Cardiovascular Systems Inc
Form 10-K
August 24, 2017

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, 2017
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 o No þ
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes o No þ
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) 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 (§ 229.405 of this chapter) 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

Emerging growth company o (Do not check if a smaller reporting company)

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act o

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, 2016, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $765.8 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 18, 2017 was 32,991,788.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the registrant's 2017 Annual Meeting of Stockholders are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this report.

Table of Contents

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 we file 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 19 federal registrations in the U.S. Patent and Trademark Office ("USPTO") of certain marks, including "Diamondback®," a first "CSI®," a second "CSI®," "CSIQ®" "Stealth 360®," a first "CSI®" logo, a second "CSI®" logo, "TAKE A STAND AGAINST AMPUTATION®," "ViperWire®," "ViperWire Advance®," "Viperwire Advance® (Stylized)," "Viperslide®," Viperslide® (Stylized)," "ViperTrack®," "Vipertrack® (Stylized)," 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 "CSIQ (Stylized)," "GLIDEASSIST", and "TAKE A STAND AGAINST AMPUTATION (and Design)." 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 artery 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 both peripheral and coronary commercial applications. Our systems are catheter-based platforms capable of treating a broad range of vessel sizes and plaque types, including calcified plaque, and address many of the limitations associated with other treatment alternatives. We

refer to the Diamondback 360® Peripheral Orbital Atherectomy Systems ("OAS") ("Diamondback 360 Peripheral"), the Stealth 360® OAS ("Stealth 360"), and the products included in the chart below collectively in this annual report on Form 10-K as the "Peripheral OAS."

The United States Food and Drug Administration ("FDA") granted us 510(k) clearance for the following Peripheral OAS as a therapy in patients with peripheral artery disease ("PAD"):

FDA 510(k) Clearance Granted	Product	Commercial Introduction
August 2007	Diamondback 360 Peripheral[(1)]	September 2007
March 2009	Predator 360[(1)]	April 2009
March 2011	Stealth 360	March 2011
February 2014	Diamondback 360 60cm Peripheral	April 2014
April 2015	Diamondback 360 Low Profile Peripheral	July 2015
October 2015	Diamondback 360 1.50 Peripheral	January 2016
October 2015	Diamondback 360 2.00 Peripheral	January 2016
June 2017	Diamondback 360 200cm Peripheral	Expected 2018
June 2017	Diamondback 360 180cm Peripheral	Expected 2018

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

As of June 30, 2017, over 292,000 of our Peripheral OAS have been sold to leading institutions across the United States. Sales of Peripheral OAS during the fiscal year ended June 30, 2017 represented 69% of revenue.

Our coronary product, the Diamondback 360® Coronary OAS ("Coronary OAS"), is a catheter-based platform designed to facilitate stent delivery in patients with coronary artery disease ("CAD") who are acceptable candidates for percutaneous transluminal coronary angioplasty or stenting due to de novo, severely calcified coronary artery lesions. The Coronary OAS design is similar to technology used in our Peripheral OAS, customized specifically for the coronary application. In October 2013, we received premarket approval ("PMA") from the FDA to market the Coronary OAS as a treatment for severely calcified coronary arteries. We commenced a commercial launch that same month and, as of June 30, 2017, over 31,000 Coronary OAS have been sold to leading institutions across the United States. Sales of Coronary OAS during the fiscal year ended June 30, 2017 represented approximately 23% of revenue. In March 2017, the Company received approval from the FDA to market its Diamondback360® Coronary OAS Micro Crown, which is the only atherectomy device designed to both pilot tight, calcific lesions and treat 2.5 to 4mm vessels with a single device. We are planning a limited release of the Coronary OAS Micro Crown in the U.S. in fiscal 2018.

In addition to the Peripheral and Coronary OAS, we offer multiple accessory products required for use with the Peripheral and Coronary OAS. Sales of accessory products, primarily guide wires, represented 8% of revenue during the fiscal year ended June 30, 2017.

In November 2016, we signed an exclusive distribution agreement with Medikit Co., Ltd. to sell the Diamondback 360® Coronary OAS Micro Crown in Japan. In March 2017, we received approval from Japan's Ministry of Health, Labor and Welfare ("MHLW") of our Diamondback 360® Coronary OAS Micro Crown. Pending reimbursement approval, Japan will become the first international market for any CSI product and represents a significant milestone for us.

We will continue to evaluate options for additional international markets to expand the coronary and peripheral opportunities.

Market Overview

Peripheral Artery Disease ("PAD")

Peripheral artery disease is widespread and can be life threatening. The disease is characterized by narrowed, hardened arteries in the legs, limiting blood flow to the legs and 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 non-healing ulcers, infections, gangrene, limb amputation or death.

