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Cardiovascular Systems Inc  
Form 10-K  
August 27, 2015

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

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

For the fiscal year ended June 30, 2015

OR

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)

The NASDAQ Stock Market LLC

Par Value Per Share

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

None.

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

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

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  No

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

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

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

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

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(Do not check if a smaller reporting company)

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

As of December 31, 2014, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately \$916.3 million based on the closing sale price as reported on the NASDAQ Global Market.

The number of shares of the registrant's common stock outstanding as of August 21, 2015 was 32,480,435.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the proxy statement for the registrant's 2015 Annual Meeting of Stockholders are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this report.

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

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



## PART I

### Item 1. Business.

#### Special Note Regarding Forward Looking Statements

This report contains plans, intentions, objectives, estimates and expectations that constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act, which are subject to the “safe harbor” created by those sections. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “intend,” “should,” “could,” “would,” “expect,” “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](http://www.csi360.com). The information contained in or accessible through our website is not incorporated by reference into, and should not be considered part of, this Annual Report on Form 10-K.

We have received 18 federal registrations in the U.S. Patent and Trademark Office (“USPTO”) of certain marks, including “Diamondback®,” a first “CSI,” a second “CSI,” “Predator 360®,” “Stealth 360®,” a first “CSI” logo, a second “CSI” logo, “Lumen Library®,” “ViperWire®,” “ViperWire Advance®,” “Viperslide®,” “ViperTrack®,” “ViperCaddy®,” “Stealth 360®,” a first “Diamondback 360®,” a second “Diamondback 360®,” “Diamondback 360 (Stylized) Logo,” and “Stay A Step Ahead of PAD®”. We have applied for federal trademark registration with the USPTO of certain marks, including “Viperslide (Stylized),” “Vipertrack (Stylized),” and “Viperwire Advance (Stylized).” All other trademarks, trade names and service marks appearing in this Form 10-K are the property of their respective owners.

#### Business Overview

We are a medical technology company leading the way in the effort to successfully treat patients suffering from peripheral and coronary arterial diseases, including those with arterial calcium, the most difficult arterial disease to treat. We are committed to clinical rigor, constant innovation and a defining drive to set the industry standard to deliver safe and effective medical devices that improve lives of patients facing this difficult disease state.

We have developed a patented orbital atherectomy technology for peripheral and coronary commercial applications. Our peripheral arterial disease systems are catheter-based platforms capable of treating a broad range of plaque types in leg arteries both above and below the knee and address many of the limitations associated with other treatment alternatives. We refer to the Stealth 360° Peripheral Orbital Atherectomy System (“OAS”) (“Stealth 360”), the

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

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

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

<sup>(1)</sup> We are not currently marketing this product.

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

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

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

In addition to the PAD and CAD Systems, we intend to expand our product portfolio through internal product development and establishment of business relationships with other medical device companies. We offer multiple accessory products designed to complement the use of the PAD and CAD Systems. Sales of complementary products, primarily guide wire sales, represented 11% of revenue during the fiscal year ended June 30, 2015. Included in this amount are revenues from our exclusive distribution agreement with Asahi to market its peripheral guide wire line in the United States, which expired in June 2015. Sales of Asahi products were 4% of revenue during the fiscal year ended June 30, 2015.

## Market Overview

### Peripheral Arterial Disease

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

year in the United States.

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

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

### Coronary Arterial Disease

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

### Our PAD and CAD Systems

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

### Components of the OAS

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

Catheter. The catheter for our OAS consists of:

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

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

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

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

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

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

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

As the crown moves outward, the centrifugal force is offset by the counterforce exerted by the arterial wall. Normal arteries are compliant and have the ability to expand and contract as needed to supply blood flow. If the tissue is compliant, it flexes away, rather than generating an opposing force that would allow the OAS to engage and sand the wall. Diseased tissue provides resistance and is able to generate an opposing force that allows the OAS to engage and sand the plaque. The sanded plaque is broken down into particles generally smaller than circulating red blood cells that are washed away downstream with the patient's natural blood flow.

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

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

CAD System testing performed in a carbon block model showed:

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

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

We believe the OAS offer the following key benefits:

#### Strong Safety Profile

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

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

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

**Allows Continuous Blood Flow During Procedure.** The OAS allows for continuous blood flow while orbiting. Other devices may restrict blood flow due to the size of the catheter required or the use of distal protection devices, which could result in complications such as excessive heat and tissue damage.

**Proven Efficacy**

**Efficacy Demonstrated for Both PAD and CAD Systems.**

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

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

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

**Orbital Motion Improves Lesion Compliance.** The orbiting action of the OAS removes the hard plaque in the artery by sanding. As the crown sands away the plaque, the lumen of the artery is opened and the vessel wall becomes more compliant. The orbital motion and speed of the crown increases, thus allowing for continuous reduction of plaque as the opening of the lumen increases during the operation of the devices.

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

## Ease of Use

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

**Single Access Site to Complete Treatment.** The orbital technology and differential sanding process of the OAS allow for a single access site to treat multiple lesions, in most cases. In the peripheral vasculature, the OAS device is capable of treating multiple lesions in multiple arteries through a single access site, thus reducing the need for multiple devices or the need for multiple access sites.

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

## Multiple Applications

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

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

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

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

## Cost and Time Efficient Procedure

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

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

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



## Our OAS Strategy

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

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

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

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

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

**Strategic Acquisitions and Partnerships.** In addition to adding to our product portfolio through internal development efforts, we intend to continue to explore the acquisition of other product lines, technologies or companies that may leverage our sales force or complement our strategic objectives. We also intend to explore distribution agreements, licensing transactions, and other strategic partnerships.

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

## Clinical Studies Summary

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

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

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

OASIS. In September 2005 our Investigational Device Exemption (“IDE”) was approved to begin OASIS, our pivotal U.S. study. OASIS was a 124-patient, 20-center, prospective study that began enrollment in January 2006. The primary efficacy study endpoint was absolute plaque reduction of the target lesions from baseline to immediately post-procedure. The primary safety endpoint was the cumulative incidence of Serious Adverse Events (“SAE”) at 30 days.

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In the OASIS study, 94.5% of lesions treated were behind or below the knee, an area where lesions have traditionally gone untreated until they require bypass surgery or amputation. Of the lesions treated in OASIS, 55% were comprised of calcified plaque, which presents a challenge to proper expansion and apposition of balloons and stents, and 48% were diffuse, or greater than 3 cm in length. Results of OASIS exceeded FDA pre-specified acceptance criteria with an overall plaque reductions of 59.4%, freedom from device related SAE of 95.2% and 90.3% overall, and freedom from TLR of 97.6%.

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

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

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

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

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

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

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

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

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

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

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

### Sales and Marketing

We market and sell our products through a direct sales force in the United States. Revenues for the PAD and CAD Systems for the years ended June 30, 2015, 2014, and 2013 were \$161.3 million, \$120.4 million and \$91.2 million, respectively. We have targeted sales and marketing efforts to interventional cardiologists, vascular surgeons and interventional radiologists with experience using similar catheter-based procedures, such as angioplasty, stenting, and cutting or laser atherectomy. Peer-to-peer education is also a key element of our sales strategy.

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

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

### Research and Development

Our research and development efforts are focused in the development of products to penetrate our three key target markets: below and behind-the-knee, above-the-knee, and coronary vessels. In addition to the key target markets, we also focus on alternative access sites. Research and development projects include the development of new products, enhancement of existing products, and PAD and CAD clinical trials. Research and development expenses for the years ended June 30, 2015, 2014, and 2013 were \$31.0 million, \$21.1 million and \$15.2 million, respectively.

### Manufacturing

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

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

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

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

We are registered with the FDA as a medical device manufacturer. We have opted to maintain quality assurance and quality management certifications to enable us to market our products in the member states of the European Union, the European Free Trade Association and countries that have entered into Mutual Recognition Agreements with the European Union. We are ISO 13485:2003 certified, and our renewal is due by December 2015. Under these registrations, our plants are audited by the FDA and our Notified Body for the EU CE Mark. Our Stealth 360 has received CE Mark.

### Third-Party Reimbursement and Pricing

Third-party payors, including private insurers, and government insurance programs, such as Medicare and Medicaid, pay for a significant portion of patient care provided in the United States. The single largest payor in the United States is the Medicare program, a federal governmental health insurance program administered by the Centers for Medicare and Medicaid Services (“CMS”). Medicare covers certain medical care expenses for eligible elderly and disabled individuals, including a large percentage of the population with PAD and CAD who could be treated with the OAS. In addition, private insurers often follow the coverage and reimbursement policies of Medicare. Consequently, Medicare's coverage and reimbursement policies are important to our operations.

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

### Competition

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

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

- safety and efficacy even in calcified plaque;
- predictable clinical performance;
- availability of clinical data;
- ease of use;
- economic benefit;
- key opinion leader support and customer base;
- customer service and support; and
- adequate third-party reimbursement.

## Patents and Intellectual Property

We rely on a combination of patent, copyright and other intellectual property laws, trade secrets, nondisclosure agreements and other measures to protect our proprietary rights. As of June 2015, we held 46 issued U.S. patents and have 39 U.S. patent applications pending, as well as 203 issued or granted foreign patents and 148 foreign patent applications, each of which corresponds to aspects of our U.S. patents and applications. Our issued U.S. patents expire between 2015 and 2032, and our most important patents, U.S. Patent No. 6,494,890 and two key design patents covering our eccentric abrasive crown technology are due to expire on June 1, 2019, February 16, 2024 and December 29, 2023, respectively, though we will pursue patent term extensions on the basis of regulatory delay where appropriate. In addition, we have many additional patents relating to our core technology currently pending in the USPTO, which will extend our key covered subject matter and coverage dates



significantly. Our issued patents and patent applications relate primarily to the design and operation of interventional atherectomy devices, including the PAD and CAD Systems. These patents and applications include claims covering key aspects of orbital atherectomy devices, including the design, manufacture and therapeutic use of certain atherectomy abrasive heads, drive shafts, control systems, handles and couplings. As we continue to research and develop our atherectomy technology, we intend to file additional U.S. and foreign patent applications related to the design, manufacture and therapeutic uses of atherectomy devices. In addition, we hold 18 registered U.S. trademarks, 12 registered marks in the Madrid Protocol with protection granted within at least one of Australia, Europe, China, Japan and Mexico, six registered marks in Europe, five registered marks in Canada, five registered marks in Mexico, and eight registered marks in Hong Kong. We have three trademark applications pending in the U.S., eight trademark applications pending in Canada and 12 trademark applications pending in India.

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

#### Government Regulation of Medical Devices

Governmental authorities in the U.S. at the federal, state and local levels and in other countries extensively regulate, among other things, the development, testing, manufacture, labeling, promotion, advertising, distribution, marketing and export and import of medical devices such as the PAD and CAD Systems.

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

#### United States

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

Unless an exemption applies, each medical device we wish to commercially distribute in the U.S. will require marketing authorization from the FDA prior to distribution. The two primary types of FDA marketing authorization are premarket notification (also called 510(k) clearance) and PMA. The type of marketing authorization applicable to a device - 510(k) clearance or PMA - is generally linked to classification of the device. The FDA classifies medical devices into one of three classes (Class I, II or III) based on the degree of risk the FDA determines to be associated with a device and the extent of control deemed necessary to ensure the device’s safety and effectiveness. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are deemed to pose the least risk and are subject only to general controls applicable to all devices, such as requirements for device labeling, premarket notification, and adherence to the FDA’s current good manufacturing practice requirements, as reflected in its Quality System Regulation (“QSR”). Class II devices are intermediate risk devices that are subject to general controls and may also be subject to special controls such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or post market surveillance. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through

general or special controls, and include life-sustaining, life-supporting or implantable devices, and devices not “substantially equivalent” to a device that is already legally marketed.

Most Class I devices and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from FDA. Class I and Class II devices that have not been so exempted are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require PMA prior to commercial marketing. The PMA process is generally more stringent, time-consuming and expensive than the 510(k) clearance process.

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

After a device has received 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, such as a significant change in the design, materials, method of manufacture or intended use, will require a new 510(k) clearance or PMA (if the device as modified is not substantially equivalent to a legally marketed predicate device). The determination as to whether new authorization is needed is initially left to the manufacturer; however, the FDA may review this determination to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing the modified device until 510(k) clearance or PMA is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

We received 510(k) clearance for use of the Diamondback 360 Peripheral as a therapy in patients with PAD in the United States on August 22, 2007. We received additional 510(k) clearances for the control unit used with the Diamondback 360 Peripheral on October 25, 2007 and for the solid crown version of the Diamondback 360 Peripheral on November 9, 2007. We were granted 510(k) clearance of the Predator 360 in March 2009 and Stealth 360 in March 2011. We received 510(k) clearance of the Diamondback 360 Peripheral 1.25 Micro OAS in November 2013 and the Diamondback 360 Peripheral 60cm OAS in March 2014. The Diamondback 360 Peripheral 1.25 Solid OAS was cleared in April 2015. We received clearance of the ViperWire Advance Flex Tip Guide Wire in June 2015.

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

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

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

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

the FDA's evaluation of the PMA application or manufacturing facilities is not favorable, the FDA will deny PMA or issue a not approvable letter. The FDA may also determine that additional clinical trials are necessary, in which case the PMA may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA application. Even if a PMA application is approved, the FDA may approve the device with an indication that is narrower or more limited than originally sought. The agency can also impose restrictions on the sale, distribution or use of the device as a condition of approval, or impose post approval requirements such as continuing evaluation and periodic reporting on the safety, efficacy and reliability of the device for its intended use.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling, device specifications, materials or design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application and may not require as extensive clinical data or the convening of an advisory panel.

