Cardiovascular Systems Inc
Form 10-K
August 27, 2015

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

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

For the fiscal year ended June 30, 2015
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.)
1225 Old Highway 8 Northwest St. Paul, Minnesota	55112-6416
(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 þ No o

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 þ 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.

Large accelerated filer x Accelerated filer o Non-accelerated filer o Smaller reporting company o

(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, 2014, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $916.3 million 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 21, 2015 was 32,480,435.

DOCUMENTS INCORPORATED BY REFERENCE
Portions of the proxy statement for the registrant's 2015 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 website, 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 website as a part of, or incorporating it by reference into, our Form 10-K.

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at http://www.sec.gov. We file annual reports, quarterly reports, proxy statements, and other documents with the SEC under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The public may read and copy any materials that the Company files with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

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 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," "intend," "should," "could," "would," "exp "plans," "anticipates," "believes," "estimates," "projects," "predicts," "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 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 Securities and Exchange Commission. 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

Cardiovascular Systems, Inc. ("CSI") was incorporated in Delaware in 2000. Our principal executive office is located at 1225 Old Highway 8 Northwest, 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 18 federal registrations in the U.S. Patent and Trademark Office ("USPTO") of certain marks, including "Diamondback®," a first "CSI," a second "CSI," "Predator 360°," "Stealth 360°," a first "CSI" logo, a second "CSI" logo, "Lumen Library®," "ViperWire®," "ViperWire Advance®," "Viperslide®," "ViperTrack®," "ViperCaddy®," "Stealth 360°," a first "Diamondback 360®," a second "Diamondback 360°," "Diamondback 360 (Stylized) Logo," and "Stay A Step Ahead of PAD®". We have applied for federal trademark registration with the USPTO of certain marks, including "Viperslide (Stylized)," "Vipertrack (Stylized)," and "Viperwire Advance (Stylized)." 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 technology company leading the way in the effort to successfully treat patients suffering from peripheral and coronary arterial diseases, including those with arterial calcium, the most difficult arterial disease to treat. We are committed to clinical rigor, constant innovation and a defining drive to set the industry standard to deliver safe and effective medical devices that improve lives of patients facing this difficult disease state.

We have developed a patented orbital atherectomy technology for peripheral and coronary commercial applications. Our peripheral arterial disease systems 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 other treatment alternatives. We refer to the Stealth 360° Peripheral Orbital Atherectomy System ("OAS") ("Stealth 360"), the

Diamondback 360 Peripheral OAS (“Diamondback 360 Peripheral”), and the products included in the chart below, collectively in this annual report as the “PAD Systems.”

The U.S. Food and Drug Administration ("FDA") granted us 510(k) clearance for the following PAD Systems as a therapy in patients with peripheral arterial disease ("PAD"):

FDA 510(k) Clearance Granted	Product	Commercial Introduction
August 2007	Diamondback 360 Peripheral	September 2007
March 2009	Predator 360[(1)]	April 2009
March 2011	Stealth 360	March 2011
March 2014	Diamondback 360 60cm Peripheral OAS	April 2014
April 2015	Diamondback 360 4 French 1.25 Peripheral	July 2015

[(1)] We are not currently marketing this product.

As of June 30, 2015, over 200,000 of our PAD Systems have been sold to leading institutions across the United States. Sales of PAD Systems during the fiscal year ended June 30, 2015 represented 74% of revenue.

We are evaluating options for international expansion to maximize the coronary and peripheral market opportunities.

Our coronary product, the Diamondback 360 Coronary OAS ("CAD System"), is a catheter-based platform designed to facilitate stent delivery in patients with coronary arterial disease ("CAD") who are acceptable candidates for percutaneous transluminal coronary angioplasty or stenting due to de novo, severely calcified coronary artery lesions. The CAD System design is similar to technology used in our PAD Systems, customized specifically for the coronary application. In October 2013, we received premarket approval ("PMA") from the FDA to market the CAD System as a treatment for severely calcified coronary arteries. We commenced a commercial launch that same month and as of June 30, 2015, over 9,000 CAD Systems have been sold to leading institutions across the United States. Sales of CAD Systems during the fiscal year ended June 30, 2015 represented approximately 15% of revenue.

In addition to the PAD and CAD Systems, we intend to expand 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 and CAD Systems. Sales of complementary products, primarily guide wire sales, represented 11% of revenue during the fiscal year ended June 30, 2015. Included in this amount are revenues from our exclusive distribution agreement with Asahi to market its peripheral guide wire line in the United States, which expired in June 2015. Sales of Asahi products were 4% of revenue during the fiscal year ended June 30, 2015.

Market Overview

Peripheral Arterial Disease

Peripheral arterial disease typically refers to the chronic obstruction of the arteries supplying the lower extremities due to plaque deposition on the walls of the arteries resulting in inadequate blood flow to the limbs. The anatomy of lower extremity arteries varies by location: arteries above the knee are generally long, straight and relatively wide compared to arteries below the knee, which tend to be shorter, more tortuous, and branch into progressively smaller in diameter arteries distally. The most common early symptoms of PAD are pain, cramping, or fatigue in the leg or hip muscles while walking, which typically subsides at rest. 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. If left untreated, PAD may continue to progress to Critical Limb Ischemia ("CLI"), a condition in which the amount of oxygenated blood being delivered to the limb is insufficient to keep the tissue alive. CLI may lead to large non-healing ulcers, infections, gangrene, limb amputation or death. Within the first year of diagnosis, an estimated 25 to 30% of CLI patients will die and 30% will undergo amputation ("ACC/AHA 2005 Guidelines for the Management of Patients with Peripheral Arterial Disease," Hirsch et al, 2005). CLI results in an estimated 160,000 amputations per

year in the United States.

According to estimates by the American Heart Association, as many as 8 to 12 million Americans have PAD. In addition, there are two other primary references used for estimating PAD prevalence: the patient Ankle Brachial Index ("ABI") and the diabetes method. The most recent comprehensive study, based on ABI, estimates the U.S. prevalence at 8.5 million (Allison et al, "Ethnic-Specific Prevalence of Peripheral Arterial Disease in the United States," Circulation, 2007). Alternatively, a study by The SAGE Group, based on the diabetes method, estimated prevalence at 17.6 million in 2010 (The SAGE Group, "The Diabetes Method," 2011). An aging population, coupled with increasing incidence of diabetes and obesity, is likely to continue

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 can be very challenging to treat. Although we believe the rate of PAD diagnoses is increasing, we also believe that under-diagnosis continues, due to patients failing to display symptoms or physicians misinterpreting symptoms as normal aging. Emphasis on PAD education from industry, medical associations, insurance companies and other groups, coupled with publications in medical journals and public news channels, is increasing physician and patient awareness of PAD risk factors, symptoms, and treatment options. Guidelines from the American College of Cardiology Foundation/American Heart Association in 2011 lowered the recommended age for testing for PAD from 70 to 65, or 50 if the patient has a history of smoking or diabetes. As these guidelines are incorporated into physician practice, PAD diagnosis rates are forecasted to increase. Physicians manage a significant portion of the PAD diagnosed population by recommending lifestyle changes, such as diet and exercise, and by prescribing prescription drugs. While medications, diet and exercise may improve blood flow, they do not treat the underlying obstructions created by calcium, and many patients have difficulty maintaining lifestyle changes. As a result of these challenges, many medically managed patients develop more severe symptoms that require procedural intervention.

