Cardiovascular Systems Inc
Form 10-K
August 25, 2016

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, 2016
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 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 o Accelerated filer x 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, 2015, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $475.3 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 19, 2016 was 33,345,785.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the registrant's 2016 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 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 21 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 secon "CSI" logo, "Lumen Library®," "ViperWire®," "ViperWire Advance®,""Viperwire Advance® (Stylized)," "Viperslide®," Viperslide® (Stylized)," "ViperTrack®," "Vipertrack® (Stylized)," "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 "A (Stylized)," "CSIQ," "TAKE A STAND," and "TAKE A STAND AGAINST AMPUTATION." 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 peripheral artery 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 Diamondback 360® Peripheral Orbital Atherectomy System ("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 U.S. 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	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

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

As of June 30, 2016, over 244,000 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, 2016 represented 72% 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, 2016, over 18,000 Coronary OAS have been sold to leading institutions across the United States. Sales of Coronary OAS during the fiscal year ended June 30, 2016 represented approximately 20% of revenue.

In addition to the Peripheral and Coronary OAS, 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 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, 2016.

In October 2014, we received CE Mark for our Stealth 360 device and are currently evaluating the timing and structure of our plans to commercialize our products in Europe.

In July 2016, we submitted an application to Japan's Pharmaceuticals and Medical Devices Agency ("PMDA") for approval of our Diamondback 360® Coronary OAS Micro Crown, our second generation coronary device. Pending approval, Japan would become the first international market for any CSI product and would represent a significant milestone for us. We are currently evaluating potential distribution partners in Japan.

We will continue to evaluate options for international expansion to maximize the coronary and peripheral market opportunities.

Market Overview

Peripheral Artery Disease

Peripheral artery 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, 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

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 United States 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 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, and severe calcium affects up to 20% 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 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 offset diamond-coated crown. The peripheral device is often used for vessel preparation to enable low pressure percutaneous transluminal angioplasty and results in lower use of bail out stents, and many physicians also use OAS to prepare vessels for the use of drug coated balloons. The coronary device is used to treat severe calcium prior to stent delivery to facilitate 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. 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 powered by saline infusion pumps that also help 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:

- a 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 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 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 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 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. Our Coronary OAS 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. 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 Peripheral OAS is 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. Varying catheter lengths allow physicians options to treat via retrograde pedal approach in addition to the common femoral artery access point. The Peripheral OAS is versatile, and by adjusting the speed in conjunction with crown selection, multiple lesions and vessel sizes can be treated. The crown for the Coronary OAS is available in one configuration: 1.25 millimeter classic.

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 is broken down into particles generally

smaller than circulating red blood cells that are washed away downstream with the patient's natural blood flow.

Peripheral OAS 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).

Coronary OAS 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 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. 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 CONFIRM trial. Analysis by an independent pathology laboratory of more than 434 consecutive cross sections of porcine arteries treated with the Stealth 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 coronary ORBIT II trial, with 0.9% perforations device related. Analysis by an independent core-lab 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.

- Benefits of Smaller Sheaths. The Diamondback 360 Peripheral OAS portfolio is uniquely compatible with 4 French (“Fr”) to 6Fr sheaths (1.25mm crowns - 4Fr, 1.5mm crowns - 5Fr, 2.00mm crowns - 6Fr). 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. Access site complications were shown to be 41.4% more frequent in procedures where 7Fr or 8Fr sheaths were used compared to 4Fr to 6Fr (4.5% vs. 3.2%, $p < 0.001$). 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. Because the Predator 360 and Stealth 360 mechanism of action is identical to that of the Diamondback 360 Peripheral OAS, no additional efficacy trials were required by the FDA for 510(k) clearance of either of those systems.

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. 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, as well as 1-year outcomes with target lesion revascularization ("TLR") (4.7%) and TLR in the drug-eluting stent subset (3.4%). ORBIT II patients were tracked out to three years, demonstrating long term durable results with a low TLR rate of 7.8% and TLR in the drug eluting stent subset of 6.6%.

- 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 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, while the centrifugal motion of the eccentrically mounted crown creates pulsatile forces. Compliance change is achieved by sanding away superficial plaque, which also creates an open lumen, and by modification or fractionation of deeper plaque by delivering pulsatile forces into the vessel wall. 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 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 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 re-narrowing 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. 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 2-4mm 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 adds 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 diseased, 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, as demonstrated in our CALCIUM 360° randomized clinical trial, where 100% of the lesions treated with the Peripheral OAS were located below the knee. 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 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 Diamondback 360 Coronary OAS 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 in coronary procedures.

- 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.

- 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.

- Retrograde Access Treatment Option Benefits.. Many of the patients treated with the Peripheral OAS have advanced PAD and suffer from Critical Limb Ischemia. 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 minimally invasive solutions for the treatment of peripheral and coronary artery disease. The key elements of our strategy include:

- Drive Adoption through Our Direct Sales Organization, Medical Education 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 regarding the proper use and application of OAS technology through physician faculty, 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 and payers are increasingly requesting clinical and economic evidence to allow them to make decisions regarding optimal

treatment of patients. We are focused on collecting clinical and economic evidence to demonstrate the advantages of the OAS in treating complex disease states such as peripheral and coronary artery disease. We believe that the clinical advantages and cost effectiveness of our OAS technology will help drive physician utilization of the OAS and sustain ongoing reimbursement coverage for our devices.

- 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 for use with 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 and we have applied for regulatory approval for the next generation coronary OAS device in Japan. 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.

Research and Development Activities

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. A total of 5,698 subjects (4,740 PAD and 958 CAD) have been enrolled in our clinical studies as of June 30, 2016. Our clinical studies incorporate rigorous long-term clinical and healthcare economic data that are critical to improving patient care and ongoing healthcare changes. Both the PAD and CAD studies illustrate the versatility of our technology and our focus on improving the standard of care.

We have completed numerous clinical studies to demonstrate the safety and efficacy of the Peripheral OAS, including our OASIS (pivotal study for clearance of the Peripheral OAS), CONFIRM post market registries (CONFIRM I, II, and III), CALCIUM 360°, COMPLIANCE 360°, and TRUTH. The results of these studies consistently demonstrate that the Peripheral OAS provides predictable, repeatable and durable results that differentiate it from other PAD treatments. We recently completed enrollment in the LIBERTY 360° study and began enrollment in the OPTIMIZE BTK study.

