financial assets, in order to match the changes in the fair value of the ARS.

The Company had previously obtained a margin loan from UBS Bank USA for the full par value of the ARS. On June 30, 2010, the auction rate securities had been redeemed at par value by issuers or repurchased by UBS at par value pursuant to the Rights. Proceeds were used to pay off the margin loan as required by the Rights agreement. See Note 4 for additional information.

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.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Patents

The capitalized costs incurred to obtain patents are amortized using the straight-line method over their remaining estimated lives, not exceeding 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.

Operating Lease

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.

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 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.

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 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.

FASB guidance around arrangements with multiple deliverables addresses the timing and method of revenue recognition for revenue arrangements that include the delivery of more than one product or service. In these cases, the Company recognizes revenue from each element of the arrangement as long as separate values for each element can be determined, the Company has completed its obligation to deliver or perform on that element, and collection of the resulting receivable is reasonably assured.

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.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2009 and 2008 were as follows:

	Amount
Balance at June 30, 2008	$ 12
Provision	559
Claims	(506)
Balance at June 30, 2009	$ 65
Provision	257
Claims	(206)
Balance at June 30, 2010	$ 116

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.

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 two financial institutions. 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

Effective July 1, 2008, the Company adopted fair value guidance issued by the FASB, which provides a framework for measuring fair value under Generally Accepted Accounting Principles and expands disclosures about fair value measurements. In February 2008, the FASB provided a one-year deferral on the effective date of the guidance for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

financial statements at least annually. This guidance did not have a material impact on the Company s financial position or consolidated results of operations for the year ended June 30, 2010.

The fair value guidance classifies inputs into the following hierarchy:

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

The following table sets forth the fair value of the Company s auction rate securities that were measured on a recurring basis as of June 30, 2010. Assets are measured on a recurring basis if they are remeasured at least annually:

		Level 3		
	Available-for-Sale Securities	Trading Securities	Auction Rate Securities Put Option	Conversion Option
Balance at June 30, 2008	$	$ 20,000	$ 2,800	$
Transfer to trading securities	(21,733)	21,733		
Gain on auction rate securities put option			2,800	
Sales of investments		(50)		
Impairment on investments		(1,683)		
Balance at June 30, 2009	$	$ 20,000	$ 2,800	$
Sales of investments		(20,150)	(2,800)	
Gain on investments		150		
Issuance of conversion option				224
Balance at June 30, 2010	$	$	$	$ 224

The conversion option is related to the loan and security agreement with Partners for Growth (see Note 4). The 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.

As of June 30, 2010, 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

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

expensed in the consolidated statements of operations 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 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) income 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

In accordance with FASB guidance, 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).

Recent Accounting Pronouncements

In January 2010, the FASB issued further guidance regarding additional disclosures relating to fair value of transfers in and out of Levels 1 and 2 and for activity in Level 3 and clarifies certain other existing disclosure requirements. This guidance had no impact on the Company s consolidated financial position, results of operations or cash flows.

In October 2009, the FASB issued guidance providing principles for allocation of consideration among multiple-elements, and accounting for separate deliverables under such an arrangement. The guidance introduces an estimated selling price method for valuing the elements of a bundled arrangement if vendor-specific objective evidence or third-party evidence of selling price is not available, and significantly expands related disclosure requirements. This standard is effective on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Alternatively, adoption may be on a retrospective basis, and early application is permitted. The Company does not expect the adoption of this standard will have a material impact on its consolidated financial position, results of operations or cash flows.

2. Merger with Replidyne

On February 25, 2009, the Company completed its reverse merger with Replidyne, Inc. Immediately prior to the merger each share of CSI-MN s Series A, A-1, and B convertible preferred stock automatically converted into approximately one share of CSI-MN s common stock.