Coronary Arterial Disease

Coronary arterial disease is a life-threatening condition and leading cause of death in both men and women in the United States. CAD occurs when a fatty material called plaque builds up on the walls of arteries that supply blood to the heart. The plaque buildup causes the arteries to harden and narrow (atherosclerosis), reducing blood flow. The risk of CAD increases if a person has one or more of the following: high blood pressure, abnormal cholesterol levels, diabetes, or family history of early heart disease. According to the American Heart Association, 15.4 million people in the United States suffer from CAD, the most common form of heart disease. Heart disease claims more than 600,000 lives in the United States each year. According to estimates, significant arterial calcium is present in nearly 40% of patients undergoing a percutaneous coronary intervention (“PCI”). Significant calcium contributes to poor outcomes and higher treatment costs in coronary interventions when traditional therapies are used, including a significantly higher occurrence of death and major adverse cardiac events (“MACE”).

Our PAD and CAD Systems

Our OAS represents an innovative approach to the treatment of PAD and CAD that provides physicians and patients with a procedure that addresses many of the limitations of traditional treatment alternatives. The PAD Systems and CAD System devices are single-use catheters that incorporate a flexible drive shaft with an offset diamond-grit-coated crown. The peripheral device is often used as vessel prep to enable low pressure percutaneous transluminal angioplasty and drug coated balloons, and results in lower use of bail out stents. The coronary device is used as vessel prep to facilitate stent delivery and prevent stent malposition. Physicians position the crown at the site of a lesion containing arterial plaque and orbit the crown against it at high speeds to sand away the plaque and create a smooth lumen, or channel, in the vessel. The Peripheral OAS treats atherosclerotic soft plaque, which is harder than a normal vessel wall. The OAS are designed to differentiate between hard, diseased plaque and healthy, compliant arterial tissue, a concept that we refer to as “differential sanding.” The diamond-grit-coated crown preferentially engages and sands the harder material, but is designed not to damage more compliant parts of the artery.

Components of the OAS

Our OAS uses a single-use, low-profile catheter that travels over our proprietary guide wires and is powered by a saline infusion pumps that also helps cool the system and remove debris. The PAD Systems reduce plaque on peripheral vessel walls by using an orbiting, diamond-coated crown within peripheral arteries. Similarly, the CAD System uses the same method to reduce severely calcified plaque on coronary vessel walls within coronary arteries in order to facilitate stent delivery.

Catheter. The catheter for our OAS consists of:

- a control handle, which allows 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 guide wire; and
- a sheath, which covers the drive shaft and permits delivery of saline or medications to the treatment area.

ViperWire Advance Guide Wire and ViperWire Advance Coronary Guide Wire. The ViperWire guide wires were designed to offer an improved ability to maneuver through tortuous, twisting blood vessels and cross challenging lesions. The OAS travels 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 OAS.

OAS Pump with Diamondback. The saline infusion pump mounts directly to the intravenous pole and bathes the OAS shaft and crown and provides an electric power supply for the operation of the catheter. The constant flow of saline, during orbit, reduces the risk of heat generation and improves the flush of particulates.

The mechanism of action is a function of the centrifugal force generated by the OAS as it rotates and orbits inside the vessel. As the speed of the crown's rotation increases, centrifugal force increases the crown's radius of orbit and presses the diamond-grit-coated offset crown against the lesion or plaque, removing a small amount of plaque with each orbit. The centrifugal force exerted onto the vessel wall decreases as the orbital radius increases, reducing the likelihood of adverse events during treatment. The characteristics of the orbit and the resulting lumen size can be adjusted by modifying the following two variables:

- Speed. An increase in speed creates a larger orbital radius, thus accommodating larger diameter vessels. Our current PAD Systems allow the user to choose between three rotational speeds. Our CAD System allows the user to choose between two rotational speeds.

- Crown Characteristics. The crowns for the OAS are designed with various weights (as determined by crown geometry and material density) and are coated with diamond grit. The PAD Systems' crowns are available in three configurations: classic, micro and solid. Physicians select crown sizes and configurations based on several case criteria, including reference vessel size, lesion length and degree of stenosis, stenosis morphology, and anatomy tortuosity. Physicians often use the classic or micro crown configuration in small, more tortuous vessels or when less aggressive sanding is desired. The solid crown configuration is designed with a tapered, leading edge for frontal sanding, which can be used in tight calcified disease. The PAD Systems are available with a 1.50 millimeter and 2.00 millimeter classic crown, and a 1.25 millimeter, 1.50 millimeter and 2.00 millimeter solid crown configuration. There is also a 1.25 millimeter micro crown available with the Diamondback 360 Peripheral device, which allows physicians options to treat very small arteries in the lower leg and foot. Catheter lengths are 145 centimeters and 60 centimeters, which address procedural approach and target lesion locations both above and below the knee and ankle. The shorter length catheters allow physicians an option to treat via retrograde pedal approach in addition to the common femoral artery access point. The PAD Systems are versatile. By adjusting the speed in conjunction with crown selection, multiple lesions and vessel sizes can be treated. The crown for the CAD System is available in one configuration: 1.25 millimeter classic.

As the crown moves outward, the centrifugal force is offset by the counterforce exerted by the arterial wall. Normal arteries are compliant and have the ability to expand and contract as needed to supply blood flow. If the tissue is compliant, it flexes away, rather than generating an opposing force that would allow the OAS to engage and sand the wall. Diseased tissue provides resistance and is able to generate an opposing force that allows the OAS 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.

PAD System testing performed in carbon blocks, animal and cadaver models showed:

- greater than 93% of particles were smaller than a red blood cell, and
- greater than 99% of particles were smaller than the lumen of the capillaries (which provide the connection between the arterial and venous system).

CAD System testing performed in a carbon block model showed:

- 98.3% of particulate is smaller than a red blood cell; and
- ~2 microns in size.

The small particle size minimizes the risk of vascular bed overload, or a saturation of the peripheral or coronary vessels with large particles, which may cause slow or reduced blood flow. The small size of the particles allows them to be naturally cleared from the blood via various types of white blood cells and macrophages.

We believe the OAS offer the following key benefits:

Strong Safety Profile

- Differential Sanding Reduces Risk of Adverse Events. The OAS is designed to differentiate between hard plaque and soft compliant arterial tissue. Arteries are composed of three tissue layers (from inside to out): the intima, media, and

adventitia. The diamond-grit-coated offset crown at the working end of the device engages and removes plaque from the artery wall with minimal likelihood of penetrating or damaging the fragile intima, or inner layer of the arterial wall because soft, compliant tissue flexes away from the crown. Furthermore, the OAS has rarely penetrated the media (middle) or adventitial (outer) layers of the artery's wall. The Diamondback 360 Peripheral's perforation rate was 0.7% during our pivotal CONFIRM trial. Analysis by an independent pathology laboratory of more than 434 consecutive cross sections of porcine arteries treated with the Diamondback 360 Peripheral revealed there was minimal to no damage, on average, to the media or associated lamina, which implies preservation of the media during treatment. Similarly, the perforation rate was 1.8% during our pivotal ORBIT II trial, with 0.9% perforations device related. Analysis by an independent pathology laboratory of more than 443 patients enrolled in the ORBIT II Trial revealed 4 patients had a perforation after the OAS treatment and another 4 patients had a perforation after stent deployment, for a total of 8 perforations reported.

- Eliminates Need for Distal Protection. The small size of the particles produced during sanding avoids the need for ancillary distal protection devices, commonly used with directional cutting atherectomy devices. The small particulate size also significantly reduces the risk of macroembolization, or larger pieces of removed plaque capable of blocking blood flow downstream.