According to estimates by the American Heart Association (“AHA”), as many as 8 to 12 million Americans have PAD. 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. Physicians manage a significant portion of the PAD diagnosed population by recommending lifestyle changes, such as diet and exercise, and by prescribing prescription drugs, such as statins. While medications, diet and exercise may improve blood flow, they do not treat the underlying obstructions, 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 Artery Disease ("CAD")

Heart disease is the leading cause of death in both men and women in the United States. Coronary artery disease is the most common type of heart disease in the U.S. and is a life-threatening condition. 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 AHA, 15.5 million people in the U.S. (or 6.2% of the adult population) suffer from CAD, the most common form of heart disease. According to the U.S. Centers for Disease Control and Prevention, over 370,000 lives are claimed in the U.S. each year from CAD. According to estimates, significant arterial calcium is present in nearly 40% of patients (Genereux et al., 2014; Bourantas et al., 2014), and severe calcium affects up to 20% of patients (Bourantas et al., 2014), 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 Peripheral OAS and Coronary OAS

Our orbital atherectomy systems represent an innovative approach to the treatment of PAD and CAD that provide physicians and patients with a procedure that addresses many of the limitations of other treatment alternatives. The Peripheral OAS and Coronary OAS devices are single-use catheters that incorporate a control handle and flexible drive shaft with an eccentrically mounted diamond-coated crown. The peripheral device is often used for vessel preparation to enable low pressure percutaneous transluminal angioplasty, including the use of drug-coated balloons ("DCB"), and results in lower use of bailout stents. The coronary device is used to treat severe calcium prior to stent delivery to help facilitate optimal stent expansion and prevent malapposition of stent struts. The OAS treats atherosclerotic plaque, which is harder than a normal vessel wall. The OAS is designed to differentiate between hard, diseased plaque and healthy, compliant arterial tissue, a concept that we refer to as "differential sanding." The diamond-coated crown preferentially engages and sands away harder material, but is designed not to damage more compliant parts of the artery, which flex away from the crown. Physicians position the crown at the site of a lesion containing arterial plaque and orbit the crown against it to sand away the superficial, or surface, plaque and create a smooth lumen, or channel, in the vessel. In addition, the crown's rotating eccentric mass and orbital motion deliver pulsatile mechanical energy into the vessel wall. These pulsatile forces may break up deeper plaque and contribute to compliance change of the diseased segment of the artery.

Components of the OAS

Our OAS uses a single-use, low-profile catheter that travels over our proprietary ViperWire guide wires and is electrically powered by a saline infusion pump that also helps cool the system and remove debris. The Peripheral OAS reduces plaque on peripheral vessel walls by using an orbiting, diamond-coated crown within peripheral arteries. Similarly, the Coronary OAS 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:

- an electrically-powered control handle, which allows movement of the crown and predictable crown location;

- a flexible drive shaft with an eccentrically mounted diamond-coated 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 Peripheral Guide Wire, ViperWire Advance Peripheral Guide Wire with Flex Tip and ViperWire Advance Coronary Guide Wire. The ViperWire guide wires are required for using the OAS and were designed to offer the ability to maneuver through tortuous, twisting blood vessels and cross challenging lesions. The OAS travels over this wire to the lesion and operates on this wire.

ViperSlide Lubricant. ViperSlide is an exclusive lubricant designed to optimize the smooth operation of the OAS.

OAS Pump. The saline infusion pump 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.

Mechanism of Action

The mechanism of action is a function of the centrifugal force generated by the eccentrically mounted crown 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-coated 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 Peripheral OAS allows the user to choose between three rotational speeds and our Coronary OAS Classic Crown 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 particles. The Peripheral OAS 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. The crown for the Diamondback 360 Coronary OAS is available in two configurations: 1.25 millimeter classic crown and the recently-approved 1.25 millimeter micro crown which is designed to both pilot through tight, severely calcified coronary lesions and treat 2.5 to 4mm vessels with a single device.

Centrifugal force propels the crown outward against the arterial wall as the crown rotates. This force is offset by the counterforce exerted by the arterial wall and the guidewire. 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, minimizing the engagement of the diamond-grit and protecting the integrity of the healthy tissue. Diseased tissue is less flexible or non-compliant and provides resistance to the centrifugal force, which generates an opposing force that enables the diamond-coated crown to engage and sand the plaque. The sanded plaque and calcium is broken down into particles generally smaller than circulating red blood cells that are washed away downstream with the patient's natural blood flow.

The small particle size and short treatment time 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 offers the following key benefits:

Strong Safety Profile

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

•

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, as well as constant flushing of particulates during treatment. 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.