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

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

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

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

Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product. The commencement or completion of any clinical trials may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a premarket notification for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial (or a change to a previously approved protocol or trial that requires approval), or place a clinical trial on hold;
- patients do not enroll in clinical trials or follow up at the rate expected;
- patients do not comply with trial protocols or experience greater than expected adverse side effects;
- institutional review boards and third-party clinical investigators may delay or reject the trial protocol or changes to the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreements, good clinical practices or other FDA requirements;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of the clinical trials or manufacturing facilities, which may, among other things, require corrective action or suspension or termination of the clinical trials;

- changes in governmental regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; or
- the FDA concludes that the trial design is inadequate to demonstrate safety and efficacy.

Continuing Regulation. After a device is cleared or approved for use and placed in commercial distribution, numerous regulatory requirements continue to apply. These include:

- establishment registration and device listing upon the commencement of manufacturing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow design, testing, control, documentation and other quality assurance procedures during medical device design and manufacturing processes;
- labeling regulations, which prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling and promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if malfunctions were to recur;
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections; and
- product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health.

In addition, the FDA may require a company to conduct post market surveillance studies or order it to establish and maintain a system for tracking its products through the chain of distribution to the patient level.

Failure to comply with applicable regulatory requirements, including those applicable to the conduct of clinical trials, can result in enforcement action by the FDA, which may lead to any of the following sanctions:

- warning letters or untitled letters;
- fines, injunctions and civil penalties;
- product recall or seizure;
- unanticipated expenditures;
- delays in clearing or approving or refusal to clear or approve products;
- withdrawal or suspension of FDA approval;
- orders for physician notification or device repair, replacement or refund;
- operating restrictions, partial suspension or total shutdown of production or clinical trials; or
- criminal prosecution.

We and our contract manufacturers, specification developers and suppliers are also required to manufacture our products in compliance with current Good Manufacturing Practice requirements set forth in the QSR.

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

Fraud and Abuse

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



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

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

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

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

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

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

#### International Regulation

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

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

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

### Environmental Regulation

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

### Employees

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

Item 1A. Risk Factors.

Risks Relating to Our Business and Operations

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

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

We may be unable to sustain our revenue growth.

Our revenue has grown in each of the fiscal years since we commenced commercial sales of the PAD Systems in September 2007. Our ability to continue to increase our revenues in future periods will depend on our ability to increase sales of the PAD Systems and generate significant sales from the CAD System and new and improved products we introduce, which will, in turn, depend in part on our success in growing our customer base and reorders from those customers. We may not be able to generate, sustain or increase revenues on a quarterly or annual basis. If we cannot achieve or sustain revenue growth for an extended period, our financial results will be adversely affected and our stock price may decline.

Economic conditions may adversely affect our business.

Adverse worldwide economic conditions may negatively impact our business. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in their purchases and also in our receivable collections and additional allowances may be required, which could adversely affect our operating results. Adverse worldwide economic conditions may also adversely impact our suppliers' ability to provide us with materials and components, which could adversely affect our business and operating results.

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

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

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

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

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

Our customers may not be able to achieve adequate reimbursement for using the PAD and CAD Systems, which could affect the acceptance of our products and cause our business to suffer.

The availability of insurance coverage and reimbursement for newly approved medical devices and procedures is uncertain. The commercial success of our products is substantially dependent on whether third-party insurance coverage and reimbursement for the use of such products and related services are available. We expect our products to continue to be purchased by hospitals and other providers who will then seek reimbursement from various public and private third-party payors, such as Medicare, Medicaid and private insurers, for the services provided to patients. While third-party payors are currently providing reimbursement for our products, we can give no assurance that these third-party payors will continue to provide adequate reimbursement for use of the PAD and CAD Systems to permit hospitals and doctors to consider the products cost-effective for patients requiring treatment, or that current reimbursement levels for our products will continue. In addition, the overall amount of reimbursement available for PAD and CAD treatment could decrease in the future. Failure by hospitals and other users of our products to obtain sufficient reimbursement could cause our business to suffer.

Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement, and, as a result, they may not cover or provide adequate payment for use of our products. In order to position our products for acceptance by third-party payors, we may have to agree to lower prices than we might otherwise charge.

Governmental and private sector payors have instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. It is uncertain whether our current products or any future products we may develop will be viewed as sufficiently cost-effective to warrant adequate coverage and reimbursement levels.

If third-party coverage and reimbursement for our products is limited or not available, the acceptance of our products and, consequently, our business will be substantially harmed.

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

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

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

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

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

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

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

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

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

Our competitors may:

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

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

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

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

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

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



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

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

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

We have increased the size of our organization and expect to continue to do so, and we may experience difficulties managing growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected.

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

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

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

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

We may be dependent on additional financing to execute our business plan. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. In the event we need or desire additional financing, we may be unable to obtain it by borrowing money in the credit markets or raising money in the capital markets. If adequate funds are not available on a timely basis, we may terminate or delay the development of one or more of our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products.

We are dependent on our senior management team and highly skilled personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.

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

Our stock price is volatile and subject to significant fluctuations.

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

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

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

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

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

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

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

#### Risks Related to Government Regulation

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

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

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

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

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

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

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

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

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

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

The PAD and CAD Systems and related manufacturing processes, clinical data, adverse events, recalls or corrections and promotional activities are subject to extensive regulation by the FDA and other regulatory bodies. In particular, we are required to comply with the QSR and other regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing clearance or approval. We are also responsible for the quality of components received by our suppliers. Failure to comply with the QSR requirements or other statutes and regulations administered by the FDA and other regulatory bodies, or failure to adequately respond to any observations, could result in, among other things:

- warning or other letters from the FDA;
- fines, injunctions and civil penalties;
- product recall or seizure;
- unanticipated expenditures;
- delays in clearing or approving or refusal to clear or approve products;
- withdrawal or suspension of approval or clearance by the FDA or other regulatory bodies;
- orders for physician notification or device repair, replacement or refund;
- operating restrictions, partial suspension or total shutdown of production or clinical trials; and
- criminal prosecution.

If any of these actions were to occur, it would harm our reputation and cause our product sales to suffer.

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

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

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

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

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

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

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

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

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

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



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

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

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

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

#### Risks Relating to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

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

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

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

Item 3. Legal Proceedings.

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

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

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

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

Item 4. Mine Safety Disclosures.

None.



Executive Officers of the Registrant.

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

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

David L. Martin, President and Chief Executive Officer. Mr. Martin has been our President and Chief Executive Officer since February 2007, and a director since August 2006. Mr. Martin also served as our Interim Chief Financial Officer from January 2008 to April 2008. Prior to joining us, Mr. Martin was Chief Operating Officer of FoxHollow Technologies, Inc. from January 2004 to February 2006, Executive Vice President of Sales and Marketing of FoxHollow Technologies, Inc. from January 2003 to January 2004, Vice President of Global Sales and International Operations at Cardiovention Inc. from October 2001 to May 2002, Vice President of Global Sales for RITA Medical Systems, Inc. from March 2000 to October 2001 and Director of U.S. Sales, Cardiac Surgery for Guidant Corporation from September 1999 to March 2000. Mr. Martin has also held sales and sales management positions for The Procter & Gamble Company and Boston Scientific Corporation.

Laurence L. Betterley, Chief Financial Officer. Mr. Betterley joined us in April 2008 as our Chief Financial Officer. Previously, Mr. Betterley was Chief Financial Officer at Cima NanoTech, Inc. from May 2007 to April 2008, Senior Vice President and Chief Financial Officer of PLATO Learning, Inc. from 2004 to 2007, Senior Vice President and Chief Financial Officer of Diametrics Medical, Inc. from 1996 to 2003, and Chief Financial Officer of Cray Research Inc. from 1994 to 1996.

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

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

Robert J. Thatcher, Chief Healthcare Policy Officer. Mr. Thatcher joined us as Senior Vice President of Sales and Marketing in October 2005 and became Vice President of Operations in September 2006. Mr. Thatcher became Executive Vice President in August 2007 and became our Chief Healthcare Policy Officer in July 2013. Previously, Mr. Thatcher was Senior Vice President of TriVirix Inc. from October 2003 to October 2005. Mr. Thatcher has more than 30 years of medical device experience in both large and start-up companies. Mr. Thatcher has held various sales management, marketing management and general management positions at Medtronic, Inc., Schneider USA, Inc. (a former division of Pfizer Inc.), Boston Scientific Corporation and several startup companies.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Price Range of Common Stock and Dividend Policy

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

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

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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Securities Authorized For Issuance Under Equity Compensation Plans

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

Performance Graph

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



## Item 6. Selected Financial Data.

## Five-Year Selected Financial Data

(in thousands, except per share amounts)

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

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this Form 10-K. This discussion and analysis contains forward-looking statements about our business and operations, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those we currently anticipate as a result of many important factors, including the factors we describe under "Risk Factors" and elsewhere in this Form 10-K.

## OVERVIEW

We are a medical device company focused on developing and commercializing innovative solutions for vascular and coronary disease. Our peripheral arterial disease ("PAD") products, the Stealth 360<sup>®</sup> Peripheral Orbital Atherectomy System ("OAS") (the "Stealth 360"), the Diamondback<sup>®</sup> 360 Peripheral OAS (the "Diamondback 360 Peripheral"), the Diamondback 360<sup>®</sup> 60cm Peripheral OAS access device, and the Diamondback 360 4 French 1.25 Peripheral OAS access device are catheter-based platforms capable of treating a broad range of plaque types in leg arteries both above and below the knee and address many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. The micro-invasive devices use smaller access sheaths that can provide procedural benefits and allow physicians to treat PAD patients in the small and tortuous vessels located below the knee through alternative access sites in the ankle and foot as well as in the groin. We no longer market the Diamondback Predator 360<sup>®</sup> (the "Predator 360"). We refer to the Stealth 360, Diamondback 360 Peripheral, Diamondback 360 60cm Peripheral OAS, Diamondback 360 4 French 1.25 Peripheral OAS, and Predator 360 collectively in this report as the "PAD Systems."

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

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

From 2003 to 2005, we conducted numerous bench and animal tests in preparation for application submissions to the U.S. Food and Drug Administration (“FDA”). We initially focused our testing on providing a solution for coronary in-stent restenosis, but later changed the focus to PAD. In 2006, we obtained an investigational device exemption from the FDA to conduct our pivotal OASIS PAD clinical trial, which was completed in January 2007. The OASIS clinical trial was a prospective 20-center study that involved 124 patients with 201 lesions.

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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, which are no longer marketed. We received 510(k) clearance of the Diamondback 360 60cm Peripheral OAS in March 2014, and in April 2015, we received 510(k) clearance of the Diamondback 360 4 French 1.25 Peripheral OAS. We market the PAD Systems in the United States through a direct sales force and expend significant capital on our sales and marketing efforts to expand our customer base and utilization per customer. We assemble at our facilities the saline infusion pump and the single-use catheter used in the PAD Systems with components purchased from third-party suppliers, as well as with components manufactured in-house. Supplemental products are purchased from third-party suppliers.

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

We have developed modified versions of the PAD System 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 CAD System as a treatment for severely calcified coronary arteries. We commenced a controlled commercial launch of our CAD System following receipt of PMA.

As of June 30, 2015, we had an accumulated deficit of \$271.4 million. We expect our losses to continue as we invest in sales, marketing, medical education, clinical studies and product research and development for our next phase of growth in the peripheral market and continue the commercialization of our CAD System. 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 PAD Systems, the CAD System and other ancillary products. The PAD and CAD Systems 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. Our 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 and professional fees.

**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).

**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.

**Change in Fair Value of Debt Conversion Option.** Change in fair value of debt conversion option represents the period to period change in fair value of the debt conversion option associated with outstanding convertible debt.

**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, including state taxes.

**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, 2015, we had net operating loss carryforwards for federal and state income tax reporting purposes of approximately \$197.5 million, which will expire at various dates through fiscal 2033.

## 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 office-based labs. 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 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, 2015 with Fiscal Year Ended June 30, 2014

	Year Ended June 30,		\$ Change	Percent Change	
	2015	2014			
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 )	
Interest and other, net	(185 )	(1,801 )	1,616	(89.7 )	
Net loss	\$(32,822 )	\$(35,290 )	\$2,468	(7.0 )	

**Net Revenues.** Revenues increased by \$44.9 million, or 32.9%, from \$136.6 million for the year ended June 30, 2014 to \$181.5 million for the year ended June 30, 2015. This increase was primarily attributable to sales of our CAD System which contributed approximately \$26.9 million in revenues for the year ended June 30, 2015, compared to approximately \$5.0 million in the year ended June 30, 2014 following our PMA in October 2013. Revenues from our PAD Systems increased \$19.0 million, or 16.5%, which reflects 16.7% more device units sold. Other product revenue also increased \$4.1 million, or 25.1%, during the year ended June 30, 2015 as compared to the year ended June 30, 2014, primarily driven by increased sales of PAD and CAD Systems, which the other products support. 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. 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, continue the controlled commercial launch of our CAD System, and expand into new geographies.





**Cost of Goods Sold.** Cost of goods sold increased by \$8.5 million, or 27.3%, from \$31.0 million for the year ended June 30, 2014 to \$39.5 million for the year ended June 30, 2015. These amounts represent the cost of materials, labor and overhead for single-use catheters, guide wires, pumps, and other ancillary products. The increase was due to an increase in the quantities of products sold, partially offset by lower indirect costs per unit from higher production volumes and manufacturing efficiencies. The increase in gross margin from 77.3% for the year ended June 30, 2014, to 78.2% for the year ended June 30, 2015, was primarily due to the increase in sales of our CAD System, which has a higher average selling price than the PAD Systems, and to lower indirect costs per unit. Cost of goods sold for the years ended June 30, 2015 and 2014 includes \$1.0 million and \$0.7 million, respectively, for stock-based compensation. We expect that gross margin in fiscal 2016 will improve slightly compared to fiscal 2015. Quarterly fluctuations could occur based on production volumes, timing of new product introductions, sales mix, changes in selling prices, or other unanticipated circumstances.