- Allows Continuous Blood Flow During Procedure. The OAS allows for continuous blood flow while orbiting. 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 for Both PAD and CAD Systems.

Our pivotal OASIS clinical trial was a prospective 20-center study that involved 124 patients with 201 lesions treated by the Diamondback 360 PAD System. Performance targets were established cooperatively with the FDA before the trial began. Despite 55% of the lesions consisting of calcified plaque, the Diamondback 360 Peripheral 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 Peripheral, no additional efficacy trials were required by the FDA for 510(k) clearance of either of those PAD Systems.

For the CAD System, our ORBIT II coronary OAS trial was designed to evaluate the safety and efficacy of OAS in treating severely calcified coronary lesions. The trial met both the primary safety and efficacy endpoints by significant margins. Preparation of severely calcified plaque with the OAS not only helped facilitate stent delivery, but also improved both acute and 30-day clinical outcomes compared with the outcomes of historic control subjects in this difficult-to-treat patient population. The pre-procedure mean minimal lumen diameter of 0.5 mm increased to 2.9 mm after the procedure. The primary safety endpoint was 89.6% freedom from 30-day MACE compared with the performance goal of 83%. The primary efficacy endpoint (residual stenosis <50% post-stent without in-hospital major adverse cardiac events) was 88.9% compared with the performance goal of 82%. Stent delivery was successful in 97.7% of cases; <50% stenosis was observed in 98.6% of subjects. Low rates of in-hospital Q-wave myocardial infarction (0.7%), cardiac death (0.2%), and target vessel revascularization (0.7%) were reported.

- Treats Difficult, Fibrotic and Calcified Lesions. The OAS enables physicians to remove plaque from long, fibrotic, calcified or bifurcated lesions, as well as lesions with softer plaque, in peripheral arteries both above and below the knee. In the coronaries, the OAS enables physicians to treat complex, severely calcified lesions, enabling optimal stent placement in these difficult to treat lesions. To date, the coronary OAS is the only FDA-approved device for treatment of severely calcified coronary lesions.

Orbital Motion Improves Lesion Compliance. The orbiting action of the OAS 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 reduction of plaque as the opening of the lumen increases during the operation of the devices.

Differential Sanding Creates Smooth Lumens. The differential sanding of the OAS creates a smooth surface lumen, or channel, inside the vessel. We believe that the smooth lumens created by the device 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 OAS 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 Access Site to Complete Treatment. The orbital technology and differential sanding process of the OAS allow for a single access site to treat multiple lesions, in most cases. In the peripheral vasculature, the OAS device is capable of treating multiple lesions in multiple arteries through a single access site, thus reducing the need for multiple devices or the need for multiple access sites.

- No Need for Collection Reservoir. Because the particles of plaque sanded away are of such small sizes, the OAS does not require a collection reservoir that needs to be repeatedly emptied or cleaned during the procedure, or add time and cost to the procedure.

Multiple Applications

The unique OAS mechanism of action used in both the PAD and CAD Systems can be used to treat multiple anatomic locations.

- Below-the-Knee and Behind-the-Knee Peripheral Artery Disease. Arteries below and behind the knee are small in diameter and may be diffusely diseased, calcified or both. Reaching and treating these small vessels requires a low profile which several competitive devices do not offer. Behind-the-knee, or popliteal, lesions also present challenges if a stent is used because stents frequently fracture in this area due to the forces exerted on the vessels when the knee bends or flexes. The Diamondback 360 Peripheral is effective in treating those vessels, as demonstrated in our CALCIUM360 randomized clinical trial, where 100% of the lesions treated with the Diamondback 360 Peripheral were located below the knee. The Diamondback 360 60cm Peripheral OAS offers a shorter shaft length, a smaller profile and a more flexible shaft than the predecessors for improved ease of use, and uses a 4 French catheter that enables physicians to access lesions below-the-knee using retrograde access (access through the ankle or foot).

- Above-the-Knee Peripheral Artery Disease. Arteries above the knee are typically longer, straighter and wider than below-the-knee vessels. Plaque in these arteries may also be diffuse, fibrotic and calcific. Physicians often use higher speeds or larger crown sizes of our products to treat lesions above the knee.

- Coronary Artery Disease. The individuals more at risk for being diagnosed with CAD are those that are suffering from high blood pressure, abnormal cholesterol levels, diabetes, or have a family history of heart disease. Once CAD occurs, a fatty material called plaque builds up on the walls of arteries that supply blood to the heart. The plaque buildup causes the arteries to harden and narrow (atherosclerosis), reducing blood flow. The CAD System is the only atherectomy device indicated for severe coronary calcium.

Cost and Time Efficient Procedure

- Short Procedure Time The OAS has a short treatment time, typically less than two minutes.

- Single Crown Can Treat Various Lumen Sizes Limiting Hospital Inventory Costs The OAS orbital mechanism of action allows one device to treat 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.

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Single Access Site May Reduce Procedural Time Since the physician can treat multiple arteries through a single access site, this reduces the risk of bleeding complications that can occur during arterial access, ultimately reducing patient recovery time.

Our OAS Strategy

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

- Drive Adoption through Our Direct Sales Organization and Key Opinion Leaders. We expect to continue to drive adoption of the OAS through our direct sales force in both hospital and office-based lab settings, which targets interventional cardiologists, vascular surgeons, and interventional radiologists. As a key element of our strategy, we focus on educating physicians about the disease state and our clinical data, and training physicians on OAS technology through our direct sales force and through seminars where physician industry leaders discuss case studies and treatment techniques using the devices.

- Collect Additional Clinical Evidence on Safety, Effectiveness and Economic Benefits of the OAS. Physicians are increasingly requesting clinical study evidence to allow them to make 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 OAS and drive physician acceptance.

- Enhance OAS and Expand Product Portfolio within the Market for Treatment of Peripheral and Coronary Arteries. In addition to enhancing the OAS, we have expanded our product portfolio. We offer multiple accessory devices designed to complement the use of the OAS. We are continuing product development to further expand our portfolio of PAD and CAD treatment solutions.

- International Expansion. CE Mark was granted for the Stealth 360 device in October 2014, we expect CE Mark for the CAD System in fiscal 2016, and we also anticipate approval for the next generation coronary OAS device in Japan during the fiscal 2017 timeframe. We are evaluating options for international expansion to maximize the coronary and peripheral market opportunities. Sales channels will be based on specific country dynamics. As a result, distributors, including potential strategic partners, and direct sales channels are being evaluated.

- Strategic Acquisitions and Partnerships. 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 also intend to explore distribution agreements, licensing transactions, and other strategic partnerships.

- Healthcare Policy and Reimbursements. Our healthcare policy initiatives goal is to raise awareness with public and private payors, along with key medical societies, of the clinical and economic issues associated with peripheral and coronary arterial calcium. By educating payors and medical societies about the clinical advantages and cost effectiveness of our OAS technology, we believe we can sustain reimbursement coverage for our devices and ensure practice guidelines include appropriate treatment options for patients with arterial disease.

Clinical Studies Summary

We continue to study the most challenging patient populations and are committed to providing relevant clinical evidence that enables physicians to select and utilize the best treatment options for their patients. Our clinical studies incorporate rigorous long-term clinical and healthcare economic data that are critical to improving long-term patient care and ongoing healthcare changes. Our studies in PAD and CAD illustrate the versatility of our technology and a focus on improving the standard of care.