- Benefits of Smaller Sheaths. The Diamondback 360 Peripheral OAS portfolio is uniquely compatible with 4 French ("Fr") to 6Fr sheaths. Centrifugal force enables the OAS to treat large vessels through small sheaths; for example, it can treat up to 5mm vessel through a 4Fr sheath. Smaller sheaths may be associated with less femoral bleeding, shortened post-procedure ambulation time and reduced radiation exposure. In addition, the primary complication in peripheral interventions is a vascular access site complication. Exchanging to a larger sheath has been shown to be the strongest predictor of bleeding complication during peripheral interventions.

Proven Efficacy

- Efficacy Demonstrated for Both Peripheral OAS and Coronary OAS.

Peripheral OAS - Our pivotal OASIS clinical trial was a prospective 20-center study that involved 124 patients with 201 lesions treated by the Diamondback 360 Peripheral OAS. 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 OAS successfully met the study endpoints.

Coronary OAS - Our pivotal ORBIT II coronary OAS trial was designed to evaluate the safety and efficacy of OAS in treating de novo severely calcified coronary lesions. The trial met both the primary safety and efficacy endpoints by significant margins. Preparation of severely calcified plaque with the Coronary OAS not only helped facilitate stent delivery, but also improved both peri-procedural and 30-day clinical outcomes compared with the outcomes of historic control subjects in this difficult-to-treat patient population.

- 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 coronary arteries, the OAS enables physicians to treat complex, severely calcified lesions, enabling stent placement in these difficult to treat lesions. To date, the Coronary OAS is the only FDA-approved device approved specifically 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, while the centrifugal motion of the eccentrically mounted crown creates pulsatile forces. Compliance change is achieved as the OAS differentiates between hard, diseased plaque and healthy, compliant arterial tissue, a concept that we refer to as "differential sanding." The diamond-coated crown preferentially engages and sands away harder material, but is designed not to damage more compliant parts of the artery, which flex away from the crown. Physicians position the crown at the site of a lesion containing arterial plaque and orbit the crown against it to sand away the superficial, or surface, plaque and create a smooth lumen, or channel, in the vessel. In addition, the crown's rotating eccentric mass and orbital motion deliver pulsatile mechanical energy into the vessel wall. These pulsatile forces may break up deeper plaque and contribute to compliance change of the diseased segment of the artery. Together, these mechanistic components sufficiently remove or modify hard plaque, allowing for low pressure balloon inflation. The orbital motion and speed of the eccentrically mounted crown increases, thus allowing for continuous reduction of plaque with differential sanding and pulsatile forces, 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 lumen surface, 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 re-narrowing of the arteries.

Ease of Use

- Set Up Time. Given the relative simplicity of the OAS, physicians and lab staff can usually set up and begin using the device in under two minutes.

- 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 Crown Treats Multiple Lesions in Various Sized Vessels. Centrifugal force unique to OAS allows for a single access site to treat multiple lesions, in most cases. In the coronary arteries, Coronary OAS is the only atherectomy device able to treat 2.5 to 4mm vessels with one device through a 6Fr radial approach. 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, which would potentially add time and cost to the procedure.

Multiple Applications

The unique OAS mechanism of action used in both the Peripheral OAS and Coronary OAS 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 stenosed, calcified or both. Reaching and treating these small vessels requires a low profile, which most 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 OAS is effective in treating those vessels. The Peripheral OAS offers a shorter shaft length (60cm), a smaller profile and a more flexible shaft than the predecessors for improved ease of use, and includes a 4 Fr 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, renal insufficiency, or have a family history of heart disease. The pathogenesis of CAD is marked by the accumulation of a fatty material called plaque 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 Diamondback 360 Coronary OAS is the only atherectomy device specifically 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 Helping Limit Hospital 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.

- Trans-Radial Access Provides Multiple Benefits. Treating complex, calcified lesions in the peripheral or coronary arteries remains difficult, particularly where patients may present challenging access sites. The OAS allows for trans-radial access with benefits to both physicians and patients. For physicians, this smaller access site provides lower vascular and bleeding complication rates, faster patient recovery time, and the ability to treat bilateral disease in one setting, address obese patients and work around previous, compromised access sites. For patients, this contributes to comfort during- and post-operation, earlier ambulation, reduced risk of infection, and faster healing.

Retrograde Access Treatment Option Benefits. Many of the patients treated with the Peripheral OAS have advanced PAD and suffer from CLI. These patients often have complex, calcified lesions in their lower leg, which are challenging to access and treat using the traditional femoral artery access site. If left untreated, these cases may result in lower limb amputation. CSI's family of 1.25mm Peripheral OASs with 4Fr compatibility allows for more options to treat those lesions by providing a low-profile system that is fully compatible with alternative access sites in the foot or ankle. Smaller sheaths have been shown to reduce procedure times and decrease complications.

Our OAS Strategy

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

•