At closing, Replidyne s net assets, as calculated pursuant to the terms of the Merger Agreement, were $36,607. Based on the amount of net assets, each outstanding share of CSI-MN s common stock, including each share issuable upon conversion of CSI-MN Series A, Series A-1 and Series B convertible preferred stock as described above, was converted at the effective time of the merger into the right to receive 0.647 shares of Company common stock, taking into account a 1-for-10 reverse stock split approved by Replidyne s stockholders and board of directors on February 24, 2009. All share and per share amounts reflect the effect of the conversion factor for all periods presented. Immediately following the effective time of the merger, former CSI-MN stockholders owned

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

approximately 80.2% of the outstanding common stock of the Company, and Replidyne stockholders owned approximately 19.8% of the outstanding common stock of the Company. Options exercisable for a total of 5,681,974 shares of CSI-MN common stock (equivalent to a total of 3,676,208 shares of Company common stock) and warrants exercisable for a total of 4,836,051 shares of CSI-MN common stock (equivalent to a total of 3,128,740 shares of Company common stock) were assumed by the Company in connection with the merger.

Immediately prior to the merger, warrants to purchase shares of CSI-MN Series A and Series B convertible preferred stock were converted into warrants to purchase shares of CSI-MN common stock at the same ratios as the preferred stock converted into common stock. Each option and warrant to purchase CSI-MN common stock outstanding at the effective time of the merger was assumed by the Company at the effective time of the merger. Each such option or warrant became an option or warrant, as applicable, to acquire that number of shares of Company common stock equal to the product obtained by multiplying the number of shares of CSI-MN common stock subject to such option or warrant by 0.647, rounded down to the nearest whole share of Company common stock. Following the merger, each such option or warrant has a purchase price per share of Company common stock equal to the quotient obtained by dividing the per share purchase price of CSI-MN common stock subject to such option or warrant by 0.647, rounded up to the nearest whole cent.

The Company s common stock was accepted for listing on the Nasdaq Global Market under the symbol CSII and trading commenced on February 26, 2009.

The Company believes that Replidyne did not meet the definition of a business in accordance with FASB guidance, because as of the date of merger Replidyne had reduced its employee headcount to three employees that were not engaged in development or commercialization efforts and did not transition to the combined company, and had discontinued and engaged in a process to sell or otherwise dispose of its research and development programs. As such, at the time the transaction was consummated, Replidyne s sole business activity was liquidation through the merger. According to FASB guidance, the total estimated purchase price was allocated to the assets acquired and liabilities assumed in connection with the transaction, based on their estimated fair values. As a result, the cost of the merger has been measured at the estimated fair value of the net assets acquired, and no goodwill has been recognized. While the accounting treatment of the transaction is an acquisition of assets and assumption of certain liabilities by the Company, the manner in which such transaction was consummated is a merger whereby former CSI-MN stockholders control the combined entity. Accordingly, consistent with guidance relating to such transactions, CSI-MN (the legal acquiree, but the accounting acquirer) is considered to be the continuing reporting entity that acquires the registrant, Replidyne (the legal acquirer, but the accounting acquiree), and therefore the transaction is considered to be a reverse merger. The merger qualified as a tax-free reorganization under provisions of Section 368(a) of the Internal Revenue Code. CSI-MN directors constitute a majority of the combined company s board of directors and CSI-MN executive officers constitute all members of executive management of the combined company.

The financial statements of the combined entity reflect the historical results of CSI-MN before the merger and do not include the historical financial results of Replidyne before the completion of the merger. The combined entity has changed its year-end to June 30 to correspond to the historical results of CSI-MN. Stockholders equity and earnings per share of the combined entity and, except as noted, all other share references have been retroactively restated to reflect the number of shares of common stock received by CSI-MN security holders in the merger, after giving effect to the difference between the par values of the capital stock of CSI-MN and Replidyne, with the offset to additional paid-in capital.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A summary of the estimated fair value of the net assets acquired and merger costs incurred in the merger are as follows:

Description	Amount
Cash and cash equivalents	$ 38,479
Prepaid expenses and other current assets	1,135
Property and equipment	138
Other assets	525
Liabilities	(3,670)
Net assets acquired	$ 36,607

The Company incurred merger related costs of $1,110 that were recorded in additional paid in capital as part of the transaction.

The Company has recorded a current and long-term asset totaling $370 and $651 at June 30, 2010 and 2009, respectively, related to a deposit for a portion of the vacated Replidyne office and production facility that has been subleased to two tenants. The tenants have prepaid the entire sublease amount and this prepayment has been netted against the lease liability that is included in accrued expenses and lease obligation and other liabilities on the balance sheet. The deposit is being held at an escrow agent and returned in monthly payments until lease expiration in September 2011. The Company has recorded the unreturned portion of the deposit at June 30, 2010 and 2009, resulting in $75 and $281, respectively, in prepaid expenses and other current assets and $295 and $370, respectively, in other assets on the balance sheet.