We have conducted 14 clinical studies to demonstrate the safety and efficacy of the PAD Systems. A total of 3,777 patients were enrolled in various studies including our PAD I and PAD II pilot studies, OASIS pivotal study, CONFIRM post market registries (CONFIRM I, II, and III), CALCIUM 360°, COMPLIANCE 360°, and multiple

physician-initiated studies. The results of these studies consistently demonstrate that the PAD Systems provide predictable, repeatable and durable results that differentiate them from other PAD treatments. We recently completed follow-up on the CLARITY post market, randomized feasibility study and the TRUTH post market study. The LIBERTY 360° study is still enrolling patients. The following PAD clinical studies have been completed, are in process, or are being further analyzed:

- OASIS. In September 2005 our Investigational Device Exemption ("IDE") was approved to begin OASIS, our pivotal U.S. study. OASIS was a 124-patient, 20-center, prospective study that began enrollment in January 2006. 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 Serious Adverse Events ("SAE") at 30 days.

In the OASIS study, 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. Results of OASIS exceeded FDA pre-specified acceptance criteria with an overall plaque reductions of 59.4%, freedom from device related SAE of 95.2% and 90.3% overall, and freedom from TLR of 97.6%.

- CONFIRM. The CONFIRM series enrolled 3135 patients at over 200 U.S. institutions in order to evaluate the use of orbital atherectomy for the treatment of PAD. The CONFIRM registry confirmed that orbital atherectomy was safe and effective in a large registry of "all-comer" patients. Multiple sub-analyses have been performed and published on the CONFIRM series. There were no safety or efficacy differences for patients treated in outpatient based labs versus hospitals. The device was also found to be safe and effective for patients with diabetes or renal disease and in women and the elderly.

- TRUTH. The study is a prospective, single-arm (non-randomized), post-market study that used intravascular ultrasound ("IVUS") imaging and angiography to assess procedural outcomes in patients with symptomatic PAD and who are treated with the OAS and adjunctive balloon angioplasty. An independent IVUS Core Lab was used to provide adjudicated analyses for IVUS outcomes. TRUTH identified that the OAS can remove and modify calcified plaque. IVUS results suggested that the OAS also polishes plaque surface and changes plaque shape.

- CLARITY. This pilot study is designed to identify the clinically appropriate endpoint(s) of a possible larger, statistically powered pivotal trial for treatment of patients with CLI. Enrolled patients had lesions of any morphology in vessels preventing direct blood perfusion to a foot wound. The study utilized five core labs, IVUS, and Fractional Flow Reserve for significant clinical rigor. CLARITY patients will be followed for one year.

- LIBERTY 360°. We are currently enrolling up to 1,200 patients in our LIBERTY 360° clinical PAD study, which is a prospective, observational, multi-center clinical study to evaluate acute and long term clinical, quality of life and economic outcomes of various endovascular device intervention in patients with distal outflow PAD. This study is a novel trial that studies patients with all endovascular PAD treatments and will increase the understanding of the clinical and economic outcomes of endovascular treatment for Claudicants and CLI patients with PAD. Patients are currently enrolling into the LIBERTY 360° study and will be followed for up to five years.

CAD, the most common form of heart disease, continues to affect more patients worldwide. Performing PCI on calcified lesions can lead to MACE rates as high as 24% at 30 days, stent malposition, and a number of procedural complications. Despite being a relatively common problem, there had been no FDA IDE PMA trials studying only patients with severe coronary calcification, before our ORBIT I and ORBIT II trials. We have completed our ORBIT I pilot study and recently published 5-year follow-up data and are completing 3-year follow-up on the pivotal ORBIT II IDE study. We are also enrolling patients in the COAST trial.

- ORBIT I. The ORBIT I feasibility study evaluated performance of the Diamondback 360° for the treatment of de novo calcified coronary lesions. The ORBIT I study completed in India in 2009 enrolled 50 patients. The endpoints were measured by device performance, MACE rate, and TLR at six months. Device performance success was 98%. The freedom from MACE at 30 days and at 6 months was 94% and 92% respectively. The 30-day and 6-month freedom from target lesion revascularization ("TLR") was 98%. Three-year and 5-year freedom from MACE was 81.8% and 78.8%, respectively.

- ORBIT II. In 2010, we began the ORBIT II pivotal study in the U.S, which evaluated the use of the CAD System in treating severely calcified coronary arteries. In October 2013, we received PMA from the FDA. ORBIT II was mandated by the FDA to be conducted as a single-arm study without a comparator arm, as no other device was approved to treat severely calcified arteries. One year ORBIT II study results were recently published in the American

Journal of Cardiology. The 1-year freedom from MACE was 83.6%, freedom from target lesion revascularization was 95.3%, and freedom from cardiac death was 97%. The revascularization rate was significantly lower compared to historic controls. We continue to expand our coronary clinical data with long term clinical and economic data demonstrating positive results for patients treated with the CAD System. ORBIT II 2-year results and economic analysis were presented at the EuroPCR conference as a Late Breaking Clinical Trial in May 2015. Results demonstrated a 2-year freedom from TLR/target vessel revasularization ("TVR") rate of 91.9% and freedom from MACE rate of 80.6% in this difficult-to-treat patient population. An economic analysis also demonstrated the cost of OAS would be fully covered by two years, with a possible extra $1,151 cost offset/savings per patient. This equated to

a total cost offset/savings of $4,946 per patient with OAS treatment, when accounting for shorter hospital stays for the index procedure.

- COAST. This is a prospective, single-arm, multi-center, global study designed to evaluate performance of the next generation coronary product, the Diamondback 360 Coronary Micro Crown OAS. We enrolled 100 subjects at 15 U.S. sites and five sites in Japan. After approval, the Diamondback 360 Coronary Micro Crown OAS will be an additional tool for the treatment of challenging coronary lesions and be the basis for receiving regulatory approval to market the device in Japan.

Our clinical portfolio is expanding as we develop future studies to answer difficult questions about PAD and CAD treatment. A number of upcoming clinical studies are in the development phase and will begin enrolling in the near future. Our clinical research continues to highlight the safety and efficacy of the OAS and current and new research illustrates our versatility in the emerging vascular market.

Sales and Marketing

We market and sell our products through a direct sales force in the United States. Revenues for the PAD and CAD Systems for the years ended June 30, 2015, 2014, and 2013 were $161.3 million, $120.4 million and $91.2 million, respectively. 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. Peer-to-peer education is also a key element of our sales strategy.

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 OAS;
- clinical results showing safety and efficacy of our products;
- educating physicians on the prevalence and complications of calcium in PAD and CAD; and
- developing relationships with key opinion leaders.

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. In additional to the key target markets, we also focus on alternative access sites. Research and development projects include the development of new products, enhancement of existing products, and PAD and CAD clinical trials. Research and development expenses for the years ended June 30, 2015, 2014, and 2013 were $31.0 million, $21.1 million and $15.2 million, respectively.

Manufacturing

We use internally-manufactured and externally-sourced components to manufacture the OAS. Most of the externally-sourced components are available from multiple suppliers; however, certain key components, including the diamond-grit-coated crown 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.

We have effectively relocated into a new, 125,000-square-foot, corporate headquarters in Minnesota. This custom-designed building has space for more than 500 employees and contains dedicated research and development, training and education, and manufacturing facilities. The operations-dedicated space expands our production and inventory capacity significantly. Depending on staffing, the new facility has the capacity to produce in excess of 75,000 devices per shift annually. The finished goods storage has capacity for nearly 20,000 devices and more than 500 saline infusion pumps, as well as other accessory products.

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 OAS devices and other accessory products and over 500 saline infusion pumps.

We believe that, once the full transfer of operations is complete (anticipated to be complete by December 2015), our facilities in Minnesota and Texas will be adequate for the foreseeable future.