The following PAD clinical studies were completed or in process during fiscal 2016:

- TRUTH. This post-market, prospective, single-arm study utilized intravascular ultrasound (“IVUS”) imaging and angiography to assess procedural outcomes in twenty-five subjects with symptomatic PAD treated with orbital atherectomy and adjunctive balloon angioplasty. The independent IVUS Core Lab analysis demonstrated that the orbital atherectomy device modified the calcified component of the plaque burden. At twelve months, the target lesion revascularization rate was 8.2%. The final TRUTH study results were published in Vascular and Endovascular Surgery (October 2015).

- LIBERTY 360°. This prospective, observational, multi-center clinical study will evaluate the procedural and long-term clinical, quality of life and economic outcomes of endovascular device interventions, including orbital atherectomy, for the treatment of PAD. We expect the results from this study to increase our understanding of the clinical and economic outcomes of endovascular treatment for PAD patients, including those with the most advanced form of the disease (Rutherford 6). Enrollment of over 1,200 subjects at 51 sites in the United States was recently completed. LIBERTY 360° baseline demographic data for the first 600 patients was presented in a late-breaking presentation at the International Symposium on Endovascular Therapy (February 2016). The LIBERTY 360° interim demographic analysis showed that the prevalence of diabetes and renal disease increased significantly as the PAD disease state progresses from Rutherford 2-3 (Claudicant) to Rutherford 6 (CLI). In addition, the data seems to indicate racial disparity in PAD/CLI treatment, which warrants further investigation. LIBERTY 360° subjects will be followed for up to five years.

- OPTIMIZE BTK. This post-market, multi-center, randomized clinical study conducted in Europe will evaluate the acute and long-term clinical outcomes of orbital atherectomy with adjunctive drug-coated balloon ("DCB") angioplasty versus DCB angioplasty alone in PAD patients with calcified, below-the-knee lesions. Fifty evaluable subjects will be enrolled in OPTIMIZE BTK and will be followed for up to two years.

CAD, the most common form of heart disease, continues to affect more patients worldwide. Percutaneous coronary intervention of calcified lesions is associated with procedural complications, stent malapposition, and high revascularization and MACE rates. We have conducted two clinical studies to evaluate the safety and efficacy of the Coronary OAS Classic Crown device: the ORBIT I feasibility study and the ORBIT II pivotal study. The Coronary OAS Micro Crown device is currently under investigation in the COAST study. The following CAD clinical studies were completed or in process during fiscal 2016:

- ORBIT II. This prospective, multi-center, single-arm Investigational Device Exemption ("IDE") study was conducted to evaluate the safety and efficacy of the Coronary OAS Classic Crown in treating de novo, severely calcified coronary lesions and enrolled 443 subjects at 49 US sites. Two year ORBIT II study results were recently published in Catheterization and Cardiovascular Interventions (April 2016). The final ORBIT II 3-year data was presented at the Society for Cardiovascular Angiography and Interventions conference in a featured clinical research presentation (May 2016). The overall 3-year MACE rate was 23.5%, including 6.7% cardiac death, 10.2% target vessel revascularization, and 11.2% myocardial infarction.

- Coronary Flow Reserve. This prospective, single-arm, multi-center, post-market study will evaluate coronary flow reserve after treatment with the Coronary OAS Classic Crown and stenting of de novo, severely calcified coronary lesions. Enrollment of the fifteen subjects was completed in May 2016. Study results are pending following completion of analysis.

- COAST. This prospective, single-arm, multi-center, global IDE study is designed to evaluate the safety and efficacy of the next-generation Coronary OAS Micro Crown in treating patients with severely calcified lesions. CSI completed COAST enrollment of 100 patients, including 74 patients at 12 sites in the United States and 26 patients at five sites in Japan, in July 2015. The 30-day study results were presented at the Cardiovascular Research Technologies conference in a late-breaking presentation (February 2016). In the COAST study, successful stent delivery was achieved in 99.0% of the subjects and 30-day freedom from MACE was 85.0%.

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.

Development Activities

Our product research and development activities are dedicated to the development and commercialization of products that serve the peripheral and coronary vascular disease space, with emphasis towards high margin products and complex arterial disease states treated by our primary customers. The focus and value proposition of our products is to enable positive acute and long-term clinical outcomes, with efficiency and predictability, in challenging patient subsets.

Research and development resources have been strategically allocated between opportunities that maximize the clinical effectiveness and user satisfaction of our OAS product line and the development of additional products that offer portfolio diversification and incremental revenue opportunities.

Specific to the peripheral vascular disease market, we will continue our commitment to patients suffering from CLI through a breadth of above-the-knee and below-the-knee differentiated products that treat or uniquely expand the ability of our devices to treat obstructive lesions throughout the leg and foot. Most recently, we launched the Diamondback 360 Low Profile Peripheral, a line of next generation low profile orbital atherectomy devices that enable physicians to intervene through 4Fr and 5Fr access sheaths. Low profile devices offer numerous benefits, including a reduction in access site complications, improved device deliverability, compatibility with alternative access sites and a reduction in post-procedure time to ambulation. Specific to the coronary vascular disease market, we are building a portfolio of differentiated products that are used to treat complex CAD. We are currently seeking FDA and Japanese PMDA approval of a next generation coronary OAS that utilizes a micro crown design and distal tip sanding surface that aid in crossing sub-total occlusion lesions. Emphasis in both franchises is placed on novel and differentiated devices that address unmet or under-met clinical or technical needs.

Research and development expenses for the years ended June 30, 2016, 2015, and 2014 were $25.9 million, $31.0 million and $21.1 million, respectively.

Sales and Marketing

We market and sell our products through a direct sales force in the United States. Revenues for the years ended June 30, 2016, 2015, and 2014 were $178.2 million, $181.5 million and $136.6 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 medical conferences, seminars, peer-reviewed journals and marketing materials. Our sales and marketing program focuses on:

- 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.

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 are located in 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. 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 approximately 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 fully staffed and equipped, also has the capacity to produce approximately 75,000 devices per shift annually. This facility has finished goods storage capacity for greater than 15,000 devices and other accessory products and over 500 saline infusion pumps.

We believe that our facilities in Minnesota and Texas will provide adequate production, assembly, and warehousing capacity 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 (“EU”), the European Free Trade Association and countries that have entered into Mutual Recognition Agreements with the EU. We are ISO 13485:2003 certified, and our renewal is due by December 2018. 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. We are registered as a Foreign Medical Device Manufacturer in Japan and our registration certificate renewal is due by June 2021.