**Selling, General and Administrative Expenses.** Selling, general, and administrative expenses increased by \$25.7 million, or 21.8%, from \$118.0 million for the year ended June 30, 2014 to \$143.7 million for the year ended June 30, 2015. Our selling, general and administrative expenses for the year ended June 30, 2015 have increased due to higher expenses from the coronary commercial launch, the expansion of our sales and marketing organization, increased medical education, and higher incentive and stock-based compensation. Selling, general, and administrative expenses for the years ended June 30, 2015 and 2014 include \$12.2 million and \$9.2 million, respectively, for stock-based compensation. We expect our selling, general and administrative expenses to increase in the future as a result of the costs associated with expanding our sales and marketing organization to further commercialize our PAD Systems and expand the commercial launch of our CAD System.

**Research and Development Expenses.** Research and development expenses increased by \$9.9 million, or 47.0%, from \$21.1 million for the year ended June 30, 2014 to \$31.0 million for the year ended June 30, 2015. 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 PAD and CAD Systems, shaft designs, crown design, and PAD and CAD clinical studies. The increase primarily related to additional product development projects and clinical studies, and the related increase in headcount. Research and development expenses for the year ended June 30, 2015 and 2014 include \$1.5 million and \$1.1 million, respectively, for stock-based compensation. As we continue to expand our product portfolio and clinical studies within the PAD and CAD markets, we generally expect to incur research and development expenses above amounts incurred for the year ended June 30, 2015. Fluctuations could occur based on the number of projects and studies and the timing of expenditures.

**Interest and Other, net.** Interest and other, net was \$(0.2) million and \$(1.8) million for the years ended June 30, 2015 and 2014, respectively. The decrease was primarily driven by lower interest expense related to lower outstanding debt balances, as well as charges in the prior year from debt conversions and changes in fair value of the debt conversion option that were associated with previously outstanding convertible debt.

**Net Loss.** Net loss for the year ended June 30, 2015 was \$(32.8) million, compared to \$(35.3) million for the year ended June 30, 2014. Our net loss decreased as a result of higher revenues and gross profit, partially offset by increased operating expenses.

Comparison of Fiscal Year Ended June 30, 2014 with Fiscal Year Ended June 30, 2013

	Year Ended June 30,		\$ Change	Percent Change	
	2014	2013			
Net revenues	\$136,612	\$103,897	\$32,715	31.5	%
Cost of goods sold	31,041	24,382	6,659	27.3	
Gross profit	105,571	79,515	26,056	32.8	
Gross margin	77.3	% 76.5	% 0.8	% 1.0	

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Expenses:

Selling, general and administrative	117,994	86,718	31,276	36.1
Research and development	21,066	15,216	5,850	38.4
Total expenses	139,060	101,934	37,126	36.4
Loss from operations	(33,489 )	(22,419 )	(11,070 )	49.4
Interest and other, net	(1,801 )	(1,618 )	(183 )	11.3
Net loss	\$(35,290 )	\$(24,037 )	\$(11,253 )	46.8

**Net Revenues.** Revenues increased by \$32.7 million, or 31.5%, from \$103.9 million for the year ended June 30, 2013 to \$136.6 million for the year ended June 30, 2014. This increase was primarily attributable to a \$24.2 million, or 26.5%, increase in revenue from PAD Systems sold, which reflects a 30.8% increase in number of device units sold, partially offset by a 3.3% reduction in average selling prices. Additionally, sales of our CAD System contributed approximately \$5.0 million in revenues following our PMA in October 2013. Other product revenue also increased \$3.5 million, or 28.0%, during the year ended June 30, 2014 as compared to the year ended June 30, 2013, primarily driven by increased sales of PAD and CAD Systems, which the products support.

**Cost of Goods Sold.** Cost of goods sold increased by \$6.6 million, or 27.3%, from \$24.4 million for the year ended June 30, 2013 to \$31.0 million for the year ended June 30, 2014. These amounts represent the cost of materials, labor and overhead for single-use catheters, guide wires, control units, and other ancillary products. The increase was due to an increase in the quantities of products sold, partially offset by lower indirect costs per unit from higher production volumes and manufacturing efficiencies. The increase in gross margin from 76.5% during the year ended June 30, 2013, to 77.3% for the year ended June 30, 2014, was primarily due to lower indirect costs per unit, partially offset by lower average selling prices of PAD Systems. Cost of goods sold for the years ended June 30, 2014 and 2013 includes \$0.7 million and \$0.4 million, respectively, for stock-based compensation.

**Selling, General and Administrative Expenses.** Selling, general, and administrative expenses increased by \$31.3 million, or 36.1%, from \$86.7 million for the year ended June 30, 2013 to \$118.0 million for the year ended June 30, 2014. Our selling, general and administrative expenses for the year ended June 30, 2014 increased due to our commercial CAD System launch, the expansion of our sales and marketing organization, increased variable compensation, increased promotion and medical education programs, higher stock-based compensation, increased costs related to health care policy initiatives and higher medical device excise taxes. Selling, general, and administrative expenses for the years ended June 30, 2014 and 2013 include \$9.2 million and \$6.2 million, respectively, for stock-based compensation.

**Research and Development Expenses.** Research and development expenses increased by \$5.9 million, or 38.4%, from \$15.2 million for the year ended June 30, 2013 to \$21.1 million for the year ended June 30, 2014. 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 the PAD and CAD Systems, shaft designs, crown design, and PAD and CAD clinical studies. The increase primarily related to additional product development projects and clinical studies that began in fiscal 2014, and the related increase in headcount. Research and development expenses for the years ended June 30, 2014 and 2013 include \$1.1 million and \$0.8 million, respectively, for stock-based compensation.

**Interest and Other, net.** Interest and other, net was \$(1.8) million and \$(1.6) million for the years ended June 30, 2014 and 2013, respectively. The increase was primarily due to the change in fair value of the debt conversion option that was associated with the previously outstanding convertible debt (changes in fair value were primarily driven by the change in the market value of our common stock) and the write-offs associated with the debt conversions. Slightly offsetting this was a decrease in interest expense as a result of lower debt balances.

**Net Loss.** Net loss for the year ended June 30, 2014 was \$(35.3) million, compared to \$(24.0) million for the year ended June 30, 2013. Our net loss increased as a result of increased operating expenses, partially offset by higher gross profit.

#### NON-GAAP FINANCIAL INFORMATION

To supplement our consolidated financial statements prepared in accordance with GAAP, our management uses a non-GAAP financial measure referred to as "Adjusted EBITDA." The following table sets forth, for the periods indicated, a reconciliation of Adjusted EBITDA to the most comparable U.S. GAAP measure expressed as dollar amounts (in thousands):

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	Year Ended June 30,	
	2015	2014
Loss from operations	\$(32,637 )	\$(33,489 )
Add: Stock-based compensation	14,718	10,928
Add: Depreciation and amortization	2,321	1,367
Adjusted EBITDA	\$(15,598 )	\$(21,194 )

The improvement in Adjusted EBITDA of \$5.6 million, or 26.4%, is primarily the result of the \$3.8 million, or 34.7%, increase in stock-based compensation. Stock-based compensation increased as a result of increased employee stock awards granted due to our expanded headcount and higher grant date fair values. Adjusted EBITDA was also impacted by an increase in

depreciation and amortization, which increased as a result of the completion of our new headquarters in March 2015, additional investment in capital equipment and patents, as well as a decrease in the loss from operations. The loss from operations was impacted by an increase in revenues and gross profit, slightly offset by increased operating expenses.

#### Use and Economic Substance of Non-GAAP Financial Measures Used and Usefulness of Such Non-GAAP Financial Measures to Investors

We use Adjusted EBITDA as a supplemental measure of performance and believe this measure facilitates operating performance comparisons from period to period and company to company by factoring out potential differences caused by non-cash charges such as stock-based compensation and depreciation and amortization expense. Our management uses Adjusted EBITDA to analyze the underlying trends in our business, assess the performance of our core operations, establish operational goals and forecasts that are used to allocate resources and evaluate our performance period over period and in relation to our competitors' operating results.

We believe that presenting Adjusted EBITDA provides investors greater transparency to the information used by our management for its financial and operational decision-making and allows investors to see our results "through the eyes" of management. We also believe that providing this information better enables our investors to understand our operating performance and evaluate the methodology used by our management to evaluate and measure such performance.

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

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

**Depreciation and amortization expense.** We exclude depreciation and amortization expense from our non-GAAP financial measures primarily because such expenses, while constituting ongoing and recurring expenses, are not expenses that require cash settlement and are not used by our management to assess the core profitability of our business operations. Our management also believes that excluding these items from our non-GAAP results is useful to investors to understand our operational performance, liquidity and ability to make additional investments in the Company.

#### Material Limitations Associated with the Use of Non-GAAP Financial Measures and Manner in which We Compensate for these Limitations

Non-GAAP financial measures have limitations as analytical tools and should not be considered in isolation or as a substitute for our financial results prepared in accordance with GAAP. Some of the limitations associated with our use of these non-GAAP financial measures are:

Items such as stock-based compensation do not directly affect our cash flow position; however, such items reflect economic costs to us and are not reflected in our Adjusted EBITDA and therefore these non-GAAP measures do not reflect the full economic effect of these items.

Non-GAAP financial measures are not based on any comprehensive set of accounting rules or principles and therefore other companies may calculate similarly titled non-GAAP financial measures differently than we do, limiting the

usefulness of those measures for comparative purposes.

Our management exercises judgment in determining which types of charges or other items should be excluded from the non-GAAP financial measures we use.

We compensate for these limitations by relying primarily upon our GAAP results and using non-GAAP financial measures only supplementally.

## LIQUIDITY AND CAPITAL RESOURCES

We had cash and cash equivalents of \$83.8 million and \$126.6 million at June 30, 2015 and 2014, respectively. During the year ended June 30, 2015, net cash used in operations amounted to \$22.4 million. As of June 30, 2015, we had an accumulated deficit of \$271.4 million. We have historically funded our operating losses primarily from the issuance of stock, convertible promissory notes, and debt. Our prior line of credit with Silicon Valley Bank matured on December 31, 2014, and our loan and security agreement with Partners for Growth III, L.P. matured on April 14, 2015. See Note 3 to our Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K for additional information.

## Equity Offerings

We had the following registered underwritten public offerings during the years ended June 30, 2015, 2014 and 2013:

Offering Date	Shares Sold	Sale Price	Net Proceeds <sup>(1)</sup>
November 26, 2013	3,000,000	\$ 30.00	\$ 84,369
March 25, 2013	2,300,000	\$ 17.60	\$ 38,209

(1) Proceeds after deducting underwriting discounts, commissions and expenses (in thousands).

We have used, and intend to use, the net proceeds from the offerings for working capital and general corporate purposes, which may include, but are not limited to:

- the funding of clinical trials and studies;
- expanding our sales and marketing organization;
- physician education and awareness programs;
- funding the commercialization of our coronary application;
- expansion into international markets; and
- development of new products.

We may also use a portion of the net proceeds offering for the potential acquisition of businesses, technologies and products.

We cannot specify with certainty all of the particular uses for the net proceeds to us from the offerings. Accordingly, we will retain broad discretion over the use of these proceeds. Pending these uses, we intend to invest the net proceeds in investment-grade, interest-bearing securities.

## Changes in Liquidity

**Cash and Cash Equivalents.** Cash and cash equivalents was \$83.8 million and \$126.6 million at June 30, 2015 and 2014, respectively. The decrease was primarily attributable to net cash used in operating and investing activities during the year ended June 30, 2015.

**Operating Activities.** Net cash used in operating activities was \$22.4 million, \$26.8 million, and \$10.8 million for the years ended June 30, 2015, 2014, and 2013, respectively. For the years ended June 30, 2015, 2014, and 2013, we had a net loss of \$32.8 million, \$35.3 million, and \$24.0 million, respectively. Changes in working capital accounts also contributed to the net cash used in the years ended June 30, 2015, 2014, and 2013. Significant changes in working capital during these periods included:

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Cash used in accounts receivable was \$10.6 million, \$6.7 million, and \$1.3 million during the years ended June 30, 2015, 2014, and 2013, respectively. Cash used in accounts receivable is due to higher receivable balances from revenue growth, which has grown in each of the last three fiscal years.

Cash (used in) provided by inventory was \$(1.1) million, \$(6.6) million, and \$0.8 million during the years ended June 30, 2015, 2014, and 2013, respectively. Cash used by inventory in fiscal 2015 and 2014 was due to higher levels of inventory for future sales growth, including the CAD System commercial launch, as well as timing of inventory purchases and sales. Cash provided by inventories in fiscal 2013 was primarily due to the timing of inventory purchases and sales.



Cash (used in) provided by prepaid expenses and other current assets was \$(1.2) million, \$(0.6) million, and \$0.9 million during the years ended June 30, 2015, 2014, and 2013, respectively. Cash (used in) provided by prepaid expenses and other current assets was primarily due to payment timing of vendor deposits and other expenditures.

Cash provided by accounts payable was \$0.6 million, \$2.4 million, and \$1.5 million during the years ended June 30, 2015, 2014, and 2013, respectively. Cash provided by accounts payable was primarily due to timing of purchases and vendor payments and overall increased levels of expenses.

Cash provided by accrued expenses and other liabilities was \$4.4 million, \$6.7 million, and \$2.5 million during the years ended June 30, 2015, 2014, and 2013, respectively. Cash provided in fiscal 2015 was primarily due to the executive deferred compensation plan, higher payroll and vacation liabilities related to increased headcount, clinical study accruals for increased activity, and the general timing and payment of accruals. Cash provided by accrued expenses and other liabilities in fiscal 2014 was primarily related to increased incentive compensation related to performance above goals, higher accrued commissions due to increased sales, and higher payroll related expenses related to headcount and timing of payments. Cash provided by accrued expenses and other liabilities in fiscal 2013 was primarily related to the timing of payment of accruals.