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 2015. Under these registrations, our plants are audited by the FDA and our Notified Body for the EU CE Mark. Our Stealth 360 has received CE Mark.

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 (“CMS”). Medicare covers certain medical care expenses for eligible elderly and disabled individuals, including a large percentage of the population with PAD and CAD who could be treated with the OAS. In addition, private insurers often follow the coverage and reimbursement policies of Medicare. Consequently, Medicare's coverage and reimbursement policies are important to our operations.

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

Competition

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

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

- safety and efficacy even in calcified plaque;
- predictable clinical performance;
- availability of clinical data;
- ease of use;
- economic benefit;
- key opinion leader support and customer base;
- 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 June 2015, we held 46 issued U.S. patents and have 39 U.S. patent applications pending, as well as 203 issued or granted foreign patents and 148 foreign patent applications, each of which corresponds to aspects of our U.S. patents and applications. Our issued U.S. patents expire between 2015 and 2032, and our most important patents, U.S. Patent No. 6,494,890 and two key design patents covering our eccentric abrasive crown technology are due to expire on June 1, 2019, February 16, 2024 and December 29, 2023, respectively, though we will pursue patent term extensions on the basis of regulatory delay where appropriate. In addition, we have many additional patents relating to our core technology currently pending in the USPTO, which will extend our key covered subject matter and coverage dates

significantly. Our issued patents and patent applications relate primarily to the design and operation of interventional atherectomy devices, including the PAD and CAD Systems. These patents and applications include claims covering key aspects of orbital 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 18 registered U.S. trademarks, 12 registered marks in the Madrid Protocol with protection granted within at least one of Australia, Europe, China, Japan and Mexico, six registered marks in Europe, five registered marks in Canada, five registered marks in Mexico, and eight registered marks in Hong Kong. We have three trademark applications pending in the U.S., eight trademark applications pending in Canada and 12 trademark applications pending in India.

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

Government Regulation of Medical Devices

Governmental authorities in the U.S. at the federal, state and local levels and in other countries extensively regulate, among other things, the development, testing, manufacture, labeling, promotion, advertising, distribution, marketing and export and import of medical devices such as the PAD and CAD 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 (“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 U.S. 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 PMA. The type of marketing authorization applicable to a device - 510(k) clearance or PMA - 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 the 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 (“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 post market 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 prior to commercial marketing. The PMA process is generally more stringent, time-consuming and expensive than the 510(k) clearance process.

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

After a device has received 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, such as a significant change in the design, materials, method of manufacture or intended use, will require a new 510(k) clearance or PMA (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 the modified device until 510(k) clearance or PMA 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 Peripheral 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 Peripheral on October 25, 2007 and for the solid crown version of the Diamondback 360 Peripheral on November 9, 2007. We were granted 510(k) clearance of the Predator 360 in March 2009 and Stealth 360 in March 2011. We received 510(k) clearance of the Diamondback 360 Peripheral 1.25 Micro OAS in November 2013 and the Diamondback 360 Peripheral 60cm OAS in March 2014. The Diamondback 360 Peripheral 1.25 Solid OAS was cleared in April 2015. We received clearance of the ViperWire Advance Flex Tip Guide Wire in June 2015.

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 facilities to ensure compliance with the FDA's 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 letter authorizing commercial marketing of the device for certain indications. If

the FDA's evaluation of the PMA application or manufacturing facilities is not favorable, the FDA will deny PMA or issue a not approvable letter. The FDA may also determine that additional clinical trials are necessary, in which case the PMA may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA application. 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 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.

The FDA granted unconditional IDE approval in April 2010 to begin the ORBIT II coronary trial in the United States. This pivotal trial was set up in two phases: Phase I allowed us to enroll up to 100 patients at as many as 50 U.S. sites, and Phase II allowed us to expand the trial to the full complement of 429 patients. In May 2011, we received approval from the FDA to complete enrollment of 429 patients in our ORBIT II clinical trial for a coronary application for the Diamondback 360, which followed the FDA's review of data from the first 50 cases in the ORBIT II trial. In July 2012, we received approval from the FDA to include the new electric coronary device (similar to Stealth 360 technology used in PAD and customized specifically for the coronary application), which improves ease of use. The FDA required 100 enrollments with the new electric coronary device and would have allowed up to 50 additional patients in the trial, as needed, to achieve that enrollment level. A total of 443 patients were enrolled in the trial. In March 2013, we completed submission of our PMA application to the FDA for our OAS to treat calcified coronary arteries. In October 2013, we received PMA from the FDA to market the Diamondback 360 Coronary OAS as a treatment for severely calcified coronary arteries. We commenced a controlled commercial launch of the CAD System following receipt of PMA. In 2014, we initiated the COAST study, an IDE clinical trial, to evaluate a modified design of the Diamondback 360 Coronary OAS.

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 investigational 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; or
- the FDA concludes that the trial design is inadequate to demonstrate safety and efficacy.

Continuing Regulation. After a device is cleared or approved for use 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 post market 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; or
- 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 requirements set forth in the QSR.

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

Fraud and Abuse

Our operations are directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the FDCA, the federal Anti-Kickback Statute and the False Claims Act. These laws may impact, among other things, our proposed sales, marketing, education and clinical 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.

On May 8, 2014, we received a letter from the U.S. Attorney's Office for the Western District of North Carolina stating that it is investigating the Company to determine whether we had violated the False Claims Act. The letter enclosed a Civil Investigative Demand for written interrogatories and document requests. See Item 3 of this Form 10-K for additional information on this matter.

The federal Physician Payments Sunshine Act, or the Sunshine Act, and certain state laws require persons to collect and report certain data on payments and other transfers of value to physicians and teaching hospitals. It is widely anticipated that public reporting under the Sunshine Act and implementing Open Payment regulations will result in increased scrutiny of the financial relationships between industry, physicians and teaching hospitals.

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, our internal business processes are and will continue to be affected by the numerous legal requirements and regulatory guidance at the state, federal and industry levels.

International Regulation

International sales of medical devices are subject to foreign government regulations, which may vary substantially from country to country. The time required to obtain approval in a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ. For example, the primary regulatory environment in Europe with respect to medical devices is that of the European Union, which includes most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the European Union, although actual implementation of these directives may vary on a country-by-country basis. The method of assessing conformity varies depending on the class of the product,

but normally involves a combination of submission of a design dossier, self-assessment by the manufacturer, a third-party assessment, and review of the design dossier by a "Notified Body." This third-party assessment generally consists of an audit of the manufacturer's quality system and manufacturing site, as well as review of the technical documentation used to support application of the CE Mark to one's product and possibly specific testing of the manufacturer's product. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union.

In addition, any international expansion, operations and sales that we undertake will require us to comply with the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions and with U.S. and foreign export control, trade embargo and custom laws.

Environmental Regulation

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

Employees

As of June 30, 2015, we had 597 employees, including 134 employees in manufacturing, 284 employees in sales, 38 employees in marketing, 40 employees in clinical, 59 employees in general and administrative, and 42 employees in research and development, all of which are full-time employees. None of our employees are represented by a labor union or are parties to a collective bargaining agreement, and we believe that our employee relations are good.

Item 1A. Risk Factors.