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 devices compete with a variety of other products or devices for the treatment of vascular disease, including stents, balloon angioplasty catheters and atherectomy catheters, as well as products used in vascular surgery. Large competitors in the stent and balloon angioplasty market segments include Abbott

Laboratories, Boston Scientific, Cook Medical, Johnson & Johnson, 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 high-speed rotational atherectomy systems either currently on the market or in development that also generate an orbital motion with an eccentric solid abrasive crown to create lumens with diameters that are larger than the diameter of the abrasive crown 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 Peripheral OAS and Coronary OAS compete primarily on the basis of:

- safety and efficacy, even in calcified plaque;
- low profile and alternative access site capabilities;
- predictable clinical performance;
- availability of clinical data;
- ease of use;
- economic benefit;
- key opinion leader support and customer base; and
- customer service and support.

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 2016, we held 53 issued U.S. patents and have 52 U.S. patent applications pending, as well as 276 issued or granted foreign patents and 158 foreign patent applications, each of which corresponds to aspects of our U.S. patents and applications. Our issued U.S. patents expire between 2016 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 Peripheral OAS and Coronary OAS. 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 Peripheral OAS and Coronary OAS.

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 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 in November 2013 and the Diamondback 360 60cm Peripheral in February 2014. The Diamondback 360 Low Profile Peripheral received FDA clearance in April 2015. We received clearance of the ViperWire Advance Flex Tip Guide Wire in June 2015. The Diamondback 360 1.50 Peripheral and Diamondback 360 2.00 Peripheral were granted 510(k) clearance in October 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 approval from the FDA to market the Diamondback 360 Coronary OAS as a treatment for severely calcified coronary arteries and subsequently commenced a controlled commercial launch of the Coronary OAS. In 2014, we initiated the COAST study, an IDE clinical trial, to evaluate the safety and efficacy of the next-generation Coronary OAS in treating patients with severely calcified lesions. We completed COAST enrollment of 100 patients, including 74 patients at 12 sites in the United States and 26 patients at five sites in

Japan, in July 2015.

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
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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 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 (the "DOJ") stating that it is investigating us to determine whether we had violated the False Claims Act. On June 28, 2016, we entered into a Settlement Agreement with the United States of America, acting through the DOJ and on behalf of the Office of Inspector General of the Department of Health and Human Services (the "OIG"), and Travis Thams, who filed the qui tam complaint underlying the DOJ's investigation (the "Civil Action"), to resolve the investigation by the DOJ and the Civil Action, with no admission of liability. In connection with the resolution of this matter, we entered into a five-year Corporate Integrity Agreement with the OIG. 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 EU, 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 EU with respect to medical devices. The EU 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 EU, 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 EU is required in order for a manufacturer to commercially distribute the product throughout the EU.

As noted above, in July 2016, we submitted an application to Japan's Pharmaceuticals and Medical Devices Agency (“PMDA”) for approval of our Coronary OAS Micro Crown. Pending approval, Japan would become the first international market for any CSI product. As part of our anticipated Japan commercialization process we will be subject to the requirements of the Japanese Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (the “PMD Act”). Our quality management system and products will be subject to review and examination by PMDA and subject to approval and enforcement by Japan’s Ministry of Health, Labor and Welfare. The critical suppliers named in our application will also be subject to this review and examination for the activities they perform for us. Non-compliance with the PMD Act could result in revocation or suspension of our license, revocation of approvals, and criminal sanctions such as fines and/or imprisonment.

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, 2016, we had 581 employees, including 130 employees in manufacturing, 323 employees in sales and marketing, 65 employees in general and administrative, and 63 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.

Executive Officers of the Registrant.

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

Name	Age	Position
Scott R. Ward	56	President and Chief Executive Officer
Laurence L. Betterley	62	Chief Financial Officer
Kevin J. Kenny	51	Chief Operating Officer
Laura Gillund	55	Chief Talent Officer
Paul Koehn	53	Senior Vice President of Manufacturing and Operations
Alexander Rosenstein	44	General Counsel and Corporate Secretary

Scott R. Ward, President and Chief Executive Officer. Mr. Ward has been a member of our Board of Directors since 2013 and has served as Chairman of our Board of Directors since November 2014. Mr. Ward served as our Interim President and Chief Executive Officer commencing in November 2015, and in August 2016, Mr. Ward was appointed as our regular full-time President and Chief Executive Officer. Since 2013, Mr. Ward has been one of the Managing Directors at SightLine Partners. Following his appointment as our President and Chief Executive Officer, Mr. Ward will continue to be a Managing Director of Sightline Opportunity Management Fund II, LLC and may provide limited advisory and consulting services to Sightline Partners in this capacity. From 1981 to 2010, Mr. Ward was employed by Medtronic, Inc. and held a number of senior leadership positions. Mr. Ward was Senior Vice President and President of Medtronic's CardioVascular business from May 2007 to November 2010. Prior to that he was Senior Vice President and President of Medtronic's Vascular business from May 2004 to May 2007, Senior Vice President and President of Medtronic's Neurological and Diabetes Business, from February 2002 to May 2004, and was President of Medtronic's Neurological business from January 2000 to January 2002. He was Vice President and General Manager of Medtronic's Drug Delivery Business from 1995 to 2000. Prior to that, Mr. Ward led Medtronic's Neurological Ventures in the successful development of new therapies. Mr. Ward serves on the boards of several private companies. Until April 4, 2016, Mr. Ward was the Chairman of the Board of Creganna Medical. Mr. Ward served as a member of the Board of Surmodics, Inc. from September 2010 to March 2015.

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 J. 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.

Laura Gillund, Chief Talent Officer. Ms. Gillund joined us in September 2013 as Vice President of Human Resources and Professional Development and was promoted to Chief Talent Officer in April 2016. Previously, Ms. Gillund was Vice President of Human Resources for C.H. Robinson Worldwide, Inc. from August 2002 to May 2012. Ms. Gillund serves as a member of the Board of Allina Health System.

Paul Koehn, Senior Vice President of Manufacturing 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. In 2016, his title changed to Senior Vice President of Manufacturing 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.

Alexander Rosenstein, General Counsel and Corporate Secretary. Mr. Rosenstein joined us in September 2014 as Corporate Legal and Compliance Counsel, became Corporate Secretary in November 2014, and was promoted to General Counsel in March 2015. From October 2005 to September 2014, Mr. Rosenstein was an attorney at Fredrikson & Byron, P.A., which provides legal services to us from time to time.

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 $56.0 million, $32.8 million, and $35.3 million for the years ended June 30, 2016, 2015, and 2014, respectively. As of June 30, 2016, we had an accumulated deficit of approximately $327.4 million. We commenced commercial sales of the Peripheral OAS in September 2007 and the Coronary OAS in October 2013, and our short commercialization experience makes it difficult for us to predict future performance. We expect to continue to incur significant expenses for sales and marketing, research and development, and manufacturing as we continue to commercialize the Peripheral OAS and the Coronary OAS and develop and commercialize future versions of the Peripheral OAS, the Coronary OAS, and any future products. Additionally, we expect that our general and administrative expenses may increase to support business growth. We instituted a number of cost reduction initiatives in the year ended June 30, 2016, which, combined with revenue growth, may reduce our net losses in future periods. However, if we are unable to balance revenue growth and cost management, our operating losses are likely to continue.