**Investing Activities.** Net cash used in investing activities was \$23.0 million, \$13.4 million, and \$2.5 million for the years ended June 30, 2015, 2014, and 2013, respectively. During fiscal 2015, cash was used primarily for the construction of our new headquarters and the related equipment purchases. In addition, we purchased available-for-sale marketable securities for the deferred compensation plans. Cash used in investing activities in fiscal 2014 primarily related to the payments towards the construction of our new headquarters as well as investments in equipment and patents. Cash used in investing activities during fiscal 2013 related to investments in equipment and patents.

**Financing Activities.** Net cash provided by financing activities was \$2.6 million, \$99.0 million, and \$45.6 million during the years ended June 30, 2015, 2014, and 2013, respectively. Cash provided by financing activities during these periods included:

• Proceeds from the sale of common stock, net of issuance costs, of \$84.4 million and \$38.2 million during the years ended June 30, 2014 and 2013, respectively:

- Exercise of stock options and warrants of \$2.2 million, \$16.3 million, and \$5.9 million during the years ended June 30, 2015, 2014, and 2013, respectively;

• Proceeds from long-term debt of \$4.8 million and \$4.5 million during the years ended June 30, 2014 and 2013, respectively; and

• Employee stock purchase plan purchases of \$2.9 million, \$3.4 million, and \$1.8 million during the years ended June 30, 2015, 2014, and 2013, respectively.

Cash used in financing activities in these periods included payments on long-term debt of \$2.4 million, \$9.9 million, and \$4.8 million during the years ended June 30, 2015, 2014, and 2013, respectively.

Our future liquidity and capital requirements will be influenced by numerous factors, including the extent and duration of future operating losses, the level and timing of future sales and expenditures, the results and scope of ongoing research and product development programs, working capital required to support our sales growth, the receipt of and time required to obtain regulatory clearances and approvals, our sales and marketing programs, the continuing acceptance of our products in the marketplace, competing technologies, market and regulatory developments, ongoing facility requirements and potential strategic transactions (including the potential acquisition of businesses, technologies and products). As of June 30, 2015, we believe our current cash and cash equivalents and available debt will be sufficient to fund working capital requirements, capital expenditures (including the new corporate headquarters discussed below) and operations for the foreseeable future, including at least the next twelve months. We intend to

retain any future earnings to support operations and to finance the growth and development of our business and we do not anticipate paying any dividends in the foreseeable future. We may raise additional capital in the future, to fund acceleration of our current growth initiatives or additional growth opportunities, if we believe it will significantly enhance our value.

New Corporate Headquarters. On June 11, 2014, we entered into a Design-Build Contract and a Development Services Agreement, as well as various ancillary agreements related to the acquisition of real property located in New Brighton, Minnesota and the development of such property into our new corporate headquarters. Pursuant to the Development Services Agreement with Ryan Companies, Inc. (“Ryan”), Ryan was to perform certain development services to facilitate development of the project, including coordination with the City of New Brighton and overall coordination of development strategy. We pay Ryan a fee for the development services, which includes a sum equal to 3.25% of the adjusted total project costs, payable at certain points in the construction process, and a sum equal to 5% of the adjusted total project costs, payable upon substantial

completion of the project, as well as reimbursement of certain expenses incurred by Ryan. The construction was substantially completed in March 2015 and we have accrued all remaining payments due to Ryan under the Development Services Agreement.

Contractual Cash Obligations. Our contractual obligations and commercial commitments as of June 30, 2015 are summarized below:

Contractual Obligations	Payments Due by Period (in thousands)				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Operating leases <sup>(1)</sup>	\$2,651	\$770	\$1,065	\$816	\$—
Purchase commitments <sup>(2)</sup>	10,903	10,903	—	—	—
Total	\$13,554	\$11,673	\$1,065	\$816	\$—

(1) The amounts represent future minimum payments under a non-cancellable operating leases for our offices and production facility along with equipment.

(2) This amount represents the estimated remaining minimum payments on open purchase orders, as well as the final payment on the construction of our new corporate headquarters.

## INFLATION

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

## OFF-BALANCE SHEET ARRANGEMENTS

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

## RECENT ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, “Revenue From Customers With Contracts.” The guidance requires an entity to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. ASU 2014-09 is effective for annual periods beginning after December 15, 2016, including interim periods within that reporting period, using one of two prescribed retrospective methods. Early adoption is not permitted. In August 2015, the FASB issued ASU 2015-14 to defer the effective date of ASU 2014-09 by one year and allow early adoption for all entities but not before the original public entity effective date. We are evaluating the impact of the amended revenue recognition guidance on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, “Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.” The guidance requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements. The entity must also provide certain disclosures if there is substantial doubt about the entity's ability to continue as a going concern. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and interim periods thereafter. Early adoption is permitted. We do not anticipate a material impact on our financial statements upon adoption.

In April 2015, the FASB issued ASU No. 2015-05, "Customer's Accounting for Fees Paid in a Cloud Computing Arrangement." The guidance provides guidance to customers about whether a cloud computing arrangement includes a software license. ASU 2015-05 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted and companies can elect to adopt the guidance prospectively to all arrangements entered into or materially modified after the effective date, or retrospectively. We not anticipate a material impact on our financial statements upon adoption.

In July 2015, the FASB issued ASU No. 2015-11, "Simplifying the Measurement of Inventory." The guidance requires an entity to measure inventory within the scope of the ASU at the lower of cost and net realizable value. ASU 2015-11 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2016 and should be applied prospectively. Early adoption is permitted. We do not anticipate a material impact on our financial statements upon adoption.

## PRIVATE SECURITIES LITIGATION REFORM ACT

The Private Securities Litigation Reform Act of 1995 provides a “safe harbor” for forward-looking statements. Such “forward-looking” information is included in this Form 10-K and in other materials filed or to be filed by us with the Securities and Exchange Commission (as well as information included in oral statements or other written statements made or to be made by the Company). Forward-looking statements include all statements based on future expectations. This Form 10-K contains forward-looking statements that involve risks and uncertainties, including (i) the expectation of selling our products internationally in the future and the timing and structure of our plans to do so; (ii) our strategy; (iii) our expectations regarding timing of approval for our coronary OAS device in Japan; (iv) potential strategic acquisitions and partnerships; (v) reimbursement of our products; (vi) the timing of full transfer of our operations to our new facility and the adequacy of our facilities; (vii) our expectation that our losses will continue; (viii) our expectation of increased revenue and increased selling, general and administrative expenses; (ix) our expectation that gross margin in fiscal 2016 will improve slightly compared to fiscal 2015; (x) the broadening of the commercial launch of the CAD System; (xi) our plans to continue to expand our sales and marketing efforts as well as our product portfolio and clinical studies; (xii) our expectation that we will incur research and development expenses in fiscal 2016 above the amounts incurred for fiscal 2015; (xiii) the use of proceeds from our equity offerings; (xiv) our belief that our current cash and cash equivalents will be sufficient to fund working capital requirements, capital expenditures and operations for the foreseeable future; (xv) our intention to retain any future earnings to support operations and to finance the growth and development of our business; (xvi) our dividend expectations; (xvii) the potential to raise additional capital in the future; and (xviii) the anticipated impact of adoption of recent accounting pronouncements on the Company's financial statements.

In some cases, you can identify forward-looking statements by the following words: “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would,” these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements are only predictions and are not guarantees of performance. These statements are based on our management’s beliefs and assumptions, which in turn are based on their interpretation of currently available information.

These statements involve known and unknown risks, uncertainties and other factors that may cause our results or our industry’s actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. These factors include regulatory developments in the U.S. and foreign countries; FDA and similar foreign clearances and approvals; approval of our products for distribution in foreign countries; approval of products for reimbursement and the level of reimbursement; dependence on market growth; agreements with third parties to sell their products; the experience of physicians regarding the effectiveness and reliability of the PAD and CAD Systems; the reluctance of physicians, hospitals and other organizations to accept new products; the potential for unanticipated delays in enrolling medical centers and patients for clinical trials; actual clinical trial and study results; the impact of competitive products and pricing; unanticipated developments affecting our estimates regarding expenses, future revenues and capital requirements; the difficulty of successfully managing operating costs; our inability to expand our sales and marketing organization; our ability to manage employee turnover, growth and training; actual research and development efforts and needs; our ability to obtain and maintain intellectual property protection for product candidates; our actual financial resources and our ability to obtain additional financing; fluctuations in results and expenses based on new product introductions, sales mix, unanticipated warranty claims, and the timing of project expenditures; and general economic conditions. These and additional risks and uncertainties are described more fully in Item 1A of this Form 10-K under “Risk Factors.”

You should read these risk factors and the other cautionary statements made in this Form 10-K as being applicable to all related forward-looking statements wherever they appear in this Form 10-K. We cannot assure you that the forward-looking statements in this Form 10-K will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. You should read this Form 10-K completely. Other

than as required by law, we undertake no obligation to update these forward-looking statements, even though our situation may change in the future.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk or availability. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and investments in a variety of marketable securities, including money market funds, U.S. government securities, and certain bank obligations. Our cash and cash equivalents as of June 30, 2015 include liquid money market accounts. Due to the short-term nature of these investments, we believe that there is no material exposure to interest rate risk.

Additionally, we have acquired certain available-for-sale marketable securities under our deferred compensation plan. See Note 1 to our Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K for additional information on these available-for-sale marketable securities and the related risks.

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Item 8. Financial Statements and Supplementary Data.  
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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Cardiovascular Systems, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of comprehensive loss, of changes in shareholders' equity and of cash flows present fairly, in all material respects, the financial position of Cardiovascular Systems, Inc. at June 30, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2015 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2015, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Minneapolis, Minnesota  
August 27, 2015



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Cardiovascular Systems, Inc.

Consolidated Balance Sheets

(Dollars in thousands, except per share and share amounts)

	June 30, 2015	June 30, 2014
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$83,842	\$126,592
Accounts receivable, net	30,830	21,383
Inventories	13,966	12,890
Marketable securities	1,876	—
Prepaid expenses and other current assets	3,380	1,846
Total current assets	133,894	162,711
Property and equipment, net	32,883	15,297
Patents, net	4,511	3,823
Other assets	40	70
Total assets	\$171,328	\$181,901
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Current maturities of long-term debt	\$—	\$2,400
Accounts payable	9,763	9,703
Accrued expenses	20,125	17,626
Total current liabilities	29,888	29,729
Long-term liabilities		
Other liabilities	2,005	117
Total liabilities	31,893	29,846
Commitments and contingencies		
Common stock, \$0.001 par value at June 30, 2015 and 2014; authorized 100,000,000 common shares at June 30, 2015 and 2014; issued and outstanding 31,898,124 at June 30, 2015 and 31,084,742 at June 30, 2014	32	31
Additional paid in capital	410,700	390,589
Accumulated other comprehensive income	90	—
Accumulated deficit	(271,387	) (238,565 )
Total stockholders' equity	139,435	152,055
Total liabilities and stockholders' equity	\$171,328	\$181,901

The accompanying notes are an integral part of these consolidated financial statements.

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Cardiovascular Systems, Inc.

Consolidated Statements of Operations

(Dollars in thousands, except per share and share amounts)

	Year Ended June 30,		
	2015	2014	2013
Net revenues	\$181,544	\$136,612	\$103,897
Cost of goods sold	39,520	31,041	24,382
Gross profit	142,024	105,571	79,515
Expenses:			
Selling, general and administrative	143,684	117,994	86,718
Research and development	30,977	21,066	15,216
Total expenses	174,661	139,060	101,934
Loss from operations	(32,637 )	(33,489 )	(22,419 )
Interest and other, net	(185 )	(1,801 )	(1,618 )
Net loss	\$(32,822 )	\$(35,290 )	\$(24,037 )
Net loss per common share:			
Basic and diluted	\$(1.04 )	\$(1.25 )	\$(1.11 )
Weighted average common shares used in computation:			
Basic and diluted	31,547,711	28,295,758	21,685,932

The accompanying notes are an integral part of these consolidated financial statements.

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Cardiovascular Systems, Inc.  
 Consolidated Statements of Comprehensive Loss  
 (Dollars in thousands, except per share and share amounts)

	Year Ended June 30,		
	2015	2014	2013
Net loss	\$ (32,822 )	\$ (35,290 )	\$ (24,037 )
Other comprehensive income:			
Unrealized gain on available for sale securities	90	—	—
Comprehensive loss	\$ (32,732 )	\$ (35,290 )	\$ (24,037 )

The accompanying notes are an integral part of these consolidated financial statements.

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Cardiovascular Systems, Inc.

