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

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended June 30, 2012

OR

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

Commission file number: 000-52082

CARDIOVASCULAR SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

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

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

None.

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

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

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

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

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

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

Large accelerated filer ¨	Accelerated filer þ	Non-accelerated filer ¨	Smaller reporting company ¨

(Do not check if a smaller reporting company)

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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

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PART I

Item 1. ***Business.***

Special Note Regarding Forward Looking Statements

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

Corporate Information

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

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

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

Business Overview

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

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

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

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

Market Overview

Peripheral Artery Disease

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

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

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

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

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

Coronary Artery Disease

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

Our Product

Components of the PAD Systems

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

Catheter. The catheter consists of:

- a control handle, which allows precise movement of the crown and predictable crown location;
- a flexible drive shaft with a diamond grit coated offset crown, which tracks and orbits over the guidewire; and
- a sheath, which covers the drive shaft and permits delivery of saline or medications to the treatment area.

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

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

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

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

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Technology Overview

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

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

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

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

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

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

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

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

Applications

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

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

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

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

Potential Applications

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

Our Solution

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

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

We believe the PAD Systems offer the following key benefits:

Strong Safety Profile

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

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

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

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

Proven Efficacy

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

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

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

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

Ease of Use

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

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

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

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Treatment Area

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

Cost and Time Efficient Procedure

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

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

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

Our Strategy

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

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

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

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

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

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

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

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

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

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

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

Clinical Trials and Studies for Our Products

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

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

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Metrics Used in PAD Trials

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

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

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

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

PAD Feasibility Trials

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

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

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

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

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

OASIS Pivotal Trial

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

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

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

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

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

* Mean ± Standard Deviation

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

CLEAR 360° Study

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

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Post-Market Feasibility Studies

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

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

CONFIRM Post-Market Clinical Registry Series

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

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

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

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

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

ORBIT I Coronary Feasibility Safety Study

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

ORBIT II Coronary IDE Study

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

Sales and Marketing

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

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

- educating physicians regarding the proper use and application of the PAD Systems;
- clinical results showing safety and efficacy of products;

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developing relationships with key opinion leaders; and

facilitating regional referral marketing programs.

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

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

Research and Development

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

Manufacturing

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

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

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

We are registered with the FDA as a medical device manufacturer. We have opted to maintain quality assurance and quality management certifications to enable us to market our products in the member states of the European Union, the European Free Trade Association and cou