The Company has recorded a current and long-term liability totaling $1,391 and $2,389 at June 30, 2010 and 2009, respectively, related to Replidyne s lease on the vacated office and production facility. The lease currently requires monthly base rent payments of $53 plus common area maintenance and operating expenses. Monthly base rent escalates over the remaining lease term to a maximum of $59 at lease expiration in September 2011. The Company has recorded the estimated net present value of the base rent, common area maintenance and operating expenses offset by estimated rental income at June 30, 2010 and 2009, resulting in $1,099 and $998, respectively, in accrued expenses and $292 and $1,391, respectively, in other liabilities on the balance sheet.

3. Selected Consolidated Financial Statement Information

	June 30, 2010	June 30, 2009
Accounts Receivable		
Accounts receivable	$ 9,797	$ 8,727
Less: Allowance for doubtful accounts	(403)	(253)

	$ 9,394	$ 8,474
Inventories		
Raw materials	$ 1,256	$ 1,536
Work in process	282	348
Finished goods	2,781	1,485
	$ 4,319	$ 3,369

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	June 30, 2010	June 30, 2009
Property and equipment		
Equipment	$ 3,085	$ 2,313
Furniture	168	168
Leasehold improvements	131	109
	3,384	2,590
Less: Accumulated depreciation and amortization	(1,420)	(871)
	$ 1,964	$ 1,719
Patents		
Patents	$ 2,114	$ 1,715
Less: Accumulated amortization	(402)	(352)
	$ 1,712	$ 1,363

As of June 30, 2010, future estimated amortization of patents and patent licenses will be:

2011	$ 54
2012	53
2013	53
2014	53
2015	53
Thereafter	1,446
	$ 1,712

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, 2010	June 30, 2009
Accrued expenses		
Salaries and bonus	$ 1,620	$ 1,453
Commissions	1,753	1,441
Accrued vacation	1,624	1,198

Merger related lease obligation	1,099	1,079
Other	473	429
	$ 6,569	$ 5,600

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. 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 warrants provide an option to purchase 8,493 shares of common stock at an exercise price of $5.48 per share. This warrant is immediately exercisable and expires ten years after the date of amendment. The balance outstanding on the term loan at June 30, 2010 was $10,000.

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 not an outstanding balance on the line of credit at June 30, 2010.

Prior to the amendment and restatement, the Company s loan and security agreement with Silicon Valley Bank included a $3,000 term loan, a $10,000 accounts receivable line of credit, and a $5,500 term loan that reduced the availability of funds on the accounts receivable line of credit.

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, 2010. 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.

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 five-year maturity until 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.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Under the agreement, PFG provided the Company with an initial loan of $1,500 on April 15, 2010. In addition, for a period of one year until April 14, 2011, the Company may request up to $2,500 of additional proceeds from time to time, in minimum increments of $250. After this period, the Company may only request additional proceeds (in increments of not less than $250) equal to the aggregate principal amount converted into the Company s common stock through an optional conversion or mandatory conversion. At any time prior to the maturity date, PFG may at its option convert any amount into the Company s common stock at the conversion price set forth in each note, which conversion price will be subject to adjustment upon certain events as provided in such note. The initial note has a conversion price of $5.43, which equaled the ten-day volume weighted average price per share of the Company s common stock prior to the date of the agreement. 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 our common stock to satisfy this condition and effect a mandatory conversion. The balance outstanding on the convertible loan at June 30, 2010 was $1,500.

The loans are secured by certain of the Company s assets, and the agreement contains customary covenants limiting the Company s ability to, among other things, incur debt or liens, make certain investments and loans, effect certain redemptions of and declare and pay certain dividends on its stock, permit or suffer certain change of control transactions, dispose of collateral, or change the nature of its business. In addition, the PFG loan and security agreement contains financial covenants requiring the Company to maintain certain liquidity and fixed charge coverage ratios, and certain three-month EBITDA targets. The Company was in compliance with all financial covenants at June 30, 2010. 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 vests with respect to 50% on the issue date, and thereafter, vests pro rata from time to time according to a percentage equal to (a) the additional loans actually drawn until April 14, 2011, divided by (b) $2,500. The warrant expires on the fifth anniversary of the issue date, subject to earlier expiration in accordance with the terms.