Consolidated Statements of Changes in Stockholders' Equity

(Dollars in thousands, except per share and share amounts)

	Common Stock		Additional Paid In Capital	Warrants	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount					
Balances at June 30, 2012	20,089,556	\$20	\$201,793	\$9,614	\$ —	\$(179,238 )	\$32,189
Stock-based compensation related to restricted stock awards, net	799,465	1	7,240	—	—	—	7,241
Exercise of stock options and warrants at \$7.90-\$13.98 per share	681,889	1	7,179	(1,253 )	—	—	5,927
Employee stock purchase plan activity	180,000	—	2,403	—	—	—	2,403
Conversion of convertible debt	331,115	—	4,900	—	—	—	4,900
Sale of common stock, net of issuance costs of \$2,125	2,300,000	2	38,207	—	—	—	38,209
Net loss and comprehensive loss	—	—	—	—	—	(24,037 )	(24,037 )
Balances at June 30, 2013	24,382,025	\$24	\$261,722	\$8,361	\$ —	\$(203,275 )	\$66,832
Stock-based compensation related to restricted stock awards, net	695,968	1	10,083	—	—	—	10,084
Exercise of stock options and warrants at \$5.01-\$18.55 per share	2,535,813	3	24,528	(8,269 )	—	—	16,262
Expiration of common stock warrants	—	—	92	(92 )	—	—	—
Employee stock purchase plan activity	149,839	—	4,546	—	—	—	4,546
Conversion of convertible debt	321,097	—	5,252	—	—	—	5,252
Sale of common stock, net of issuance costs of \$5,631	3,000,000	3	84,366	—	—	—	84,369
Net loss and comprehensive loss	—	—	—	—	—	(35,290 )	(35,290 )
Balances at June 30, 2014	31,084,742	\$31	\$390,589	\$—	\$ —	\$(238,565 )	\$152,055
Stock-based compensation related to restricted stock awards, net	469,575	1	14,088	—	—	—	14,089
Exercise of stock options at \$5.01- \$12.37 per share	222,937	—	2,152	—	—	—	2,152
Employee stock purchase plan activity	120,870	—	3,871	—	—	—	3,871
Unrealized gain on marketable securities	—	—	—	—	90	—	90
	—	—	—	—	—	(32,822 )	(32,822 )

Net loss and comprehensive  
loss

Balances at June 30, 2015	31,898,124	\$32	\$410,700	\$—	\$ 90	\$(271,387 )	\$139,435
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The accompanying notes are an integral part of these consolidated financial statements.

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Cardiovascular Systems, Inc.  
Consolidated Statements of Cash Flows  
(Dollars in thousands)

	Year Ended June 30,		
	2015	2014	2013
Cash flows from operating activities			
Net loss	\$(32,822	) \$(35,290	) \$(24,037
Adjustments to reconcile net loss to net cash used in operations			
Depreciation of property and equipment	2,150	1,243	903
Provision for doubtful accounts	1,121	65	195
Amortization of patents	171	124	70
Write-off of patent costs	43	64	130
Amortization of discount (premium) on debt, net	—	137	(59
Debt conversion and valuation of conversion options, net	—	716	181
Loss on disposal of property and equipment	121	—	—
Stock-based compensation	14,718	10,928	7,442
Changes in assets and liabilities			
Accounts receivable	(10,568	) (6,718	) (1,281
Inventories	(1,076	) (6,647	) 818
Prepaid expenses and other assets	(1,183	) (564	) 925
Accounts payable	581	2,375	1,467
Accrued expenses and other liabilities	4,387	6,729	2,481
Net cash used in operations	(22,357	) (26,838	) (10,765
Cash flows from investing activities			
Expenditures for property and equipment	(20,325	) (12,717	) (1,672
Purchases of marketable securities	(2,112	) —	—
Sales of marketable securities	365	—	—
Patent acquisition costs	(955	) (702	) (783
Net cash used in investing activities	(23,027	) (13,419	) (2,455
Cash flows from financing activities			
Proceeds from the employee stock purchase plan	2,882	3,371	1,752
Exercise of stock options and warrants	2,152	16,262	5,927
Proceeds from borrowings	—	4,800	4,500
Payments on borrowings	(2,400	) (9,850	) (4,800
Proceeds from sale of common stock, net of issuance costs	—	84,369	38,209
Net cash provided by financing activities	2,634	98,952	45,588
Net change in cash and cash equivalents	(42,750	) 58,695	32,368
Cash and cash equivalents			
Beginning of period	126,592	67,897	35,529
End of period	\$83,842	\$126,592	\$67,897
Noncash investing and financing activities			
Equipment included in accounts payable	\$469	\$825	\$66
Patent costs included in accounts payable	52	90	43
Conversion of convertible debt	—	5,252	4,900
Premium on convertible debt	—	—	304
Beneficial conversion feature on convertible debt	—	—	108
Net exercise of common stock warrants	—	4,322	1,130
Issuance and expiration of common stock warrants	—	92	—
Supplemental cash flow information			
Interest paid	\$23	\$534	\$1,132



The accompanying notes are an integral part of these consolidated financial statements.

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CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(dollars in thousands, except per share and share amounts)

1. Summary of Significant Accounting Policies

Company Description

Cardiovascular Systems, Inc. (the “Company”) was incorporated as Replidyne, Inc. (“Replidyne”) in Delaware in 2000. On February 25, 2009, Replidyne completed its business combination with Cardiovascular Systems, Inc., a Minnesota corporation, in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of November 3, 2008. At the effective time of the merger, Replidyne changed its name to Cardiovascular Systems, Inc.

The Company develops, manufactures and markets devices for the treatment of vascular diseases. The Company’s peripheral arterial disease products, the Stealth 360<sup>®</sup> Peripheral Orbital Atherectomy System (“OAS”) (“Stealth 360”), the Diamondback 360<sup>®</sup> Peripheral OAS, the Diamondback 360<sup>®</sup> 60cm Peripheral OAS access device and the 4 Diamondback 360 French 1.25 Peripheral OAS access device, are catheter-based platforms capable of treating a broad range of plaque types, including calcified plaque, in leg arteries both above and below the knee and address many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. The micro-invasive devices use smaller access sheaths that can provide procedural benefits and allow physicians to treat PAD patients in the small and tortuous vessels located below the knee through alternative access sites in the ankle and foot as well as in the groin. The Company no longer markets its Predator 360<sup>®</sup> Peripheral OAS.

In October 2013, the Company received premarket approval from the U.S. Food and Drug Administration to market the Diamondback 360<sup>®</sup> Coronary OAS as a treatment for severely calcified coronary arteries. The Company began a controlled commercial launch of the Diamondback 360<sup>®</sup> Coronary OAS following receipt of premarket approval.

The Company is evaluating options for international expansion to maximize the coronary and peripheral market opportunities.

Principles of Consolidation

The consolidated balance sheets and statements of operations, comprehensive loss, changes in stockholders’ equity, and cash flows include the accounts of the Company and its wholly-owned subsidiary, after elimination of all intercompany transactions and accounts.

Prior Year Revision

During the fourth quarter of fiscal 2015, the Company evaluated the presentation of its accounts payable and accrued expenses line items on the consolidated balance sheet and determined that a reclassification of amounts from accounts payable to accrued expenses would provide a more meaningful presentation. There were no changes to total current liabilities and net cash used in operations as a result of these reclassifications. The Company reclassified \$2,996 from accounts payable to accrued expenses as of June 30, 2014. In addition, the Company reclassified the changes in accounts payable and accrued expenses in the operating activities section of the consolidated statement of cash flows by \$2,249 and \$17 for the years ended June 30, 2014 and June 30, 2013. The Company has concluded that these reclassifications are not material.

Cash and Cash Equivalents

The Company considers all money market funds and other investments purchased with an original maturity of three months or less to be cash and cash equivalents.

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CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. Customer credit terms are established prior to shipment with the general standard being net 30 days. Collateral or any other security to support payment of these receivables generally is not required. The Company maintains an allowance for doubtful accounts. This allowance is an estimate and is regularly evaluated by the Company for adequacy by taking into consideration factors such as past experience, credit quality of the customer base, age of the receivable balances, both individually and in the aggregate, and current economic conditions that may affect a customer's ability to pay. Provisions for the allowance for doubtful accounts attributed to bad debt are recorded in general and administrative expenses.

The following table shows the allowance for doubtful accounts activity:

	Amount	
Balances at June 30, 2013	\$458	
Provision for doubtful accounts	65	
Write-offs	(72	)
Balances at June 30, 2014	451	
Provision for doubtful accounts	1,121	
Write-offs	(135	)
Balances at June 30, 2015	\$1,437	

#### Inventories

Inventories are stated at the lower of cost or market with cost determined on a first-in, first-out method of valuation. The establishment of inventory allowances for excess and obsolete inventories is based on estimated exposure on specific inventory items.

#### Property and Equipment

Property and equipment is carried at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over estimated useful lives of 40 years for the building; five to seven years for production equipment and furniture and fixtures; three years for computer equipment and software; and the shorter of their estimated useful lives or the lease term for leasehold improvements. Expenditures for maintenance and repairs and minor renewals and betterments which do not extend or improve the life of the respective assets are expensed as incurred. All other expenditures for renewals and betterments are capitalized. The assets and related depreciation accounts are adjusted for property retirements and disposals with the resulting gains or losses included in the consolidated statement of operations.

#### Patents

The capitalized costs incurred to obtain patents are 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. The recoverability of capitalized patent costs is dependent upon the Company's ability to derive revenue-producing products from such patents or the ultimate sale or licensing of such patent rights. Patent recoverability is regularly reviewed and any patents that are abandoned are written off at the time of abandonment.

#### Long-Lived Assets

The Company regularly evaluates the carrying value of long-lived assets for events or changes in circumstances that indicate that the carrying amount may not be recoverable or that the remaining estimated useful life should be changed. An impairment loss is recognized when the carrying amount of an asset exceeds the anticipated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition. The amount of the impairment loss to be recorded, if any, is calculated by the excess of the asset's carrying value over its fair value.

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CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### Operating Leases

The Company leases its Texas manufacturing facilities under an operating lease agreement. The lease contains rent escalation clauses for which the lease expense is recognized on a straight-line basis over the lease term. Rent expense that is recognized but not yet paid is included in other liabilities on the consolidated balance sheets.

### Revenue Recognition

The Company sells the majority of its products via direct shipment to hospitals or clinics. The Company recognizes revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sales price is fixed or determinable; and collectability is reasonably assured. The Company records 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.

### Warranty Costs

The Company provides its customers with the right to receive a replacement if a product is determined to be defective at the time of shipment. Warranty reserve provisions are estimated based on Company experience, volume, and expected warranty claims. Warranty reserve, provisions and claims were as follows:

	Amount	
Balances at June 30, 2013	\$116	
Provision	308	
Claims	(308	)
Balances at June 30, 2014	116	
Provision	377	
Claims	(367	)
Balances at June 30, 2015	\$126	

### Medical Device Excise Tax

The Patient Protection and Affordable Care Act of 2010 imposes a medical device excise tax on medical device manufacturers on their sales in the U.S. of certain devices, which was effective January 1, 2013. The excise tax is 2.3% of the taxable base and applies to a substantial majority of the Company's sales. For the years ended June 30, 2015, 2014 and 2013, the Company incurred approximately \$2,731, \$2,273, and \$987, respectively.

### Income Taxes

Deferred income taxes are recorded to reflect the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts based on enacted tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

Developing a provision for income taxes, including the effective tax rate and the analysis of potential tax exposure items, if any, requires significant judgment and expertise in federal and state income tax laws, regulations and

strategies, including the determination of deferred tax assets. The Company's judgment and tax strategies are subject to audit by various taxing authorities.

Accounting guidance requires that accounting for uncertainty in income taxes is recognized in the financial statements. The guidance provides that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized. The guidance also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

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CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### Research and Development Expenses

Research and development expenses include costs associated with the design, development, testing, enhancement and regulatory approval of the Company's products. Research and development expenses include employee compensation (including stock-based compensation), supplies and materials, consulting expenses, patent amortization, travel and facilities overhead. The Company also incurs significant expenses to operate clinical trials, including trial design, third-party fees, clinical site reimbursement, data management and travel expenses. Research and development expenses are expensed as incurred. 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.

### Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentration of credit risk consist primarily of cash and cash equivalents, marketable securities and accounts receivable.

The Company maintains its cash balances primarily with one financial institution. These balances exceed federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk in cash and cash equivalents.

The Company believes that the credit risk related to marketable securities is limited due to the adherence to an investment policy and that credit risk related to accounts receivable is limited due to a large customer base.

### Marketable securities

The Company's marketable securities consist solely of available-for-sale securities and were valued in accordance with the fair value measurement guidance discussed below. Available-for-sale securities are carried at fair value with unrealized gains and losses reported as a component of stockholders' equity as accumulated other comprehensive income (loss), net of tax. Realized gains and losses, if any, are calculated on the specific identification method and are included in interest and other, net in the consolidated statements of operations.

Available-for-sale securities are reviewed for possible impairment at least quarterly, or more frequently if circumstances arise which may indicate impairment. When the fair value of the securities declines below the amortized cost basis, impairment is indicated and it must be determined whether it is other than temporary. Impairment is considered to be other than temporary if the Company: (i) intends to sell the security, (ii) will more likely than not be forced to sell the security before recovering its cost, or (iii) does not expect to recover the security's amortized cost basis. If the decline in fair value is considered other than temporary, the cost basis of the security is adjusted to its fair market value and the realized loss is reported in earnings. Subsequent increases or decreases in fair value are reported in equity as accumulated other comprehensive income (loss).

### Fair Value Measurements

Under the authoritative guidance for fair value measurements, fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. The authoritative guidance also establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing



the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors market participants would use in valuing the asset or liability developed based upon the best information available in the circumstances. The categorization of financial assets and financial liabilities within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The hierarchy is broken down into three levels defined as follows:

Level 1 Inputs — quoted prices in active markets for identical assets and liabilities

Level 2 Inputs — observable inputs other than quoted prices in active markets for identical assets and liabilities

Level 3 Inputs — unobservable inputs

CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

As of June 30, 2015, the Company believes that the carrying amounts of its other financial instruments, including accounts receivable, accounts payable and accrued liabilities, approximate their fair value due to the short-term maturities of these instruments. See Note 9 for additional information.

#### Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### Stock-Based Compensation

The Company has stock-based compensation plans, which include stock options, nonvested share awards, and an employee stock purchase plan. Fair value of option awards is determined using option-pricing models, fair value of nonvested share awards with market conditions is determined using the Monte Carlo simulation, and fair value of nonvested share awards that vest based upon performance or service conditions is determined by the closing market price of the Company's stock on the date of grant. Stock-based compensation expense is recognized ratably over the requisite service period for the awards expected to vest.

#### Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, "Revenue From Customers With Contracts." The guidance requires an entity to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. ASU 2014-09 is effective for annual periods beginning after December 15, 2016, including interim periods within that reporting period, using one of two prescribed retrospective methods. Early adoption is not permitted. In August 2015, the FASB issued ASU 2015-14 to defer the effective date of ASU 2014-09 by one year and allow early adoption for all entities but not before the original public entity effective date. The Company is evaluating the impact of the amended revenue recognition guidance on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." The guidance requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements. The entity must also provide certain disclosures if there is substantial doubt about the entity's ability to continue as a going concern. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and interim periods thereafter. Early adoption is permitted. The Company does not anticipate a material impact on its financial statements upon adoption.

In April 2015, the FASB issued ASU No. 2015-05, "Customer's Accounting for Fees Paid in a Cloud Computing Arrangement." The ASU provides guidance to customers about whether a cloud computing arrangement includes a software license. ASU 2015-05 is effective for annual periods, including interim periods within those annual periods,

beginning after December 15, 2015. Early adoption is permitted and companies can elect to adopt the guidance prospectively to all arrangements entered into or materially modified after the effective date, or retrospectively. The Company does not anticipate a material impact on its financial statements upon adoption.

In July 2015, the FASB issued ASU No. 2015-11, "Simplifying the Measurement of Inventory." The guidance requires an entity to measure inventory within the scope of the ASU at the lower of cost and net realizable value. ASU 2015-11 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2016 and should be applied prospectively. Early adoption is permitted. The Company does not anticipate a material impact on its financial statements upon adoption.

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CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 2. Selected Consolidated Financial Statement Information

## Accounts Receivable, Net

Accounts receivable consists of the following:

	June 30, 2015	2014
Accounts receivable	\$32,267	\$21,834
Less: Allowance for doubtful accounts	(1,437	) (451 )
Total Accounts receivable	\$30,830	\$21,383

## Inventories, Net

Inventories consist of the following:

	June 30, 2015	2014
Raw materials	\$7,292	\$5,879
Work in process	1,108	855
Finished goods	5,566	6,156
Total Inventories	\$13,966	\$12,890

## Property and Equipment

Property and equipment consists of the following:

	June 30, 2015	2014
Land	\$500	\$500
Building	22,468	—
Equipment	11,745	6,436
Furniture	2,581	626
Leasehold improvements	110	233
Construction in progress	1,218	11,499
	38,622	19,294
Less: Accumulated depreciation	(5,739	) (3,997 )
Total Property and equipment, net	\$32,883	\$15,297

In June 2014, the Company announced plans to build a new corporate headquarters in New Brighton, Minnesota, construction of which was completed in March 2015. The 125,000-square-foot, two-story building has space for more than 500 employees and contains dedicated research and development, training and education, manufacturing facilities and office space. The new headquarters replaces the two previous St. Paul, Minnesota leased facilities.

## Patents, net

Patents, net consist of the following:

	June 30, 2015	2014
Patents	\$5,388	\$4,529

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Less: Accumulated amortization	(877	) (706	)
Total Patents, net	\$4,511	\$3,823	

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CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

As of June 30, 2015, future estimated amortization of patents and patent licenses is as follows:

2016	\$ 166
2017	187
2018	182
2019	174
2020	170
Thereafter	3,632
	\$4,511

This future amortization expense is an estimate. Actual amounts may vary from these estimated amounts due to additional intangible asset acquisitions, approval of patents-in-process, potential impairment, accelerated amortization or other events.

#### Accrued Expenses

Accrued expenses consist of the following:

	June 30,	
	2015	2014
Salaries and bonus	\$3,961	\$5,244
Commissions	5,387	6,069
Accrued vacation	3,770	2,843
Accrued excise, sales and other taxes	3,217	1,812
Clinical studies	2,446	1,117
Other	1,344	541
Total Accrued expenses	\$20,125	\$17,626

### 3. Debt

#### Loan and Security Agreement with Silicon Valley Bank

On March 29, 2010, the Company entered into an amended and restated loan and security agreement with Silicon Valley Bank (“SVB”). The agreement was amended on December 27, 2011 to increase outstanding borrowings, amended on June 29, 2012 to modify financial covenants and reduce the interest rate and other fees, amended on May 10, 2013 to modify financial covenants, amended on June 26, 2014 to extend the line of credit to September 30, 2014 and reduce the interest rate, and amended on September 29, 2014 to extend the line of credit's maturity date to December 31, 2014. The agreement, as amended, included a \$15,000 line of credit. The agreement matured on December 31, 2014.

The \$15,000 line of credit had a floating interest rate equal to the Wall Street Journal's prime rate. Interest on borrowings were due monthly and the principal balance was due at maturity. Borrowings on the line of credit were based on 85% of eligible accounts. Accounts receivable receipts were deposited into a lockbox account in the name of SVB. The line of credit was subject to non-use fees, annual fees, and cancellation fees. The balance outstanding on the line of credit at June 30, 2015 and 2014 was \$0 and \$2,400, respectively.

#### Loan and Security Agreement with Partners for Growth

On April 14, 2010, the Company entered into a loan and security agreement with Partners for Growth (“PFG”), as amended on August 23, 2011, December 27, 2011, June 30, 2012 and May 10, 2013. The amended agreement provided that PFG would make loans to the Company up to \$5,000. The loans had a floating per annum interest rate equal to 2.75% above SVB's prime rate, and such interest was payable monthly. The principal balance of and any accrued and unpaid interest on any notes were due on the maturity date and could not be prepaid by the Company at any time in whole or in part. The agreement matured on April 14, 2015.

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CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

At any time prior to the maturity date, PFG could have, at its option, converted any of the outstanding loans into shares of the Company's common stock at the applicable conversion price, which in each case equaled the ten-day volume weighted average price per share of the Company's common stock prior to the issuance date of each note. The Company could have also effected at any time a mandatory conversion of amounts, subject to certain terms, conditions and limitations provided in the agreement, including a requirement that the ten-day volume weighted average price of the Company's common stock prior to the date of conversion was at least 15% greater than the conversion price. The Company could have reduced the conversion price to a price that represented a 15% discount to the ten-day volume weighted average price of its common stock to satisfy this condition and effected a mandatory conversion. The Company recorded an expense of \$0 and \$(61) for the years ended June 30, 2015 and 2014 related to the change in fair value of the conversion options on all outstanding loans. This amount is a component of interest and other, net on the accompanying statement of operations. There were no outstanding loans under the loan and security agreement at June 30, 2015 and 2014. Any net unamortized premium associated with the loans, a beneficial conversion feature, and other fees paid to the lender were recorded as a component of interest and other, net on the accompanying statement of operations.

During the year ended June 30, 2014, PFG converted various loans, in accordance with the conversion terms set forth in the agreement. The non-cash conversion activity was as follows (in thousands, except share amounts):

Date of Conversion	Amount Converted	Shares Issued Upon Conversion
August 14, 2013	\$500	32,679
October 15, 2013	\$1,000	65,530
October 23, 2013	\$1,500	96,586
November 13, 2013	\$1,150	72,784
December 3, 2013	\$850	53,518

Upon conversion of the PFG loans, the Company recorded a noncash write-off of \$0 and \$252 of premiums related to the loans during the years ended June 30, 2015 and 2014, respectively. Any loans were secured by certain of the Company's assets, and the agreement contained customary covenants limiting the Company's ability to, among other things, incur debt or liens, make certain investments and loans, effect certain redemptions of and declare and pay certain dividends on its stock, permit or suffer certain change of control transactions, dispose of collateral, or change the nature of its business. In addition, the PFG loan and security agreement contained financial covenants requiring the Company to maintain certain liquidity and fixed charge coverage ratios. The Company was in compliance with all financial covenants at June 30, 2014 and through the maturity date. If the Company did not comply with the various covenants, PFG could have, subject to various customary cure rights, declined to provide additional loans, required amortization of any future loan over its remaining term, or required the immediate payment of all amounts outstanding under any future loan and foreclosed on any or all collateral, depending on which financial covenants were not maintained.

#### 4. Interest and Other, Net

Interest and other, net, includes the following:

	Year Ended June 30,			
	2015	2014	2013	
Interest expense, net of premium amortization	\$ (23	) \$ (1,034	) \$ (1,345	)
Change in fair value of conversion options	—	(61	) 370	)
Net write-offs upon conversion (option and unamortized premium)	—	(655	) (551	)



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Other	(162	)	(51	)	(92	)
Total Interest and other, net	\$(185	)	\$(1,801	)	\$(1,618	)

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CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 5. Equity Offerings

The Company had the following registered underwritten public offerings during the years ended June 30, 2015, 2014 and 2013:

Offering Date	Shares Sold	Sale Price	Net Proceeds <sup>(1)</sup>
November 26, 2013	3,000,000	\$ 30.00	\$ 84,369
March 25, 2013	2,300,000	\$ 17.60	\$ 38,209

(1) Proceeds after deducting underwriting discounts, commissions and expenses.

## 6. Common Stock Warrants

The following summarizes common stock warrant activity:

	Warrants Outstanding	Price Range per Share
Warrants outstanding at June 30, 2012	2,457,433	\$ 8.78 - 61.30
Exercised	(362,861 )	\$ 8.83 - 9.80
Expired	(2,854 )	\$ —
Warrants outstanding at June 30, 2013	2,091,718	\$ 8.78 - 61.30
Exercised	(2,063,904 )	\$ 8.78 - 9.33
Expired	(27,814 )	\$ 8.83 - 61.30
Warrants outstanding at June 30, 2014	—	

The aggregate intrinsic value of a warrant is the amount by which the market value of the underlying stock exceeds the exercise price of the warrant. The aggregate intrinsic value for warrants at June 30, 2013 was \$25,697. There was no warrant activity during the year ended June 30, 2015.

## 7. Stock Options and Restricted Stock Awards

The Company maintains the 2014 Equity Incentive Plan (the “2014 Plan”) for the purpose of granting equity awards to employees and directors. The 2014 Plan was approved by the Company's stockholders and became effective in November 2014. The 2014 Plan was amended in May 2015. The 2014 Plan replaced the 2007 Equity Incentive Plan (the “2007 Plan”), and no further equity awards may be granted under the 2007 Plan. The Company also maintains two other terminated plans, the 1991 Stock Option Plan (the “1991 Plan”) and 2003 Stock Option Plan (the “2003 Plan”) (the 2014 Plan, the 2007 Plan, the 2003 Plan and the 1991 Plan are collectively referred to as the “Plans”).

The 2014 Plan allows for the granting of up to 2,030,000 shares of common stock as approved by the board of directors or committees thereof in the form of nonqualified or incentive stock options, restricted stock awards, restricted stock unit awards, performance share awards, performance unit awards or stock appreciation rights to officers, directors, consultants and employees of the Company.

### Stock Options

All options granted under the Plans become exercisable over periods established at the date of grant. The option exercise price is generally not less than the estimated fair market value of the Company's common stock at the date of grant, as determined by the Company's management and board of directors. In addition, the Company has granted nonqualified stock options to a director outside of the Plans.



CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price
Options outstanding at June 30, 2012	2,371,198	\$ 10.31
Exercised	(533,954	) \$ 11.59
Forfeited or expired	(97,581	) \$ 12.49
Options outstanding at June 30, 2013	1,739,663	\$ 9.79
Exercised	(816,854	) \$ 9.38
Forfeited or expired	—	\$ —
Options outstanding at June 30, 2014	922,809	\$ 10.16
Exercised	(222,937	) \$ 9.65
Forfeited or expired	—	\$ —
Options outstanding at June 30, 2015	699,872	\$ 10.32

As of June 30, 2015, all options were fully vested. An employee's vested options must be exercised at or within 90 days of termination to avoid forfeiture. The Company determined the fair value of options using the Black-Scholes option pricing model. The estimated fair value of options, including the effect of estimated forfeitures, was recognized as expense on a straight-line basis over the options' vesting periods. There were no options granted during the years ended June 30, 2015, 2014 or 2013.

The aggregate intrinsic value of a stock option award is the amount by which the market value of the underlying stock exceeds the exercise price of the award. The aggregate intrinsic value for vested and outstanding options at June 30, 2015, 2014 and 2013, was \$11,286, \$19,377 and \$19,842, respectively. The total aggregate intrinsic value of options exercised during the years ended June 30, 2015, 2014 and 2013, was \$4,907, \$16,848, and \$1,712, respectively. Cash received from option exercises was \$2,152, \$7,664 and \$5,691 for the years ended June 30, 2015, 2014 and 2013, respectively. The weighted average remaining contractual life of options outstanding at June 30, 2015 was 2.2 years. Shares supporting option exercises are sourced from new share issuances.

#### Restricted Stock Awards

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

The Company grants performance based restricted stock awards to certain executives. The awards include grants that vest based upon the achievement of certain thresholds measuring total shareholder return during periods within the fiscal year as compared to a pre-determined peer group of companies, and grants that vest based upon achievement of certain thresholds measuring annual revenue growth during the fiscal year as compared to a pre-determined peer group of companies. The aggregate maximum shares granted were as follows:

Performance Measurement	2015	2014	2013
Total shareholder return	76,112	53,566	67,854
Annual revenue growth	76,112	53,566	67,854

The total shareholder return and the revenue growth performance measures exceeded the established thresholds for fiscal 2014 and fiscal 2013. The Company's total stockholder return for fiscal 2015 was 69% of the median total stockholder return of the peer group of companies, which resulted in the forfeiture of 49,773 shares subsequent to

June 30, 2015. The Company expects the fiscal 2015 revenue growth achievement to be above the target threshold but below the maximum threshold.