We may be unable to sustain our historical revenue growth.

Other than a 4.9% decline in revenue from sales of our Peripheral OAS in the most recent fiscal year, our revenue from sales of our OAS devices has grown in each of the fiscal years since we began commercialization in September 2007. Our ability to increase our revenues in future periods will depend on our ability to increase sales of the OAS devices 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 Peripheral OAS, the Coronary OAS and future products may never achieve broad market acceptance.

The Peripheral OAS, the Coronary OAS, 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 Peripheral OAS and Coronary OAS;
- the extent to which we are successful in educating physicians about PAD and CAD in general and the existence and benefits of the Peripheral OAS and the Coronary OAS in particular;
- the strength of our marketing and distribution infrastructure;
- the level of education and awareness among physicians and hospitals concerning our products; and
- our reputation among physicians and hospitals.

Failure of the Peripheral OAS and Coronary OAS 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 Peripheral OAS and the Coronary OAS, 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 Peripheral OAS and the Coronary OAS 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.

In addition, in June 2016, we entered into a Settlement Agreement with the United States of America, acting through the U.S. Attorney for the Western District of North Carolina (the “DOJ”) and on behalf of the Office of Inspector General of the Department of Health and Human Services (the “OIG”), and Travis Thams, and a five-year Corporate Integrity Agreement with the OIG. In the event of a breach of the Settlement Agreement or the Corporate Integrity Agreement, we could be excluded from participation in federal health care programs. 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. Although the excise tax has been suspended by Congress until the end of 2017, its status is unclear for 2018 and subsequent years. 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 Peripheral OAS and Coronary OAS. 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 Peripheral OAS and the Coronary OAS in a large number of patients have not been studied and the results of short-term clinical use of the Peripheral OAS or the Coronary OAS 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 Peripheral OAS and the Coronary OAS 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 Peripheral OAS and the Coronary OAS and materially harm our business.

We face significant competition, must innovate to stay competitive, and may be unable to sell the Peripheral OAS or the Coronary OAS 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. In addition, increased consolidation in the healthcare industry has resulted in companies with greater market power, which increases competition for goods and services.

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 Peripheral OAS and the Coronary OAS or may need to depend on third parties to manufacture the products.

We have limited experience in commercially manufacturing the Peripheral OAS, even less experience in commercially manufacturing the Coronary OAS 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 Peripheral OAS and the Coronary OAS 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 Peripheral OAS and Coronary OAS 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 Peripheral OAS and the Coronary OAS. In some cases, we do not have long-term supply agreements with, or guaranteed commitments from, our suppliers. 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 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.

We have increased the size of our organization and may need to do so in the future, 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.

We have significantly expanded the size of our organization over the past two years, particularly in the number of sales and marketing personnel, and may need to do so in the future. 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.

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 $7.50 and as high as $32.91 per share during the 12-month period ended June 30, 2016. 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;
- failure to meet our own financial estimates;
- accusations that we have violated a law or regulation;
- significant litigation;
- 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.

We currently are involved in litigation, and may face future claims, that could adversely affect our business and financial results, divert management's attention from our business, and subject us to significant liabilities.

On February 12, 2016, a stockholder purporting to represent a class of persons who purchased our securities between September 12, 2011 and January 21, 2016 filed a lawsuit against us and certain of our officers in the United States District Court for the Central District of California, Paradis v. Cardiovascular Systems, Inc., et al., 2:16-cv-01011 (C.D. Cal.). The lawsuit alleges that we made materially false and misleading statements and failed to disclose material adverse facts about our business, operational and financial performance, in violation of federal securities laws, relating to (1) alleged kickbacks to health care providers, (2) alleged off-label promotion of medical devices, and (3) alleged violations of the Food and Drug Administration's laws and regulations in connection with our medical devices. On March 4, 2016, a second stockholder filed a similar lawsuit against us and certain of our officers in the United States District Court for the District of Minnesota, Shoemaker v. Cardiovascular Systems, Inc. et al., 0:16-cv-00568 (D. Minn.). The plaintiffs seek unspecified monetary damages on behalf of the alleged class, interest, and attorney's fees and costs of litigation. On April 12, 2016, four motions for appointment as lead plaintiff were filed in the Paradis action and three of the four proposed plaintiffs also filed a motion for appointment as lead plaintiff in the Shoemaker action. On April 26, 2016, the Paradis action was voluntarily dismissed by plaintiffs in favor of the Shoemaker action. That same day, the Shoemaker court entered an order appointing the City of Miami Fire Fighters' & Police Officers' Retirement Trust and the County Retirement Systems as Co-Lead Plaintiffs for representing the putative class.

In addition, on May 10, 2016, a stockholder derivative action was filed in the United States District Court for the District of Minnesota naming us as nominal defendant and certain of our current and former executive officers and directors as defendants. The complaint alleges that these current and former executive officers and directors breached their fiduciary duties and unjustly enriched themselves by failing to oversee our business, operations, and prospects,

relating to the alleged off-label promotion of medical devices and alleged kickbacks to health care providers. The complaint includes claims for breach of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement and waste of corporate assets.

Although we believe that these lawsuits are without merit and intend to defend ourselves vigorously, we are not able to predict the ultimate outcome of these lawsuits. It is possible that they could cause us to incur substantial costs and that they could be resolved adversely to us, result in substantial damages, result in or be connected to additional claims, and divert management's attention and resources, any of which could harm our business. While we maintain director and officer liability insurance, the amount of insurance coverage may not be sufficient to cover these claims and other claims to which we may become subject, and the continued availability of this insurance cannot be assured. Protracted litigation, including any adverse outcomes, may have an adverse impact on our business, results of operations or financial condition and could subject us to adverse publicity and require us to incur significant legal fees.

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.

An interruption in or breach of security of our information or manufacturing systems could cause a loss of business or damage to our reputation.

We rely on information and communication systems in our manufacturing and in the conduct our business. If there is any failure or interruption of these systems, such an incident could cause failures or disruptions in our customer relationship systems or product manufacturing. In addition, we could be subject to a cyber incident, such as an intentional attack or an unintentional event that involves a third party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data, or result in release of our confidential information. The occurrence of any failures, interruptions or cyber incidents could cause a loss of business or damage to our reputation and have a material effect on our business, financial condition, results of operations and cash flows.