Loan Payable

At June 30, 2009, the Company maintained a margin loan with UBS Bank USA with maximum available borrowings, including interest, equal to the $22,950 par value of auction rate securities held. The margin loan bore interest at variable rates that equaled the lesser of (i) 30 day LIBOR plus 1.25% or (ii) the applicable reset rate, maximum auction rate or similar rate as specified in the prospectus or other documentation governing the pledged taxable student loan auction rate securities; however, interest expense charged on the loan did not exceed interest income earned on the auction rate securities. The loan was due on demand and UBS Bank would have required the Company to repay it in full from the proceeds received from a public equity offering where net proceeds exceed $50,000. The outstanding balance on this loan at June 30, 2009 was $22,893.

On June 30, 2010, all of the Company s auction rate securities were redeemed at par value by the issuers or repurchased by UBS at par value pursuant to the Rights agreement reached with UBS in November 2008. Proceeds were used to pay off the margin loan as required by the Rights agreement.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of June 30, 2010, debt maturities (including debt discount) were as follows:

2011	$ 3,613
2012	3,812
2013	3,474
Total	$ 10,899
Less: Current Maturities	(3,613)
Long-term debt	$ 7,286

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. (PFG). 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 are immediately exercisable, and the remaining half may become exercisable as additional funds are drawn during the first 12 months of the agreement. The exercisable warrants were assigned a value of $97 for accounting purposes, and expire five years after issuance. See Note 4 for additional information.

During the year ended June 30, 2009, immediately prior to consummation of the merger, the Company issued warrants to preferred stockholders to purchase an aggregate of 2,264,264 shares of Company common stock at an exercise price at $8.83 per share. The warrants were assigned a value of $8,217 for accounting purposes and were recorded as additional paid in capital as part of the merger. The warrants are immediately exercisable and expire five years after issuance.

During the year ended June 30, 2009, the Company issued the former guarantors of the Silicon Valley Bank guaranteed term loans warrants to purchase an aggregate of 296,539 shares of the Company s common stock at an exercise price of $9.28 per share. The warrants were assigned a value of $1,810 for accounting purposes, are immediately exercisable, and expire five years after issuance.

In connection with the merger, 439,317 fully exercisable preferred stock warrants were converted into common stock warrants. The exercise prices on these warrants range from $8.83 - $14.16 and expire at various dates through September 2018.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following summarizes common stock warrant activity:

	Warrants Outstanding	Price Range per Share
Warrants outstanding at June 30, 2007	256,740	$ 1.55 - 12.37
Warrants exercised	(76,312)	$ 1.55 - 12.37
Warrants expired	(22,387)	$ 7.73
Warrants outstanding at June 30, 2008	158,041	$ 1.55 - 12.37
Warrants issued	2,560,803	$ 8.83 - 9.28
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	3,116,125	$ 1.55 - 14.16
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	3,236,696	$ 5.43 - 9.28

The following assumptions were utilized in determining the fair value of warrants issued 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 issuance under the 1991 Plan, but with the execution 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. 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 July 1, 2017, by the lesser of (i) 970,500 shares, (ii) 5% of the outstanding common

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

shares on such date, or (iii) a lesser amount determined by the board of directors. On July 1, 2010, the number of shares available for grant was increased by 757,427 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 expired 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.

In estimating the value of the Company s common stock prior to the merger for purposes of granting options and determining stock-based compensation expense, the Company s 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 the Company s preferred stock, growth of the executive management team, clinical trial activity, the FDA process, the status of the Company s commercial launch, the Company s mergers and acquisitions and public offering processes, revenues, the valuations of comparable public companies, the Company s cash and working capital amounts, and additional objective and subjective factors relating to the Company s business. The Company s 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, the Company recognized stock-based compensation expense for the excess of the fair market value of the common stock over the exercise price.