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CARDIOVASCULAR SYSTEMS, INC.  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Restricted stock award activity, including performance based awards, is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Restricted stock awards outstanding at June 30, 2012	1,244,830	\$ 9.08
Granted	880,282	\$ 11.46
Forfeited	(123,494	) \$ 9.31
Vested	(571,488	) \$ 8.76
Restricted stock awards outstanding at June 30, 2013	1,430,130	\$ 10.78
Granted	741,039	\$ 21.28
Forfeited	(106,742	) \$ 14.04
Vested	(788,024	) \$ 10.47
Restricted stock awards outstanding at June 30, 2014	1,276,403	\$ 17.37
Granted	514,296	\$ 30.01
Forfeited	(119,081	) \$ 21.43
Vested	(676,295	) \$ 17.31
Restricted stock awards outstanding at June 30, 2015	995,323	\$ 21.31

Total fair value of restricted stock that vested during fiscal 2015, 2014 and 2013 was \$11,708, \$8,252, and \$5,006, respectively. Estimated pre-vesting forfeitures are considered in determining stock-based compensation expense. As of June 30, 2015, 2014 and 2013, the Company estimated its weighted average forfeiture rate at 19.2%, 17.5% and 11.5%, respectively. As of June 30, 2015, there was approximately \$13,238 of total unrecognized compensation expense, net of the effect of estimated forfeitures, related to nonvested restricted stock awards which is expected to be recognized over a weighted-average period of 2.15 years.

#### Restricted Stock Units

The Company grants restricted stock units to members of the Board of Directors. Restricted stock units represent the right to receive payment in the form of shares of the Company's common stock or in cash at the Company's option. Restricted stock unit payments would occur within 30 days following the six month anniversary of the date that the director ceases to serve on the Board or, if the restricted stock units are granted in lieu of an annual cash retainer, on the payment date selected by the director that is at least two years after the grant date. The estimated fair value of restricted stock awards is recognized on a straight-line basis over the vesting period.

Restricted stock unit activity is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Restricted stock units outstanding at June 30, 2012	284,467	\$ 7.67
Granted	70,883	\$ 9.41
Forfeited	(42,677	) \$ 7.03
Restricted stock units outstanding at June 30, 2013	312,673	\$ 8.15
Granted	45,228	\$ 21.87
Converted to common stock	(61,770	) \$ 8.90
Restricted stock units outstanding at June 30, 2014	296,131	\$ 10.09
Granted	41,172	\$ 29.57
Converted to common stock	(74,360	) \$ 11.90

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Restricted stock units outstanding at June 30, 2015	262,943	\$ 12.62
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CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Stock-Based Compensation Expense

The following amounts were recognized as stock-based compensation expense in the consolidated statements of operations for the year ended June 30, 2015:

	Restricted Stock Awards	Employee Stock Purchase Plan	Restricted Stock Units	Total
Cost of goods sold	\$937	\$64	\$—	\$1,001
Selling, general and administrative	10,486	825	917	12,228
Research and development	1,388	101	—	1,489
Total	\$12,811	\$990	\$917	\$14,718

The following amounts were recognized as stock-based compensation expense in the consolidated statements of operations for the year ended June 30, 2014:

	Restricted Stock Awards	Employee Stock Purchase Plan	Restricted Stock Units	Total
Cost of goods sold	\$576	\$91	\$—	\$667
Selling, general and administrative	7,403	998	770	9,171
Research and development	1,003	87	—	1,090
Total	\$8,982	\$1,176	\$770	\$10,928

The following amounts were recognized as stock-based compensation expense in the consolidated statements of operations for the year ended June 30, 2013:

	Restricted Stock Awards	Employee Stock Purchase Plan	Restricted Stock Units	Total
Cost of goods sold	\$392	\$35	\$—	\$427
Selling, general and administrative	4,954	596	667	6,217
Research and development	780	18	—	798
Total	\$6,126	\$649	\$667	\$7,442

Shares Available for Grant

The following summarizes shares available for grant under the Company's 2014 Plan:

Reserved	2,030,000
Granted	(171,411 )
Forfeited, expired or cancelled	5,866
Shares available for grant at June 30, 2015 <sup>(a)</sup>	1,864,455

<sup>(a)</sup> Excludes the effect of shares granted, exercised, forfeited or expired related to activity from shares granted outside of the 2014 Plan.

8. Employee Stock Purchase Plan

The Company maintains an employee stock purchase plan ("ESPP"). The plan provides eligible employees the opportunity to acquire common stock in accordance with Section 423 of the Internal Revenue Code of 1986. Stock can be purchased each 6-month period per year (twice per year). The purchase price is equal to 85% of the lower of



the price at the beginning or the end of the respective period. Employees purchased 120,870 shares at an average price of \$23.84 per share during the year ended June 30, 2015. Shares reserved under the plan at June 30, 2015 totaled 0. The ESPP allows for an annual increase in reserved shares on each July 1 equal to the lesser of (i) 1% of the common shares outstanding, or (ii) 180,000 shares, provided that the Board of Directors may designate a smaller amount of shares to be reserved. On July 1, 2015, 180,000 shares were added to the ESPP.

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CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 9. Deferred Compensation

The Company offers certain members of management and highly compensated employees the opportunity to defer up to 100% of their base salary (after 401(k), payroll tax and other deductions), performance bonus and discretionary bonus and elect to receive the deferred compensation at a fixed future date of participant's choosing. Each participant may, at the time of his or her deferral election, choose to allocate the deferred compensation into investment alternatives set by the Human Resources and Compensation Committee at that time. The amount payable to each participant under the plan will change in value based upon the investment selected by that participant and is classified as current or long-term on the Company's balance sheet based on the disbursement elections made by the participants. As of June 30, 2015, the amount payable is all classified as long-term and is included in the other liabilities on the consolidated balance sheet.

Beginning in August 2014, the Company acquired available-for-sale marketable securities under the deferred compensation plan. These available-for-sale marketable securities are primarily comprised of investments with a fixed income and equity investments.

Investments as of June 30, 2015 consisted of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Mutual funds	1,786	90	—	1,876
Total short-term investments	1,786	90	—	1,876

During the year ended June 30, 2015, there were \$2,112 in purchases of available-for-sale securities and \$325 of available-for-sale securities were sold. There were no other-than-temporary impairments during the year ended June 30, 2015. The gross amount of realized losses on a scheduled disbursement during the year ended June 30, 2015 was not material.

The following table provides information by level for the Company's available-for-sale marketable securities as of June 30, 2015 that were measured at fair value on a recurring basis:

	Fair Value	Fair Value Measurements Using Inputs Considered as		
		Level 1	Level 2	Level 3
Mutual funds	1,876	1,275	601	—
Total short-term investments	1,876	1,275	601	—

The Company's marketable securities classified within Level 1 are valued primarily using real-time quotes for transactions in active exchange markets. Marketable securities within Level 2 are valued using readily available pricing sources. There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy during the year ended June 30, 2015. Any transfers between levels would be recognized on the date of the event or when a change in circumstances causes a transfer.

CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 10. Income Taxes

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

	June 30, 2015	2014
Deferred tax assets		
Stock-based compensation	\$4,166	\$4,135
Accrued expenses	2,374	1,779
Inventories	356	639
Compensation accruals	695	—
Depreciation and amortization	318	266
Other	582	238
Research and development credit carryforwards	4,102	3,825
Net operating loss carryforwards	71,726	57,817
Total deferred tax assets	84,319	68,699
Valuation allowance	(84,319	) (68,699
Net deferred tax assets	\$—	\$—

The Company has established valuation allowances to fully offset its deferred tax assets due to the uncertainty about the Company's ability to generate the future taxable income necessary to realize these deferred assets, particularly in light of the Company's historical losses. The future use of net operating loss carryforwards is dependent on the Company attaining profitable operations, and may be limited in any one year under Internal Revenue Code Section 382 due to significant ownership changes, as defined under such Section, as a result of the Company's equity financings. A summary of the valuation allowances are as follows:

Balance at June 30, 2013	\$64,811
Additions	3,888
Balance at June 30, 2014	68,699
Additions	15,620
Balance at June 30, 2015	\$84,319

As of June 30, 2015 and 2014, the Company had federal tax NOL carryforwards of approximately \$197,501 and \$159,237, respectively. These NOL carryforwards are available to offset taxable income through 2033 and begin to expire in 2018. The Company also had various state NOL carryforwards available to offset future state taxable income. These state NOL carryforwards typically have the same expirations as the Company's federal tax NOL carryforwards.

Our federal net operating losses at June 30, 2015 do not include \$37,192 of income tax deductions in excess of previously recorded tax benefits related to stock compensation. These additional tax deductions are not included in the net operating losses referenced above since the related tax benefit will not be recognized until the deductions reduce our income tax payable. The tax benefit of these excess deductions will be reflected as a credit to additional paid in capital when recognized. Accordingly, our deferred tax assets are reported net of the excess tax deductions for stock compensation.

As of June 30, 2015 and 2014, the Company had approximately \$3,798 and \$3,624 of federal research and development credit carryforwards, respectively. As of June 30, 2015 and 2014, the Company had approximately

\$1,150 and \$949 of state research and development credit carryforwards. The federal and state research and development credit carryforwards will expire through fiscal 2035 and 2029, respectively.

As required by FASB ASC Topic 740, "Income Taxes," the Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more likely than not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. The Company recorded a liability relating to unrecognized tax benefits of \$494 and \$458 at June 30, 2015 and 2014, respectively. Due to the Company having a full valuation allowance, this liability has been netted against the deferred tax asset. The Company recognizes interest and penalties related to uncertain tax provisions as part of the provision for income taxes. The

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CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Company has not currently reserved for any interest or penalties for such reserves due to the Company being in an NOL position. The Company does not expect to recognize any benefits from the unrecognized tax benefits within the next twelve months. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

Balance at July 1, 2013	\$ 392
Increases related to prior year tax positions	28
Increases related to current year tax positions	38
Balance at June 30, 2014	458
Increases related to prior year tax positions	4
Increases related to current year tax positions	32
Balance at June 30, 2015	\$494

The Company is subject to income taxes in the U.S. federal jurisdiction and various state jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company is potentially subject to income tax examinations by tax authorities for the tax years ended June 30, 2015, 2014, 2013, 2012, and 2011. The Company is not currently under examination by any taxing jurisdiction.

#### 11. Commitments and Contingencies

##### Operating Leases

The Company leases manufacturing and office space and equipment under various lease agreements which expire at various dates through March 2020. Rental expenses were \$1,760, \$1,404, and \$1,350, for the years ended June 30, 2015, 2014, and 2013, respectively.

Future minimum lease payments under the agreements as of June 30, 2015 are as follows:

2016	\$770
2017	548
2018	517
2019	466
2020	350
Thereafter	—
	\$2,651

##### Construction of New Headquarters

On June 11, 2014, the Company entered into a Design-Build Contract and a Development Services Agreement, as well as various ancillary agreements related to the acquisition of real property located in New Brighton, Minnesota and the development of such property into the Company's new corporate headquarters. Pursuant to the Development Services Agreement with Ryan Companies, Inc. ("Ryan"), Ryan was to perform certain development services to facilitate development of the project, including coordination with the City of New Brighton and overall coordination of development strategy. The Company pays Ryan a fee for the development services, which includes a sum equal to 3.25% of the adjusted total project costs, payable at certain points in the construction process, and a sum equal to 5% of the adjusted total project costs, payable upon substantial completion of the project, as well as reimbursement of

certain expenses incurred by Ryan. The construction was substantially completed in March 2015 and the Company has accrued all remaining payments due to Ryan under the Development Services Agreement.

#### Litigation

In the ordinary conduct of business, the Company is subject to various lawsuits and claims covering a wide range of matters including, but not limited to, employment claims and commercial disputes. While the outcome of these matters is uncertain, the Company does not believe there are any significant matters as of June 30, 2015 that are probable or estimable, for which the outcome could have a material adverse impact on its consolidated balance sheets or statements of operations.

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CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

12. Employee Benefits

The Company offers a 401(k) plan to its employees. Eligible employees may authorize up to \$18 of their annual compensation as a contribution to the plan, subject to Internal Revenue Service limitations. The plan also allows eligible employees over 50 years old to contribute an additional \$6 subject to Internal Revenue Service limitations. All employees must be at least 21 years of age to participate in the plan. The Company did not provide any employer matching contributions for the years ended June 30, 2015, 2014, and 2013.

13. Texas Production Facility

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

The Company and the PEDC entered into a Corporate Job Creation Agreement dated June 17, 2009, which was subsequently amended July 2, 2012. The Job Creation Agreement, as amended, provided the Company with \$2,975 in net cash incentive funds. The Company believes it will be able to comply with the conditions specified in the amended agreement. The PEDC will provide the Company with an additional \$425 of net cash incentive funds if: (1) the Company hires 125 full-time employee at the facility on or before June 30, 2015 and (2) maintains 125 employees at the facility through June 30, 2016. The Company had the opportunity to receive an additional \$425 of net cash incentive funds upon hiring the 75th employee on or before March 31, 2014; however, the Company did not achieve this incentive.

In order to retain all of the cash incentives, the Company must have maintained no fewer than 25 jobs at the Texas facility through June 30, 2015. Failure to meet this requirement would have resulted in an obligation to make reimbursement payments to the PEDC as outlined in the amended agreement. As of June 30, 2015, the Company was in compliance with all minimum requirements under the amended agreement. The Company will not have any reimbursement requirements after June 30, 2015.

The Job Creation Agreement, as amended, also provided the Company with a net \$1,020 award, of which \$510 was received from the PEDC and the remainder is funded through the Texas Enterprise Fund program associated with the State of Texas. As of June 30, 2015, \$340 has been received and the remaining \$170 will be provided upon the hiring of the 75th full-time employee at the facility. The grant from the State of Texas is subject to reimbursement if the Company fails to meet certain job creation targets through 2014 and maintain these positions through 2020. The Company reimbursed the State of Texas \$139 and \$46 during fiscal 2015 and 2014, respectively, as it did not meet certain employment targets.