Risks Related to Government Regulation

Our ability to market the Peripheral OAS in the United States is limited to use as a therapy in patients with PAD and our ability to market the Coronary OAS 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.

We received FDA 510(k) clearances in the U.S. for use of the Peripheral OAS as a therapy in patients with PAD, and we received PMA to use the Coronary OAS as a therapy in patients with severely calcified CAD. These general clearances and approvals restrict our ability to market or advertise the Peripheral OAS and the Coronary OAS 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 Peripheral OAS and the Coronary OAS is closely controlled by the FDA and enforcement activities could limit our ability to inform potential customers of the features of the products.

The Peripheral OAS or the Coronary OAS 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 Peripheral OAS, we have had minor instances of recalls, including, in the year ended June 30, 2016, one recall involving thirty-eight ViperWire Advance Peripheral Guide Wire shelf cartons due to a missing use by date. 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 Peripheral OAS or the Coronary OAS is 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 Peripheral OAS or the Coronary OAS 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 Peripheral OAS or the Coronary OAS 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 Peripheral OAS or the Coronary OAS 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.

In addition, we have agreements with federal, state and local government agencies and third-party healthcare providers that receive government funding to sell our products. We are subject to extensive regulatory compliance obligations in the award, performance and administration of our government contracts, including regulations relating to procurement integrity, pricing protection, export control, government security, employment practices, accuracy of records and the recording of costs. The other parties to these agreements have the right to audit us to determine whether we are in compliance with these agreements. Failure to comply with these regulations and requirements could result in reductions of the value of contracts, contract modifications or termination, the assessment of penalties and fines, and/or suspension or debarment from government contracting or subcontracting in the future, any of which could negatively affect our financial condition and results of 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, 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.

On May 8, 2014, we received a letter from the DOJ stating that it is investigating us to determine whether we had violated the False Claims Act, and on June 28, 2016, we entered into a Settlement Agreement with the United States of America, acting through the DOJ and on behalf of the OIG, and Travis Thams, who filed the qui tam complaint underlying the DOJ's investigation (the "Civil Action"), to resolve the investigation by the DOJ and the Civil Action. The existence of the investigation and subsequent settlement could negatively affect our reputation and harm our business and results of operations. In addition, the release we received from the government in the Settlement Agreement related to particular conduct alleged in the complaint underlying the investigation. If the government determines that other conduct alleged in the complaint for which the government did not grant us a release merits additional investigation or if the government pursues any action against us relating to this other alleged conduct, then we may need to expend additional amounts to defend ourselves, our management

would undergo the distraction of additional investigation and potential litigation, our reputation could be harmed, and our business and results of operations could be materially adversely affected.

Compliance with the terms and conditions of our Corporate Integrity Agreement requires significant resources and management time and, if we fail to comply, we could be subject to penalties or, under certain circumstances, excluded from government healthcare programs, which would materially adversely affect our business.

On June 28, 2016, we entered into a five-year Corporate Integrity Agreement with the OIG. The Corporate Integrity Agreement requires that we maintain our existing compliance programs and imposes certain expanded compliance-related requirements during the term of the Corporate Integrity Agreement, including establishment of specific procedures and requirements regarding consulting activities, co-marketing activities and other interactions with healthcare professionals and healthcare institutions and the sale and marketing of our products; ongoing monitoring, reporting, certification and training obligations; and the engagement of an independent review organization to perform certain auditing and reviews and prepare certain reports regarding our compliance with federal health care programs. Maintaining the broad array of processes, policies and procedures necessary to comply with the Corporate Integrity Agreement will require a significant portion of management’s attention and the application of significant resources. The costs associated with implementation of and compliance with the Corporate Integrity Agreement could be substantial and may be greater than we currently anticipate. In addition, while we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws, all potentially applicable foreign regulations and/or laws and/or all requirements of the Corporate Integrity Agreement. In the event of a breach of the Corporate Integrity Agreement, we could become liable for payment of certain stipulated penalties or could be excluded from participation in federal health care programs. The costs associated with compliance with the Corporate Integrity Agreement, or any liability or consequences associated with its breach, could have an adverse effect on our business, revenues, earnings and cash flows.

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 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.

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.

Resolution of Department of Justice Legal Investigation

On May 8, 2014, we received a letter from the U.S. Attorney's Office for the Western District of North Carolina (the "DOJ") stating that it is investigating us to determine whether we had violated the False Claims Act ("FCA"). On July 8, 2015, the qui tam complaint underlying the Department of Justice's investigation, which was filed by Travis Thams (the "Relator") in the United States District Court for the Western District of North Carolina, Charlotte Division (the "Court"), was unsealed (the "Civil Action").

On June 28, 2016, we entered into a Settlement Agreement (the "Settlement Agreement") with the United States of America, acting through the DOJ and on behalf of the Office of Inspector General of the Department of Health and Human Services (the "OIG"), and the Relator, to resolve the investigation by the DOJ and the Civil Action. Under the Settlement Agreement, we will pay $8.0 million (the "Settlement Payment"), as follows: an initial payment of $3.0 million, which we paid on July 1, 2016, with the remaining $5.0 million, which bears interest at 1.8% per annum, payable in 11 equal quarterly installments, beginning January 1, 2017. We also paid Relator's reasonable expenses, costs and attorney's fees. The Settlement Agreement contains no admissions of liability on our part. The United States and the Relator have agreed to release us from any civil or administrative monetary liability arising from allegations that we caused the submission of false claims to federal health care programs based on alleged violations of the Anti-Kickback Statute in connection with alleged marketing arrangements and practice development activities conducted on behalf of physicians. The OIG has agreed, conditioned upon our full payment of the Settlement Payment, to release its permissive exclusion rights and to refrain from instituting proceedings to exclude us or our affiliates from participating in Medicare, Medicaid or other Federal health care programs.

On July 1, 2016, the DOJ and the Relator filed a joint notice of dismissal of the Civil Action, with the United States dismissing with prejudice the claims asserted in the Civil Action that are covered under the Settlement Agreement and any remaining claims without prejudice, and the Relator dismissing the Civil Action in its entirety with prejudice, except for the Relator's claim for statutory attorneys' fees and costs. On July 11, 2016, the Court issued an order consistent with the joint notice of dismissal. On August 11, 2016, the parties filed a Stipulation of Dismissal with Prejudice voluntarily dismissing the attorney's fees and costs claim with prejudice. The Court will retain jurisdiction over the parties to the extent necessary to enforce the terms and conditions of the Settlement Agreement.