Risks Relating to Our Business and Operations

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

We are not profitable and have incurred net losses in each fiscal year since our formation in 1989. In particular, we had net losses of $32.8 million, $35.3 million, and $24.0 million for the years ended June 30, 2015, 2014, and 2013, respectively. As of June 30, 2015, we had an accumulated deficit of approximately $271.4 million. We commenced commercial sales of the PAD Systems in September 2007 and the CAD System in October 2013, 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, research and development, and manufacturing as we continue to commercialize the PAD and CAD Systems and additional expenses as we seek to develop and commercialize future versions of the PAD and CAD Systems and any future products. Additionally, we expect that our general and administrative expenses will increase as our business grows. As a result, our operating losses are likely to continue.

We may be unable to sustain our revenue growth.

Our revenue has grown in each of the fiscal years since we commenced commercial sales of the PAD Systems in September 2007. Our ability to continue to increase our revenues in future periods will depend on our ability to increase sales of the PAD Systems and generate significant sales from the CAD System and new and improved products we introduce, which will, in turn, depend in part on our success in growing our customer base and reorders 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 negatively impact our business. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in their purchases and also in our receivable collections and additional allowances may be required, which could adversely affect our operating results. Adverse worldwide economic conditions may also adversely impact our suppliers' ability to provide us with materials and components, which could adversely affect our business and operating results.

The PAD Systems, the CAD System and future products may never achieve broad market acceptance.

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

- the actual and perceived effectiveness and reliability of our products;
- the prevalence and severity of any adverse patient events involving our products;
- the results of any clinical trials relating to use of our products;
- the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for conditions treated by our products;
- the degree to which treatments using our products are approved for reimbursement by public and private insurers;
- the degree to which physicians adopt the PAD and CAD Systems;
- the extent to which we are successful in educating physicians about PAD and CAD in general and the existence and benefits of the PAD and CAD Systems in particular;

- the strength of our marketing and distribution infrastructure; and
- the level of education and awareness among physicians and hospitals concerning our products.

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

Our customers may not be able to achieve adequate reimbursement for using the PAD and CAD 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 our products to continue to 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. While third-party payors are currently providing reimbursement for our products, we can give no assurance that these third-party payors will continue to provide adequate reimbursement for use of the PAD and CAD Systems to permit hospitals and doctors to consider the products cost-effective for patients requiring treatment, or that current reimbursement levels for our products will continue. In addition, the overall amount of reimbursement available for PAD and CAD 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 our products. In order to position our products 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 our current products 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 our products is limited or not available, the acceptance of our products and, consequently, our business will be substantially harmed.

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

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control healthcare costs and, more generally, to reform the U.S. healthcare system, some of which have been enacted into law, such as the Patient Protection and Affordable Care Act, or the Patient Act. The Patient Act and any additional healthcare proposals and laws that may be enacted in the future could also limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. The Patient Act and future healthcare legislation could adversely affect our revenue and financial condition.

Our financial performance may be adversely affected by medical device tax provisions in the health care reform legislation.

The imposition of the 2.3% medical device excise tax enacted as part of the Patient Act has adversely affected our financial results and has required, and will continue to require, us to identify ways to reduce spending in other areas or raise additional capital to offset the increased expense. We have not been able to pass along the cost of the tax to our customers or offset the cost of the tax through higher sales volumes resulting from the expansion of health insurance coverage and do not expect to be able to do so in the future. Ongoing implementation of this legislation could have a material adverse effect on our results of operations and cash flows.

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

Because our technology is relatively new in the treatment of PAD and CAD, we have performed clinical trials only with limited patient populations. The long-term effects of using the PAD and CAD Systems in a large number of patients have not been studied and the results of short-term clinical use of the PAD or CAD Systems do not necessarily predict long-term clinical benefits or reveal long-term adverse effects. We are conducting and developing several clinical trials, and there are substantial risks and uncertainties involved in these trials. We must devote substantial resources to our clinical trials, clinical trials often take several years to develop and conduct, there are difficulties involved in locating sites and patients to participate in our clinical trials, and the results of every trial are uncertain until the trial is completed. These uncertainties could adversely impact our financial results, our reputation and the reputation of our products.

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

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

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

Our competitors may:

- develop and patent processes or products earlier than we will;
- obtain regulatory clearances or approvals for competing medical device products more rapidly than we will;
- market their products more effectively than we will; or
- develop more effective or less expensive products or technologies that render our technology or products obsolete or non-competitive.

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

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

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

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

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

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

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

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

We have increased the size of our organization and expect to continue to do so, 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.

During the year ended June 30, 2015, we expanded the size of our organization, particularly in the number of sales and marketing personnel, and we plan to continue this growth. The growth we may experience in the future may provide challenges to our organization, requiring us to also rapidly expand other aspects of our business, including our manufacturing operations. Rapid expansion in personnel may result in less experienced people producing and selling our products, which could result in unanticipated costs and disruptions to our operations. If we cannot scale and manage our business appropriately, our anticipated growth may be impaired and our financial results will suffer.

We intend to sell our products internationally in the future, but we may experience difficulties in obtaining approval to do so or in successfully marketing our products internationally even if approved.

Currently, all of our revenues are in the United States; however, we intend to sell internationally in the future and have commenced the process of seeking approval to do so in both Europe and Japan. There can be no guarantee that we will receive approval to sell our products internationally, nor can there be any guarantee that any sales would result even if such approval is received. In addition, we will incur substantial expenses in connection with international expansion. Our inability to successfully enter international markets and manage business on a global scale could negatively affect our financial results.

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

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

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

Our stock price is volatile and subject to significant fluctuations.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, medical device, biotechnology and other life sciences companies have historically been particularly volatile. Our common stock traded as low as $23.15 and as high as $41.28 per share during the 12-month

period ended June 30, 2015. Factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

- announcements of technological or medical innovations for the treatment of vascular disease;
- quarterly variations in our or our competitors' results of operations;
- failure to meet estimates or recommendations by securities analysts who cover our stock;
- accusations that we have violated a law or regulation;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- changes in accounting principles;
- actual or anticipated changes in healthcare policy and reimbursement levels; and

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

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

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income or taxes may be limited. In general, an "ownership change" will occur if there is a cumulative change in our ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We may have experienced an ownership change in the past and we may also experience ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards or other pre-change tax attributes to offset U.S. federal and state taxable income or taxes may be subject to limitations.

Risks Related to Government Regulation

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

The PAD Systems received FDA 510(k) clearances in the U.S. for use as a therapy in patients with PAD, and in October 2013, we received PMA to use the CAD System as a therapy in patients with severely calcified CAD. These general clearances and approvals restrict our ability to market or advertise the PAD Systems and the CAD System beyond these uses and could affect our growth.

If we determine to market our orbital technology in the U.S. for other uses, we would need to conduct further clinical trials and obtain premarket approval from the FDA. Clinical trials are complex, expensive, time consuming, uncertain and subject to substantial and unanticipated delays. There is no assurance that we will be able to obtain FDA approval to use our orbital atherectomy technology for applications other than the treatment of PAD and CAD.

We are or will be subject to an extensive set of post-market controls that apply to us as we commercialize our products, including annual PMA reports, Medical Device Reports on serious adverse events, complaint handling and analysis under the FDA's QSR, export controls, advertising and promotion requirements, and potential post-market studies required by the FDA.

We and our suppliers are also subject to regulation by various state authorities, which may inspect our or our suppliers' facilities and manufacturing processes and enforce state regulations. Failure to comply with applicable state regulations may result in seizures, injunctions or other types of enforcement actions.

Our promotion of the PAD and CAD Systems is closely controlled by the FDA and enforcement activities could limit our ability to inform potential customers of the features of the products.