Following the merger, the Company s stock valuations are based upon the market price for the common stock.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock option activity is as follows:

	Number of Options(a)	Weighted Average Exercise Price
Options outstanding at June 30, 2007	2,773,566	$ 7.67
Options granted	1,871,089	$ 11.14
Options exercised	(244,242)	$ 5.07
Options forfeited or expired	(597,289)	$ 3.56
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

(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.

Options outstanding and exercisable at June 30, 2010 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	9.43	12,940	9.43
$7.90	502,219	6.93	413,806	6.88
$8.75	92,844	8.68	46,423	8.68
$8.83	1,108,950	5.97	1,108,950	5.97

$9.28	45,611	4.41	45,611	4.41
$11.38	85,143	7.38	85,143	7.38
$12.15	1,120,107	5.67	901,744	5.34
$12.37	176,307	4.89	176,307	4.89
$13.98	111,421	7.63	111,421	7.63
$14.00	4,000	2.51	4,000	2.51
$16.40	6,000	2.51	6,000	2.51
$18.55	31,451	5.76	31,451	5.76
$18.60	60,000	1.66	60,000	1 66
	3,356,993	6.02	3,003,796	5.88

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Options issued to employees and directors that are vested or expected to vest at June 30, 2010, were as follows:

	Number of Shares	Remaining Weighted Average Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
Options vested or expected to vest	3,041,436	6.02	$ 10.49	$

Estimated pre-vesting forfeitures are considered in determining stock-based compensation expense. As of June 30, 2010, the Company estimated its forfeiture rate at 9.4%. As of June 30, 2010, 2009, and 2008 the total compensation cost for non-vested awards not yet recognized in the consolidated statements of operations was $2,266, $5,820, and $6,316, respectively, net of the effect of estimated forfeitures. These amounts are expected to be recognized over a weighted-average period of 0.61, 1.50 and 2.17 years, respectively.

Options typically vest over three years. 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	2008
Weighted average fair value of options granted	$1.23	$4.66	$5.78
Risk-free interest rates	1.32 - 2.07%	2.82%	2.45% - 4.63%
Expected life	2.5 - 5 years	6 years	3.5 - 6 years
Expected volatility	46.7 - 55.9%	55.5%	43.1% - 46.4%
Expected dividends	None	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 stock of companies within the Company s peer group and historical volatility of the Company s stock.

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 outstanding options at June 30, 2010, 2009 and 2008 was $0, $0, and $21,441, respectively. The aggregate intrinsic value for exercisable options at June 30, 2010, 2009 and 2008 was $0, $0, and $9,692, respectively. The total aggregate intrinsic value of options exercised during the years ended June 30, 2010, 2009 and 2008 was $30, $387, and $1,435, respectively. Shares supporting option exercises are sourced from new share issuances.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Number of Shares	Weighted Average Fair Value
Restricted stock awards outstanding at June 30, 2007		$
Restricted stock awards granted	543,481	$ 14.67
Restricted stock awards forfeited	(18,008)	$ 14.36
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

During the year ended June 30, 2009, the Company granted restricted stock units (RSUs) to members of the Board of Directors. Restricted stock units represented the right to receive cash payment from the Company equal in value to the market price per share of Company stock on date of payment. Restricted stock unit payments would occur on the six month anniversary of the date that the director ceases to serve on the Board. During the year ended June 30, 2010, the Company amended all outstanding RSU Agreements to provide that payment may be in the form of shares of the Company s common stock or in cash at the Company s option. 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 Fair Value
Restricted stock unit outstanding at June 30, 2008		
Restricted stock unit granted	42,238	$ 8.75
Restricted stock unit forfeited		
Restricted stock unit outstanding at June 30, 2009	42,238	$ 8.75

Restricted stock unit granted	93,024	$	8.60
Restricted stock unit forfeited	(5,814)	$	8.60
Restricted stock unit outstanding at June 30, 2010	129,448	$	8.65

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 amounts were recognized as stock-based compensation expense in the consolidated statements of operations for the year ended June 30, 2008:

	Stock Options	Restricted Stock Awards	Total
Cost of goods sold	$ 91	$ 141	$ 232
Selling, general and administrative	5,957	895	6,852
Research and development	181	116	297
Total	$ 6,229	$ 1,152	$ 7,381

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

	Shares Available for Grant(a)
Shares outstanding at June 30, 2007	376,392
Shares reserved	1,941,000
Shares granted(b)	(2,369,280)
Shares forfeited, expired or cancelled	70,953
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

(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.