In connection with the resolution of this matter, we entered into a five-year corporate integrity agreement (the "Corporate Integrity Agreement") with the OIG. The Corporate Integrity Agreement requires that we maintain our existing compliance programs and imposes certain expanded compliance-related requirements during the term of the Corporate Integrity Agreement, including establishment of specific procedures and requirements regarding consulting activities, co-marketing activities and other interactions with healthcare professionals and healthcare institutions and

the sale and marketing of our products; ongoing monitoring, reporting, certification and training obligations; and the engagement of an independent review organization to perform certain auditing and reviews and prepare certain reports regarding our compliance with federal health care programs. In the event of a breach of the Corporate Integrity Agreement, we could become liable for payment of certain stipulated penalties or could be excluded from participation in federal health care programs.

Stockholder Securities Litigation

On February 12, 2016, a stockholder purporting to represent a class of persons who purchased our securities between September 12, 2011 and January 21, 2016 filed a lawsuit against us and certain of our officers in the United States District Court for the Central District of California, Paradis v. Cardiovascular Systems, Inc., et al., 2:16-cv-01011 (C.D. Cal.). The lawsuit alleges that we made materially false and misleading statements and failed to disclose material adverse facts about our business, operational and financial performance, in violation of federal securities laws, relating to (1) alleged kickbacks to health care providers, (2) alleged off-label promotion of medical devices, and (3) alleged violations of the Food and Drug Administration's laws and regulations in connection with our medical devices. On March 4, 2016, a second stockholder filed a similar lawsuit against us and certain of our officers in the United States District Court for the District of Minnesota, Shoemaker v. Cardiovascular Systems, Inc. et al., 0:16-cv-00568 (D. Minn.). The plaintiffs seek unspecified monetary damages on behalf of the alleged class, interest, and attorney's fees and costs of litigation.

On April 12, 2016, four motions for appointment as lead plaintiff were filed in the Paradis action and three of the four proposed plaintiffs also filed a motion for appointment as lead plaintiff in the Shoemaker action.

On April 26, 2016, the Paradis action was voluntarily dismissed by plaintiffs in favor of the Shoemaker action. That same day, the Shoemaker court entered an order appointing the City of Miami Fire Fighters' & Police Officers' Retirement Trust and the County Retirement Systems as Co-Lead Plaintiffs for representing the putative class. On June 28, 2016, the Co-Lead Plaintiffs filed a new complaint. Our response to this complaint is due on August 29, 2016.

We believe that this lawsuit is without merit and we intend to defend ourselves vigorously.

Stockholder Derivative Action

On May 10, 2016, a stockholder derivative action was filed in the United States District Court for the District of Minnesota naming us as nominal defendant and certain of our current and former executive officers and directors as defendants. The complaint alleges that these current and former executive officers and directors breached their fiduciary duties and unjustly enriched themselves by failing to oversee our business, operations, and prospects, relating to the alleged off-label promotion of medical devices and alleged kickbacks to health care providers. The complaint includes claims for breach of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement and waste of corporate assets. We believe that the lawsuit is without merit and intend to defend ourselves vigorously.

Item 4. Mine Safety Disclosures.

None.

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, 2016		
First quarter	$32.91	$14.91
Second quarter	17.53	11.80
Third quarter	15.14	7.50
Fourth quarter	18.90	11.45
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

The number of record holders of our common stock on August 19, 2016 was approximately 165. No cash dividends have been previously paid on our common stock and none are anticipated during fiscal year 2017.

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, 2011 through June 30, 2016. The comparisons assume $100 was invested on June 30, 2011 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)

	2016	2015	2014	2013	2012
SUMMARY OF OPERATIONS FOR THE FISCAL YEAR:					
Net revenues	$178,184	$181,544	$136,612	$103,897	$82,490
Loss from operations	$(56,077)	$(32,637)	$(33,489)	$(22,419)	$(14,466)
Net loss	$(56,024)	$(32,822)	$(35,290)	$(24,037)	$(16,790)
Net loss per common share - basic and diluted	$(1.72)	$(1.04)	$(1.25)	$(1.11)	$(0.93)
Cash dividends declared per share	$—	$—	$—	$—	$—
FINANCIAL POSITION AT YEAR END:					
Total assets	$142,406	$171,328	$181,901	$96,897	$63,124
Total long-term liabilities	$6,010	$2,005	$117	$7,652	$13,083
Stockholders' equity	$100,897	$139,435	$152,055	$66,832	$32,189

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 Diamondback 360® Peripheral Orbital Atherectomy System ("OAS") ("Diamondback 360 Peripheral"), the Diamondback® 360 cm Peripheral OAS, the Diamondback 360 4 French 1.25 Peripheral OAS, the Diamondback 360 1.50 Peripheral OAS, and the Diamondback 360 2.00 Peripheral OAS, and the Stealth 360® Peripheral OAS ("Stealth 360"), are catheter-based platforms capable of treating a broad range of plaque types in leg arteries both above and below the knee and address many of the limitations associated with existing 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 even 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 refer to each of the products above in this report as the "Peripheral OAS."

Our coronary arterial disease ("CAD") product, Diamondback 360® Coronary OAS ("Coronary OAS"), is marketed as a treatment for severely calcified coronary arteries. The Coronary OAS 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 Coronary OAS design is similar to technology used in our Peripheral OAS, 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 Peripheral OAS and, since 2007, to the approval of our Coronary OAS.

In 2006, we obtained an investigational device exemption from the U.S. Food and Drug Administration (“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 March 2011. We no longer market the Predator 360. We received 510(k) clearance of the Diamondback 360 60cm Peripheral OAS in March 2014, in April 2015, we received 510(k) clearance of the Diamondback 360 4 French 1.25 Peripheral OAS, and in October 2015, we received 510(k) clearance of the Diamondback 360 1.50 and 2.00 Peripheral OAS.

We have developed modified versions of the Peripheral OAS to treat coronary arteries. A coronary application required us to conduct a clinical trial and file a premarket approval ("PMA") application, and obtain approval from the FDA. In March 2013, we completed submission of our PMA application to the FDA for our orbital atherectomy system to treat calcified coronary arteries. In October 2013, we received PMA from the FDA to market the Coronary OAS as a treatment for severely calcified coronary arteries. We commenced a commercial launch of our Coronary OAS following receipt of PMA.

We market the Peripheral and Coronary OAS in the United States through a direct sales force and expend significant capital on our sales and marketing efforts to expand our customer base and utilization per customer. We assemble at our facilities the saline infusion pump and the single-use catheter used in the Peripheral OAS with components purchased from third-party suppliers, as well as with components manufactured in-house. Supplemental products are purchased from third-party suppliers.

In October 2014, we received CE Mark for our Stealth 360 device and are currently evaluating the timing and structure of our plans to commercialize our products in Europe.