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

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. For example, since commercialization of the PAD Systems, we have had minor instances of recalls, including, in the year ended June 30, 2015, one recall involving thirty CAD Systems due to an issue with the polymer coating on the saline sheath. Any recalls of our products or products that we distribute would divert managerial and financial resources, harm our reputation with customers and have an adverse effect on our financial condition and results of operations.

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

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

The PAD and CAD 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 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.

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

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

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

We are subject to federal and state laws prohibiting “kickbacks” and false and fraudulent claims which, if violated, could subject us to substantial penalties. Additionally, any challenges to or investigations into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

The federal healthcare program Anti-Kickback Statute, and similar state laws, prohibit payments that are intended to induce health care professionals or others either to refer patients or to purchase, lease, order or arrange for or recommend the purchase, lease or order of healthcare products or services. A number of states have enacted laws that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other health care professionals and health care organizations. In addition, some state statutes, most notably laws in Massachusetts and Vermont, impose outright bans on certain gifts to physicians as well as requiring reporting of payments to physicians. Some of these laws, referred to as “aggregate spend” or “gift” laws, carry substantial fines if they are violated. The federal Physician Payments Sunshine Act, or the Sunshine Act, requires us to collect and report certain data on payments and other transfers of value to physicians and teaching hospitals.

It is widely anticipated that public reporting under the Sunshine Act and implementing Open Payments regulations will result in increased scrutiny of the financial relationships between industry, physicians and teaching hospitals. These anti-kickback, public reporting and aggregate spend laws affect our sales, marketing and other promotional, and clinical activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers or users of medical devices. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales offerings, including discount practices, customer support, education and training programs, physician consulting and other service arrangements, and clinical trials. If we were to offer or pay inappropriate inducements to purchase our products, we could be subject to a claim under the federal healthcare program Anti-Kickback Statute or similar state laws. If we fail to comply with particular reporting requirements, we could be subject to penalties under applicable federal or state laws. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payments to Medicare, Medicaid or other third-party payors that are false or fraudulent, or for items or services that were not provided as claimed. Although we do not submit claims directly to government healthcare programs or other payors, manufacturers can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by providing inaccurate billing or coding information to customers, by providing improper financial inducements, or through certain other activities.

In providing billing and coding information to customers, we make every effort to ensure that the billing and coding information furnished is accurate and that treating physicians understand that they are responsible for all treatment decisions. Nevertheless, we cannot provide assurance that the government will regard any billing errors that may be made as inadvertent or that the government will not examine our role in providing information to our customers and physicians concerning the benefits of therapy with our devices. Likewise, our financial relationships with customers, physicians, or others in a position to influence the purchase or use of our products may be subject to government scrutiny or be alleged or found to violate applicable fraud and abuse laws. False claims laws prescribe civil, criminal and administrative penalties for noncompliance, which can be substantial. Moreover, an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business and results of operations.

For example, on May 8, 2014, we received a letter from the U.S. Attorney’s Office for the Western District of North Carolina stating that it is investigating the Company to determine whether we had violated the False Claims Act. The letter enclosed a Civil Investigative Demand (“CID”) for written interrogatories and document requests. On July 8, 2015, the complaint underlying this investigation was unsealed. We have not yet been served the complaint and cannot predict if or when the complaint will be served on us and whether this case will proceed. The government has the option to intervene in a False Claims Act case and take over the prosecution if it concludes that the claims have merit. As of the date hereof, the government has not chosen to intervene in this case. We maintain rigorous policies and procedures to promote compliance with the False Claims Act and other regulatory requirements and intend to vigorously defend this lawsuit, should it proceed. However, we cannot predict when the investigation or this litigation will be resolved, the outcome of the investigation or this litigation, or the potential impact of either on us. The existence of the investigation and litigation and any adverse outcome of either could negatively affect our reputation, be costly to respond to, and harm our business and results of operations.

Regulations related to “conflict minerals” may force us to incur additional expenses, may result in damage to our business reputation and may adversely impact our ability to conduct our business.

Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, the SEC promulgated final rules regarding disclosure of the use of certain minerals, known as conflict minerals, that are mined from the Democratic Republic of the Congo and adjoining countries, as well as procedures regarding a manufacturer's efforts to prevent the sourcing of such minerals and metals produced from those minerals. These disclosure requirements require ongoing due diligence efforts and disclosure obligations. There are costs associated with complying with these disclosure

requirements, including for diligence in regards to the sources of any conflict minerals used in our products, in addition to the cost of remediation and other changes to products, processes, or sources of supply as a consequence of such verification activities. In addition, our ongoing implementation of these rules could adversely affect the sourcing, supply, and pricing of materials used in our products.

Our anticipated international expansion will subject us to increased legal and regulatory requirements, which could have a material effect on our business.

We intend to sell internationally in the future and have commenced the process of seeking approval to do so in both Europe and Japan. Movement into international markets will subject us and our products to different and increased laws and regulations, including foreign medical device regulations; tax laws; increased financial accounting and reporting burdens and complexities; export laws; and the Foreign Corrupt Practices Act and similar anti-corruption laws. Although we have and will continue to implement policies and procedures designed to ensure compliance with these laws, there can be no assurance that all of our employees, contractors, and agents, as well as those companies to which we will outsource certain aspects of our business

operations, including those based in foreign countries where practices that violate such U.S. laws may be customary, will comply with our internal policies. We will incur additional compliance costs associated with global operations, and any alleged or actual violations of these laws and regulations could subject us to government scrutiny, severe criminal or civil fines, sanctions and other liabilities, and prohibitions on business conduct, and could negatively affect our business, reputation, operating results, and financial condition.

Risks Relating to Our Intellectual Property

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

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

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

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

Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not be successful in doing so or the steps taken by us in this regard may not be adequate to detect or deter misappropriation of our technology or to prevent an unauthorized third party from copying or otherwise obtaining and using our products, technology or other information that we regard as proprietary. In addition, we may not have sufficient resources to litigate, enforce or defend our intellectual property rights. Additionally, third parties may be able to design around our patents.

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

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

The medical technology industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. The likelihood that patent infringement or misappropriation claims may be brought against us increases as we achieve more visibility in the marketplace and introduce products to market. We are aware of numerous patents issued to third parties that relate to the manufacture and use of medical devices for the

treatment of vascular disease. The owners of each of these patents could assert that the manufacture, use or sale of our products infringes one or more claims of their patents. There could also be existing patents of which we are unaware that one or more aspects of our technology may inadvertently infringe. In some cases, litigation may be threatened or brought by a patent-holding company or other adverse patent owner who has no relevant product revenues and against whom our patents may provide little or no deterrence.

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive offices are located in our new headquarters, a 125,000 square foot facility in St. Paul, Minnesota, which contains dedicated research and development, training and education, and manufacturing facilities, and our central administrative offices. We also have a 47,000 square foot leased facility in St. Paul, Minnesota, that was used for our prior headquarters. This lease ends in November 2015.

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

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

Item 3. Legal Proceedings.

On May 8, 2014, we received a letter from the U.S. Attorney's Office for the Western District of North Carolina (the "Department of Justice") stating that it is investigating the Company to determine whether we had violated the False Claims Act ("FCA"). The letter enclosed a Civil Investigative Demand ("CID") for written interrogatories and document requests. We are cooperating with the Department of Justice and have provided documents in response to the CID.