(b) Excludes a grant of 45,290 shares outside of plans.

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

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2010, 151,485 shares were added to plan. Employees purchased 309,944 shares at an average price of $3.86 per share in the year ended June 30, 2010. Shares reserved under the plan for the year ended June 30, 2011 totaled 160,838.

7. Income Taxes

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

	June 30,	
	2010	2009
Deferred tax assets		
Stock-based compensation	$ 5,568	$ 3,398
Accrued expenses	749	508
Inventories	510	488
Debt Warrant Amortization	563	466
Depreciation and amortization	19	
Other	197	188
Research and development credit carryforwards	3,120	2,974
Net operating loss carryforwards	38,368	33,124
Total deferred tax assets	49,094	41,146
Deferred tax liabilities		
Depreciation and amortization		(29)
Total deferred tax liabilities		(29)
Valuation allowance	(49,094)	(41,117)
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	8,191
Balance at June 30, 2010	$ 49,308

As of June 30, 2010 and 2009, the Company had federal tax NOL carryforwards of approximately $109,114 and $92,652, respectively. These NOL carryforwards are available to offset taxable income through 2030 and will

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

begin to expire in 2011. The Company also had various state NOL carryforwards available to offset future state taxable income. These state NOL carryforwards typically will have the same expirations as our federal tax NOL carryforwards.

As of June 30, 2010 and 2009, the Company had approximately $2,783 and $2,540 of federal research and development credit carryforwards, respectively. As of June 30, 2010 and 2009, the Company had approximately $685 and $624 of state research and development credit carryforwards. 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 realized upon ultimate settlement with the relevant tax authority. The Company recorded a liability relating to unrecognized tax benefits of $347 at June 30, 2010. Due to the Company having a full valuation allowance, this liability has been netted against the deferred tax asset. The Company had no liabilities recorded related to unrecognized tax benefits at June 30, 2009. 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

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, 2010, 2009, and 2008. 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 $659, $658, and $572 for the years ended June 30, 2010, 2009, and 2008, respectively.

Future minimum lease payments under the agreements as of June 30, 2010 are as follows:

2011	$ 913
2012	920
2013	645
2014	415
2015	425
Thereafter	2,185
	$ 5,503

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 grant payable long-term liability rather than being recorded as expense. See Note 11 for additional information.

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, 2010, 2009, and 2008.

10. Redeemable Convertible Preferred Stock and Convertible Preferred Stock Warrants

The Company issued 3,081,375 shares of Series A redeemable convertible preferred stock during fiscal 2007, no par value, for total proceeds of $27,000. In addition, Series A convertible preferred stock warrants were issued to purchase 436,710 shares of Series A redeemable convertible preferred stock in connection with the sale of the Series A redeemable convertible preferred stock. The Series A convertible preferred stock warrants have a purchase price of $8.83 per share with a five-year term and were assigned an initial value of $1,767 for accounting purposes using the Black-Scholes model. The change in value of the Series A convertible preferred stock warrants due to decretion (accretion) as a result of remeasurement was $2,991, and ($916) for the years ended June 30, 2009, and 2008, respectively, and is included in the consolidated statements of operations.

As of June 30, 2007, the Company had sold 652,377 shares of Series A-1 redeemable convertible preferred stock, no par value, for total proceeds of $8,271, net of offering costs of $34. During the period from July 2007 to September 2007, the Company sold an additional 808,843 shares of Series A-1 redeemable convertible preferred stock for total proceeds of $10,282, net of offering costs of $14.

On December 17, 2007, the Company completed the sale of 1,412,591 shares of Series B redeemable convertible preferred stock for total proceeds of $19,963, net of offering costs of $37.

In connection with the closing of the merger at February 25, 2009, and preparation of the Company s financial statements as of June 30, 2008, the Company s management and Board of Directors established what it believed to be a fair market value of the Company s Series A, Series A-1, and Series B redeemable convertible preferred stock. This determination was based on concurrent significant stock transactions with third parties and a variety of factors, including the Company s business milestones achieved and future financial projections, the Company s position in the industry relative to its competitors, external factors impacting the value of the Company in its marketplace, the stock volatility of comparable companies in its industry, general economic trends and the application of various valuation methodologies.