In July 2016, we submitted an application to Japan's Pharmaceuticals and Medical Devices Agency ("PMDA") for approval of our Diamondback 360® Coronary OAS Micro Crown, our second generation coronary device. Pending approval, Japan would become the first international market for any CSI product and would represent a significant milestone for us. We are currently evaluating potential distribution partners in Japan.

As of June 30, 2016, we had an accumulated deficit of $327.4 million. We expect our losses to decline as we balance revenue growth with a pathway to profitability and positive cash flow. To date, we have financed our operations primarily from the issuance of common and preferred stock, convertible promissory notes, and debt.

FINANCIAL OVERVIEW

Net Revenues. We derive substantially all of our revenues from the sale of Peripheral OAS, the Coronary OAS and other ancillary products. The Peripheral OAS and Coronary OAS each use a disposable, single-use, low-profile catheter that travels over our proprietary ViperWire guide wire. The systems use a saline infusion pump as a power supply for the operation of the catheter. Additional ancillary products include the ViperSlide Lubricant and ViperTrack Radiopaque Tape. We also had an exclusive distribution agreement with Asahi to market its peripheral guide wire line in the United States, which expired in June 2015.

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

Selling, General and Administrative Expenses. Selling, general and administrative expenses include compensation for executive, sales, marketing, finance, information technology, human resources and administrative personnel, including stock-based compensation. Other significant expenses include the medical device excise tax, bad debt expense, travel, marketing costs, professional fees and professional education.

Research and Development Expenses. Research and development expenses include costs associated with the design, development, testing, enhancement and regulatory approval of our products. Research and development expenses include employee compensation including stock-based compensation, supplies and materials, patent expenses, consulting expenses, travel and facilities overhead. We also incur significant expenses to operate clinical trials, including trial design, third-party fees, clinical site reimbursement, data management and travel expenses. All research and development expenses are expensed as incurred. Approved patent applications are capitalized and amortized using the straight-line method over their remaining estimated lives. Patent amortization begins at the time of patent application approval, and does not exceed 20 years.

Interest and Other, Net. Interest and other, net primarily includes interest expense (including premium and discount amortization), interest income, change in the fair value of the debt conversion option, debt refinancing costs, and net write-offs upon debt conversion (option and unamortized premium or discount).

- Realized Gain/Loss. Realized gain/loss results from the distribution of investments under our deferred compensation plan.
- Interest Expense. Interest expense (including premium and discount amortization) results from outstanding debt balances and debt premiums and discounts.
- Interest Income. Interest income is attributed to interest earned on deposits in investments that consist of money market funds.
- Net Write-offs Upon Debt Conversion. Net write-offs upon debt conversion are the result of the conversion of convertible debt, and include the write-off of the related debt conversion option and any unamortized debt premium or discount.
- Other. Other consists of miscellaneous non-operating expenses.

Net Operating Loss Carryforwards. We have established valuation allowances to fully offset our deferred tax assets due to the uncertainty about our ability to generate the future taxable income necessary to realize these deferred assets, particularly in light of our historical losses. The future use of net operating loss carryforwards is dependent on us attaining profitable operations and will be limited in any one year under Internal Revenue Code Section 382 due to significant ownership changes (as defined in Section 382) resulting from our equity financings. At June 30, 2016, we had net operating loss carryforwards for federal and state income tax reporting purposes of approximately $244.2 million, which will expire at various dates through fiscal 2036.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect amounts reported in those statements. Our estimates, assumptions and judgments, including those related to revenue recognition, allowance for doubtful accounts, excess and obsolete inventory, and stock-based compensation are updated as appropriate at least quarterly. We use authoritative pronouncements, our technical accounting knowledge, cumulative business experience, valuation specialists, judgment and other factors in the selection and application of our accounting policies. While we believe that the estimates, assumptions and judgments that we use in preparing our consolidated financial statements are appropriate, these estimates, assumptions and judgments are subject to factors and uncertainties regarding their outcome. Therefore, actual results may materially differ from these estimates.

Some of our significant accounting policies require us to make subjective or complex judgments or estimates. An accounting estimate is considered to be critical if it meets both of the following criteria: (1) the estimate requires assumptions about matters that are highly uncertain at the time the accounting estimate is made, and (2) different estimates that reasonably could have been used, or changes in the estimate that are reasonably likely to occur from period to period, would have a material impact on the presentation of our financial condition, results of operations, or cash flows.

Revenue Recognition. We sell the majority of our products via direct shipment to hospitals or clinics. We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sales price is fixed or determinable; and collectability is reasonably assured. We record estimated sales returns, discounts and rebates as a reduction of net sales.

Costs related to products delivered are recognized in the period the revenue is recognized. Cost of goods sold consists primarily of raw materials, direct labor, and manufacturing overhead.

Allowance for Doubtful Accounts. We maintain an allowance for doubtful accounts. This allowance is an estimate and is regularly evaluated for adequacy by taking into consideration factors such as past experience, credit quality of the customer base, age of the receivable balances, both individually and in the aggregate, and current economic conditions that may affect a customer's ability to pay. Provisions for the allowance for doubtful accounts attributed to bad debt are recorded in general and administrative expenses.

Excess and Obsolete Inventory. We have inventories that are principally comprised of capitalized direct labor and manufacturing overhead, raw materials and components, and finished goods. Due to the technological nature of our products, there is a risk of obsolescence for changes in our technology and the market, which is impacted by technological developments and events. Accordingly, we write down our inventories as we become aware of any situation where the carrying amount exceeds the estimated realizable value based on assumptions about future demands and market conditions. The evaluation includes analysis of inventory levels, expected product lives, product at risk of expiration, sales levels by product and projections of future sales demand.

Stock-Based Compensation. We have stock-based compensation plans, which include stock options, nonvested share awards, and an employee stock purchase plan. We determine the fair value of our option awards using option-pricing models. We determine the fair value of nonvested share awards with market conditions using the Monte Carlo simulation. Fair value of nonvested share awards that vest based upon performance or time conditions is determined by the closing market price of our stock on the date of grant. Stock-based compensation expense is recognized ratably over the requisite service period for the awards expected to vest. Management's key assumptions are developed with input from independent third-party valuation advisors.

Legal Proceedings. In accordance with FASB guidance, we record a liability in our consolidated financial statements related to legal proceedings when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible, but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed in the notes to the consolidated financial statements. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded.