On July 8, 2015, the complaint underlying the Department of Justice's investigation was unsealed. The complaint was filed in the United States District Court for the Western District of North Carolina (the "Court") on July 15, 2013 by Travis Thams (the "relator") under a provision of the FCA that allows private citizens the ability to file suit on behalf of the United States and various states. The complaint alleges various causes of action under the federal FCA and several state FCA provisions relating to alleged kickbacks and off-label promotion of medical devices and that this alleged conduct has resulted in false claims being submitted to obtain payment or reimbursement. The relator is seeking, on behalf of the United States, damages in the amount of each allegedly false and fraudulent claim, trebled as per statute, plus civil penalties of up to $11,000 per claim, plus, on behalf of various states, the maximum amounts allowed under various state laws. The aggregate damages and penalties claimed are currently indeterminable as the alleged unlawful claims have not been specified.

We have not yet been served the complaint and cannot predict if or when the complaint will be served on us and whether this case will proceed. The government has the option to intervene in an FCA case and take over the prosecution if it concludes that the claims have merit. As of the date hereof, the Department of Justice has not chosen to intervene in this case. Instead, the Department of Justice wishes to take more time to evaluate the merits of the claims, so it filed a Notice of the United States That It Is Not Intervening At This Time with the Court.

We maintain rigorous policies and procedures to promote compliance with the FCA and other regulatory requirements and intend to vigorously defend this lawsuit, should it proceed. However, we cannot predict when the Department of Justice's investigation or this litigation will be resolved, the outcome of the investigation or this litigation, or the potential impact of either on us.

Item 4. Mine Safety Disclosures.

None.

Executive Officers of the Registrant.

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

Name	Age	Position
David L. Martin	51	President and Chief Executive Officer
Laurence L. Betterley	61	Chief Financial Officer
Kevin Kenny	50	Chief Operating Officer
Paul Koehn	52	Senior Vice President of Quality and Operations
Robert J. Thatcher	60	Chief Healthcare Policy Officer

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 2004 to 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.

Kevin Kenny, Chief Operating Officer. Mr. Kenny joined us in May 2011 as Executive Vice President of Sales and Marketing and was promoted to Chief Operating Officer in February 2015. From 2002 to 2011, Mr. Kenny served in various positions with Medtronic Inc.'s U.S. Spine and Biologics division, including Vice President of Sales. Previously, Mr. Kenny served as Vice President of U.S. sales for Bausch and Lomb and held various sales and marketing leadership roles with B. Braun/McGaw and Smithkline Beecham.

Paul Koehn, Senior Vice President of Quality and Operations. Mr. Koehn joined us in March 2007 as Director of Manufacturing and was promoted to Vice President of Quality and Manufacturing in October 2007. In August 2011, Mr. Koehn became Vice President of Quality and Operations and in September 2013, he became Senior Vice President of Quality and Operations. Previously, Mr. Koehn was Vice President of Operations for Sewall Gear Manufacturing from 2000 to March 2007 and before joining Sewall Gear, Mr. Koehn held various quality and manufacturing management roles with Dana Corporation.

Robert J. Thatcher, Chief Healthcare Policy Officer. 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 and became our Chief Healthcare Policy Officer in July 2013. Previously, Mr. Thatcher was Senior Vice President of TriVirix Inc. from October 2003 to October 2005. Mr. Thatcher has more than 30 years of medical device experience in both large and start-up companies. Mr. Thatcher has held various sales management, marketing management and general management positions at Medtronic, Inc., Schneider USA, Inc. (a former division of Pfizer Inc.), Boston Scientific Corporation and several startup companies.

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

We trade on the Nasdaq Global Market under the symbol "CSII." The following table sets forth the high and low sales prices for our common stock (based upon intra-day trading) as reported by the Nasdaq Global Market:

	Common Stock	
	High	Low
Fiscal Year Ended June 30, 2015		
First quarter	$32.57	$23.59
Second quarter	31.33	23.15
Third quarter	39.68	27.74
Fourth quarter	41.28	25.85
Fiscal Year Ended June 30, 2014		
First quarter	$22.84	$19.00
Second quarter	34.59	18.83
Third quarter	37.73	27.79
Fourth quarter	33.71	23.81

The number of record holders of our common stock on August 21, 2015 was approximately 183. No cash dividends have been previously paid on our common stock and none are anticipated during fiscal year 2016.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Securities Authorized For Issuance Under Equity Compensation Plans

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

Performance Graph

The following graph compares the cumulative total stockholder return of our common stock (“CSII”) with the return of the Standard & Poor's 500 Stock Index (“S&P”) and the S&P Health Care Index (“S&P HC”) from June 30, 2010 through June 30, 2015. The comparisons assume $100 was invested on June 30, 2010 in our common stock, the S&P 500 Stock Index and the S&P Health Care Index and also assumes that any dividends are reinvested. The returns set forth on the following graph are based on historical results and are not intended to suggest future performance.

Item 6. Selected Financial Data.

Five-Year Selected Financial Data
(in thousands, except per share amounts)

	2015	2014	2013	2012	2011
SUMMARY OF OPERATIONS FOR THE FISCAL YEAR:					
Net revenues	$181,544	$136,612	$103,897	$82,490	$78,780
Loss from operations	$(32,637)	$(33,489)	$(22,419)	$(14,466)	$(8,809)
Net loss	$(32,822)	$(35,290)	$(24,037)	$(16,790)	$(11,125)
Net loss per common share - basic and diluted	$(1.04)	$(1.25)	$(1.11)	$(0.93)	$(0.70)
Cash dividends declared per share	$—	$—	$—	$—	$—
FINANCIAL POSITION AT YEAR END:					
Total assets	$171,328	$181,901	$96,897	$63,124	$46,758
Total long-term liabilities	$2,005	$117	$7,652	$13,083	$9,937
Stockholders' equity	$139,435	$152,055	$66,832	$32,189	$21,635

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 innovative solutions for vascular and coronary disease. Our peripheral arterial disease ("PAD") products, the Stealth 360® Peripheral Orbital Atherectomy System ("OAS")(the "Stealth 360"), the Diamondback 360® Peripheral OAS (the "Diamondback 360 Peripheral"), the Diamondback 360® 60cm Peripheral OAS access device, and the Diamondback 360 4 French 1.25 Peripheral OAS access device 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 surgical, catheter and pharmacological treatment alternatives. The micro-invasive devices use smaller access sheaths that can provide procedural benefits and allow physicians to treat PAD patients in the small and tortuous vessels located below the knee through alternative access sites in the ankle and foot as well as in the groin. We no longer market the Diamondback Predator 360°® (the "Predator 360"). We refer to the Stealth 360, Diamondback 360 Peripheral, Diamondback 360 60cm Peripheral OAS, Diamondback 360 4 French 1.25 Peripheral OAS, and Predator 360 collectively in this report as the "PAD Systems."

Our coronary arterial disease ("CAD") product, Diamondback 360® Coronary OAS ("CAD System"), is marketed as a treatment for severely calcified coronary arteries. The CAD System is a catheter-based platform designed to facilitate stent delivery in patients with CAD who are acceptable candidates for percutaneous transluminal coronary angioplasty or stenting due to de novo, severely calcified coronary artery lesions. The CAD System design is similar to technology used in our PAD Systems, customized specifically for the coronary application.

From 1989 to 1997, we engaged in research and development on several different product concepts. Since 1997, we have devoted substantially all of our resources to the development of the PAD Systems and, since 2007, to the approval of our CAD System.

From 2003 to 2005, we conducted numerous bench and animal tests in preparation for application submissions to the U.S. Food and Drug Administration ("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 PAD 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 Peripheral as a therapy in patients with PAD. We commenced commercial introduction of the Diamondback 360 Peripheral in the United States in September 2007. We were granted 510(k) clearance of the Predator 360 in March 2009 and Stealth 360 in Ma