Changes in the current market value of the Series A, Series A-1, and Series B redeemable convertible preferred stock were recorded as decretion (accretion) of redeemable convertible preferred stock and as accumulated deficit in the consolidated statements of changes in stockholders equity (deficiency) and in the consolidated statements of operations as decretion (accretion) of redeemable convertible preferred stock.

Immediately prior to the merger with Replidyne, each share of CSI-MN s Series A, A-1, and B convertible preferred stock automatically converted into approximately one share of CSI-MN s common stock pursuant to an agreement with the preferred stockholders. In addition, immediately prior to the merger, warrants to purchase shares of CSI-MN Series A and B convertible preferred stock were converted into warrants to purchase CSI-MN common stock outstanding at the effective time of the merger.

Subsequent to the merger with Replidyne, the Company has 5,000,000 preferred shares authorized. There are no preferred shares issued or outstanding at June 30, 2010.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. Texas Production Facility

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

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

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

The Company and the PEDC 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.

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, 2010, $340 has been received. The PEDC has committed, by resolution, to guarantee the award and will make payment to the Company for the remaining $765. As of June 30, 2010, $213 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, 2010, $139 in expenses has reduced the deferred grant incentive liabilities, resulting in a remaining current liability of $1,181 and long-term liability of $2,208.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. Legal Matters

ev3 Legal Proceedings

The Company is 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. In July 2010, ev3 Inc. was acquired and became an indirect wholly-owned subsidiary of Covidien plc.

The complaint, as amended, alleges the following:

That certain of the Company s employees (i) violated provisions in their employment agreements with their former employer FoxHollow, barring them from misusing FoxHollow confidential information and from soliciting or encouraging employees of FoxHollow to join the Company, and (ii) breached a duty of loyalty owed to FoxHollow.

That the Company and certain of its employees misappropriated confidential information and trade secrets of one or more of the Plaintiffs.

That all defendants engaged in unfair competition and conspired to gain an unfair competitive and economic advantage for the Company to the detriment of the Plaintiffs.

That (i) the Company tortiously interfered with the contracts between FoxHollow and certain of the Company s employees by allegedly procuring breaches of the non-solicitation encouragement provision in those agreements and that the Company aided and abetted FoxHollow employees breach their duty of loyalty, and (ii) one of the Company s employees tortiously interfered with the contracts between certain of the Company s employees and FoxHollow by allegedly procuring breaches of the confidential information provision in those agreements.

The Plaintiffs seek, among other forms of relief, an award of damages in an amount greater than $50, a variety of forms of injunctive relief, exemplary damages under the Minnesota Trade Secrets Act, and recovery of their attorney fees and litigation costs. Although the Company has requested the information, the Plaintiffs have not yet disclosed what specific amount of damages they claim.

The Company is defending this litigation vigorously, and believes that the outcome of this litigation will 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. If the Company is not successful in this litigation, it could be required to pay substantial damages and could be subject to equitable relief that could include a requirement that the Company terminate or otherwise alter the terms or conditions of employment of certain employees, including certain key sales personnel who were formerly employed by FoxHollow. In any event, the defense of this litigation, regardless of the outcome, could result in substantial legal costs and diversion of management s time and efforts from the operation of business.

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CARDIOVASCULAR SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. Earnings Per Share

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

	Year Ended June 30,		
	2010	**2009**	**2008**
Numerator			
Net loss available in basic calculation	$ 23,904	$ 31,895	$ 39,167
Accretion (decretion) of redeemable convertible preferred stock(a)		(22,781)	19,422
Loss available to common stockholders	$ 23,904	$ 9,114	$ 58,589
Denominator			
Weighted average common shares basic	14,748,293	8,068,689	4,422,326
Effect of dilutive stock options and warrants(b)(c)			
Weighted average common shares outstanding diluted	14,748,293	8,068,689	4,422,326
Loss per common share basic and diluted	$ (1.62)	$ (1.13)	$ (13.25)