RESULTS OF OPERATIONS

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts (in thousands), and, for certain line items, the changes between the specified periods:

Comparison of Fiscal Year Ended June 30, 2016 with Fiscal Year Ended June 30, 2015

	Year Ended June 30,			
	2016	2015	Change	Percent Change
Net revenues	$178,184	$181,544	$(3,360)	(1.9)%
Cost of goods sold	35,421	39,520	(4,099)	(10.4)
Gross profit	142,763	142,024	739	0.5
Gross margin	80.1%	78.2%	1.9%	2.4
Expenses:				
Selling, general and administrative	162,542	143,684	18,858	13.1
Research and development	25,934	30,977	(5,043)	(16.3)
Restructuring	2,364	—	2,364	100.0
Legal settlement	8,000	—	8,000	100.0
Total expenses	198,840	174,661	24,179	13.8
Loss from operations	(56,077)	(32,637)	(23,440)	71.8
Interest and other, net	53	(185)	238	(128.6)
Net loss	$(56,024)	$(32,822)	$(23,202)	70.7

Net Revenues. Net revenues decreased by $3.4 million, or 1.9%, from $181.5 million for the year ended June 30, 2015, to $178.2 million for the year ended June 30, 2016. This decrease was primarily attributable to expiration in June 2015 of our exclusive distribution agreement with Asahi to market its peripheral guidewire line in the United States, which contributed approximately $7.5 million in sales during the year ended June 30, 2015. Revenues from our Peripheral OAS decreased $6.6 million, or 4.9%, primarily reflecting a 3.4% decrease in the average selling prices, as well as a 1.5% decrease in the number of devices sold, primarily resulting from challenges associated with the expansion of our sales force and the transition to a dual-franchise (peripheral and coronary) sales organization. Sales of our Coronary OAS increased approximately $9.2 million, or 34.2%, reflecting 35.2% more devices sold from the expansion of our customer base. Other product revenue decreased $6.0 million, or 29.5%, during the year ended June 30, 2016, driven by the absence of sales of the Asahi guidewires, partially offset by an increase of $1.6 million in other products that support our Peripheral OAS and Coronary OAS. 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. In November 2014, we received CE Mark for the Stealth 360 and are currently evaluating the timing and structure of our plans to commercialize products in Europe. In July 2016, we submitted an application to Japan's PMDA for approval of our Diamondback 360® Coronary OAS Micro Crown. We are currently evaluating potential distribution partners in Japan. We expect our revenue to increase as we continue to increase the number of physicians using the devices, increase the usage per physician, introduce new and improved products, generate additional clinical data, and expand into new geographies.

Cost of Goods Sold. Cost of goods sold decreased by $4.1 million, or 10.4%, from $39.5 million for the year ended June 30, 2015 to $35.4 million for the year ended June 30, 2016. These amounts represent the cost of materials, labor and overhead for single-use catheters, guide wires, pumps, and other ancillary products. The decrease was primarily due to lower indirect costs per unit sold from higher production volumes and manufacturing efficiencies. Gross margin increased to 80.1% for the year ended June 30, 2016 from 78.2% for the year ended June 30, 2015 due to lower costs per unit, as discussed above. Cost of goods sold for the years ended June 30, 2016 and 2015 includes $0.8 million and $1.0 million, respectively, for stock-based compensation. We expect that gross margin in fiscal 2017 will be comparable to the year ended June 30, 2016. Quarterly margin fluctuations could occur based on production

volumes, timing of new product introductions, sales mix, pricing changes, or other unanticipated circumstances.

Selling, General and Administrative Expenses. Selling, general, and administrative expenses increased by $18.9 million, or 13.1%, from $143.7 million for the year ended June 30, 2015 to $162.5 million for the year ended June 30, 2016 primarily due to the expansion of our sales and administrative organizations. In addition, we incurred a $1.5 million expense associated with the departure of our former CEO and increased legal fees primarily associated with the Department of Justice matter discussed below. Partially offsetting the increase was a reduction in medical device excise tax expense of $1.5 million due to the suspension of the tax, effective January 1, 2016. Selling, general, and administrative expenses for the years ended June 30, 2016 and 2015 include $10.4 million and $12.2 million, respectively, for stock-based compensation, which decreased due to lower than expected attainment of performance based restricted stock award goals. We expect our selling, general and administrative expenses to decrease in fiscal 2017 due to cost management initiatives.

Research and Development Expenses. Research and development expenses decreased by $5.0 million, or 16.3%, from $31.0 million for the year ended June 30, 2015 to $25.9 million for the year ended June 30, 2016. Research and development expenses relate to the specific projects to develop new products or expand into new markets, such as the development of new versions of our Peripheral OAS and Coronary OAS, and ancillary products, and PAD and CAD clinical studies. The decrease primarily related to the completion of enrollment in several of our clinical studies. Research and development expenses for the years ended June 30, 2016 and 2015 include $1.8 million and $1.5 million, respectively, for stock-based compensation. We generally expect to incur research and development expenses slightly higher in fiscal 2017 than amounts incurred for the year ended June 30, 2016 due to timing of projects and studies. Fluctuations could occur based on the number of projects and studies and the timing of expenditures.

Restructuring Charges. In March 2016, we announced a broad-based restructuring to reduce costs as a key part of our plan to balance revenue growth with a pathway to profitability and positive cash flow. As a result, we recorded a restructuring expense of $2.4 million during the year ended June 30, 2016, which was comprised of severance and other employee related costs. We do not anticipate additional charges related to restructuring activities.

Legal Settlement. On June 28, 2016, we entered into a Settlement Agreement with the United States of America, acting through the United States Attorney for the Western District of North Carolina (the “DOJ”) and on behalf of the Office of Inspector General of the Department of Health and Human Services, and Travis Thams (the “Relator”), to resolve the previously disclosed investigation by the DOJ and the qui tam complaint filed by the Relator pursuant to the False Claims Act in the United States District Court for the Western District of North Carolina, Charlotte Division. We recorded an $8.0 million legal settlement expense during the year ended June 30, 2016. Payments will be made as follows: an initial payment of $3.0 million, made in July 2016, with the remaining $5.0 million, which bears interest at 1.8% per annum, payable in 11 equal quarterly installments, beginning January 1, 2017.

Comparison of Fiscal Year Ended June 30, 2015 with Fiscal Year Ended June 30, 2014

	Year Ended June 30,			
	2015	2014	Change	Percent Change
Net revenues	$181,544	$136,612	$44,932	32.9 %
Cost of goods sold	39,520	31,041	8,479	27.3
Gross profit	142,024	105,571	36,453	34.5
Gross margin	78.2 %	77.3 %	0.9 %	1.2
Expenses:				
Selling, general and administrative	143,684	117,994	25,690	21.8
Research and development	30,977	21,066	9,911	47.0
Total expenses	174,661	139,060	35,601	25.6
Loss from operations	(32,637)	(33,489)	852	(2.5