The Company has presented the net cash incentive funds as a current and long-term liability on the balance sheet. The liabilities are reduced through the term of the agreement and recorded as an offset to expenditures incurred using a systematic methodology. As of June 30, 2015, the deferred grant incentive liabilities have been reduced by \$59 in cumulative expenses, resulting in a remaining current liability of \$0.

14. Earnings Per Share

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

Year Ended June 30,

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	2015	2014	2013
Numerator			
Net loss	\$(32,822 )	\$(35,290 )	\$(24,037 )
Denominator			
Weighted average common shares — basic	31,547,711	28,295,758	21,685,932
Effect of dilutive stock options and warrants <sup>(a)(b)(c)(d)</sup>	—	—	—
Weighted average common shares outstanding — diluted	31,547,711	28,295,758	21,685,932
Net loss per common share — basic and diluted	\$(1.04 )	\$(1.25 )	\$(1.11 )

At June 30, 2015, 2014, and 2013; 0, 0, and 2,091,718, warrants, respectively, were outstanding. The effect of the (a) shares that would be issued upon exercise of these warrants has been excluded from the calculation of diluted loss per share, because those shares are anti-dilutive.



CARDIOVASCULAR SYSTEMS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

At June 30, 2015, 2014, and 2013; 699,872, 922,809, and 1,739,663 stock options, respectively, were outstanding.  
(b) The effect of the shares that would be issued upon exercise of these options has been excluded from the calculation of diluted loss per share, because those shares are anti-dilutive.

At June 30, 2015, 2014, and 2013; 0, 0 and 321,099 additional shares of common stock were issuable upon the conversion of outstanding convertible debt agreements. The effect of the shares that would be issued upon  
(c) conversion of these debt agreements has been excluded from the calculation of diluted loss per share because those shares are anti-dilutive.

At June 30, 2015, 2014, and 2013; 262,943, 296,131 and 312,673 additional shares of common stock were issuable upon the settlement of outstanding restricted stock units. The effect of the shares that would be issued upon  
(d) settlement of these restricted stock units has been excluded from the calculation of diluted loss per share because those shares are anti-dilutive.

#### 15. Quarterly Data (Unaudited)

The following table sets forth the Company's unaudited quarterly summary consolidated statements of operations in each of the quarters for the years ended June 30, 2015 and 2014. The information for each of these quarters is unaudited and has been prepared on the same basis as the consolidated financial statements. This data should be read in conjunction with the consolidated financial statements and related notes. These operating results may not be indicative of results to be expected for any future period (amounts in thousands, except per share data).

	2015				
	Q1	Q2	Q3	Q4	Total
Net revenue	\$41,354	\$44,732	\$47,004	\$48,454	\$181,544
Gross profit	\$32,469	\$35,386	\$36,588	\$37,581	\$142,024
Net loss	\$(8,224)	\$(5,273)	\$(10,656)	\$(8,669)	\$(32,822)
Net loss per common share (basic & diluted) <sup>(1)</sup>	\$(0.26)	\$(0.17)	\$(0.34)	\$(0.27)	\$(1.04)
	2014				
	Q1	Q2	Q3	Q4	Total
Net revenue	\$29,766	\$32,337	\$34,945	\$39,564	\$136,612
Gross profit	\$22,902	\$25,024	\$27,196	\$30,449	\$105,571
Net loss	\$(7,292)	\$(8,658)	\$(9,712)	\$(9,628)	\$(35,290)
Net loss per common share (basic & diluted) <sup>(1)</sup>	\$(0.29)	\$(0.32)	\$(0.32)	\$(0.31)	\$(1.25)

(1) The summation of quarterly per share data may not equate to the calculation for the full fiscal year as quarterly calculations are performed on a discrete basis.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, are responsible for establishing and maintaining our disclosure controls and procedures. The Certifying Officers have reviewed and evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 240.13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of June 30, 2015. Based on that review and evaluation, which included inquiries made to certain other employees of the Company, the Certifying Officers have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, the Company's disclosure controls and procedures, as designed and implemented, are effective.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) for the Company. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that the Company's internal control over financial reporting was effective as of June 30, 2015.

PricewaterhouseCoopers LLP, the independent registered public accounting firm that audited the consolidated financial statements included in this Annual Report on Form 10-K, has also audited the Company's internal control over financial reporting as of June 30, 2015, as stated in their attestation report included in Part IV, Item 15 of this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended June 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

On July 29, 2015, the Board of Directors of the Company approved the following compensation arrangements for the Company's named executive officers for fiscal 2016.

Base Salary	
Name	2016 Base Salary
David L. Martin	\$630,000
Laurence L. Betterley	\$368,095
Kevin J. Kenny	\$430,000
Robert J. Thatcher	\$344,292
Paul Koehn	\$327,928



## Bonus Plan

For the twelve month period ending June 30, 2016, each executive officer of the Company is eligible to receive cash incentive compensation pursuant to the Fiscal 2016 Executive Officer Bonus Plan (the “Bonus Plan”) as follows:

### Revenue and Adjusted EBITDA Goals

Receipt of cash incentive compensation for fiscal 2016 is based on the Company’s achievement of revenue and adjusted EBITDA financial goals for fiscal 2016. Adjusted EBITDA is defined as EBITDA with stock compensation added back into the calculation, in addition to an add-back of depreciation and amortization. Target bonus amounts are weighted 67% for the revenue goal and 33% for the adjusted EBITDA goal. Target bonus levels as a percentage of base salary are 100% for the President and Chief Executive Officer, 75% for the Chief Operating Officer, 60% for the Chief Financial Officer, and 50% for the other executive officers. Depending upon the Company’s performance against the goals, participants are eligible to earn 50% to 200% of each of the adjusted EBITDA and revenue portions of their target bonus amount. The Bonus Plan criteria are the same for all of the executive officers.

### Management by Objective Targets

The Bonus Plan also provides “management by objective” (“MBO”) targets related to certain predetermined milestones for fiscal 2016 relating to sales productivity and regulatory milestones. Achievement of the MBO targets could result in additional cash bonuses to executive officers for each target achieved of 5.0% of their annual base salaries, up to a total of 15.0% of their annual base salaries. The Compensation Committee also has authority to grant additional discretionary cash bonuses of up to 20% of annual base salary for any executive officer.

### Equity Compensation

Additionally, each executive officer of the Company received the following grants of restricted stock on August 10, 2015:

Name/Title	Time-Based	Revenue Growth	Stockholder Return
David L. Martin President and Chief Executive Officer	37,358	56,036	56,036
Laurence L. Betterley Chief Financial Officer	14,032	21,048	21,047
Kevin Kenny Chief Operating Officer	12,749	19,124	19,123
Robert J. Thatcher Chief Healthcare Policy Officer	10,208	15,312	15,312
Paul Koehn Senior Vice President of Quality and Operations	6,945	10,418	10,417

The amount of restricted stock granted to each executive officer is based upon the target equity grant for each executive officer divided by the closing price per share of the Company’s common stock on August 10, 2015; however, the restricted stock grants that vest based on revenue growth and total stockholder return provide the executive officer the opportunity to earn up to 200% of the target number of shares if performance goals are satisfied, and the grants set forth above represent such maximum amount and any shares not earned will be forfeited upon confirmation of performance achievement. Target equity grants as a percentage of base salary are 350% for the President and Chief Executive Officer, 225% for the Chief Financial Officer, 175% for the Chief Operating Officer and Chief Healthcare Policy Officer, and 125% for the other executive officers. The restricted stock grants under the column above titled (i) “Time-Based” will vest in equal installments of 1/3 on each of the first three anniversaries of

August 13, 2015; (ii) "Revenue Growth" will vest based on the Company's revenue growth versus the Company's peer group; and (iii) "Stockholder Return" will vest based on the Company's total stockholder return versus the Company's peer group.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Other than the information included in this Form 10-K under the heading “Executive Officers of the Registrant,” which is set forth at the end of Part I, the information required by Item 10 is incorporated by reference to the sections labeled “Election of Directors,” “Information Regarding the Board of Directors and Corporate Governance” and “Section 16(a) Beneficial Ownership Reporting Compliance,” all of which will appear in our definitive proxy statement for our 2015 Annual Meeting.

Item 11. Executive Compensation.

The information required by Item 11 is incorporated herein by reference to the sections entitled “Executive Compensation,” “Director Compensation,” “Human Resources and Compensation Committee” and “Compensation Committee Interlocks and Insider Participation,” all of which will appear in our definitive proxy statement for our 2015 Annual Meeting.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by Item 12 is incorporated herein by reference to the sections entitled “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information,” which will appear in our definitive proxy statement for our 2015 Annual Meeting.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by Item 13 is incorporated herein by reference to the sections entitled “Independence of the Board of Directors” and “Transactions With Related Persons,” which will appear in our definitive proxy statement for our 2015 Annual Meeting.

Item 14. Principal Accounting Fees and Services.

The information required by Item 14 is incorporated herein by reference to the section entitled “Principal Accountant Fees and Services,” which will appear in our definitive proxy statement for our 2015 Annual Meeting.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as part of this report.

(1) Financial Statements. The following financial statements are included in Part II, Item 8 of this Annual Report on Form 10-K:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of June 30, 2015 and 2014

Consolidated Statements of Operations for the years ended June 30, 2015, 2014 and 2013

Consolidated Statements of Comprehensive Loss for the years ended June 30, 2015, 2014 and 2013

Consolidated Statements of Stockholders' Equity and Comprehensive Loss for the years ended June 30, 2015, 2014 and 2013

Consolidated Statements of Cash Flows for the years ended June 30, 2015, 2014 and 2013

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules.

All financial statement schedules have been omitted, because they are not applicable, are not required, or the information is included in the Financial Statements or Notes thereto

(3) Exhibits. See "Exhibit Index" immediately following the signature page of this Form 10-K

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

## CARDIOVASCULAR SYSTEMS, INC.

Date: August 27, 2015

By: /s/ David L. Martin  
David L. Martin  
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Each person whose signature appears below constitutes and appoints David L. Martin and Laurence L. Betterley as the undersigned's true and lawful attorneys-in fact and agents, each acting alone, with full power of substitution and resubstitution, for the undersigned and in the undersigned's name, place and stead, in any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granted unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all said attorneys-in-fact and agents, each acting alone, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Signature	Title	Date
/s/ David L. Martin David L. Martin	President, Chief Executive Officer and Director (principal executive officer)	August 27, 2015
/s/ Laurence L. Betterley Laurence L. Betterley	Chief Financial Officer (principal financial and accounting officer)	August 27, 2015
/s/ Scott Bartos Scott Bartos	Director	August 27, 2015
/s/ Brent G. Blackey Brent G. Blackey	Director	August 27, 2015
/s/ Edward Brown Edward Brown	Director	August 27, 2015
/s/ William E. Cohn William E. Cohn	Director	August 27, 2015
/s/ Augustine Lawlor Augustine Lawlor	Director	August 27, 2015
/s/ Leslie Trigg Leslie Trigg	Director	August 27, 2015
/s/ Scott Ward Scott Ward	Director	August 27, 2015





EXHIBIT INDEX  
 CARDIOVASCULAR SYSTEMS, INC.  
 FORM 10-K

Exhibit No.	Description
3.1	Restated Certificate of Incorporation, as amended. <sup>(7)</sup>
3.2	Amended and Restated Bylaws. <sup>(23)</sup>
4.1	Specimen Common Stock Certificate. <sup>(2)</sup>
4.2	Registration Rights Agreement by and among Cardiovascular Systems, Inc. and certain of its stockholders, dated as of March 16, 2009. <sup>(1)</sup>
10.1	Lease, dated September 26, 2005, by and between Cardiovascular Systems, Inc., a Minnesota corporation, and Industrial Equities Group LLC. <sup>(3)</sup>
10.2	First Amendment to the Lease, dated February 20, 2007, by and between Cardiovascular Systems, Inc., a Minnesota corporation, and Industrial Equities Group LLC. <sup>(3)</sup>
10.3	Second Amendment to the Lease, dated March 9, 2007, by and between Cardiovascular Systems, Inc., a Minnesota corporation, and Industrial Equities Group LLC. <sup>(3)</sup>
10.4	Third Amendment to the Lease, dated September 26, 2007, by and between Cardiovascular Systems, Inc., a Minnesota corporation, and Industrial Equities Group LLC. <sup>(3)</sup>
10.5	Assumption of Lease, dated March 23, 2009 by Cardiovascular Systems, Inc. <sup>(7)</sup>
10.6†	Employment Agreement, dated December 19, 2006, by and between Cardiovascular Systems, Inc., a Minnesota corporation, and David L. Martin. <sup>(3)</sup>
10.7†	Employment Agreement, dated April 7, 2008, by and between Cardiovascular Systems, Inc., a Minnesota corporation, and Laurence L. Betterley. <sup>(3)</sup>
10.8†	Employment Agreement, dated May 9, 2011, by and between Cardiovascular Systems, Inc. and Kevin J. Kenny. <sup>(13)</sup>
10.9†	Form of Standard Employment Agreement. <sup>(3)</sup>
10.10†*	Fiscal Year 2016 Executive Officer Base Salaries.
10.11†*	Fiscal 2016 Executive Officer Bonus Plan and Equity Compensation.
10.12†*	Fiscal Year 2016 Director Compensation Arrangements.
10.13†	Form of Director and Officer Indemnification Agreement. <sup>(7)</sup>
10.14†	Cardiovascular Systems, Inc. Amended and Restated 2007 Equity Incentive Plan. <sup>(5)</sup>
10.15†	Form of Incentive Stock Option Agreement under the Amended and Restated 2007 Equity Incentive Plan. <sup>(7)</sup>
10.16†	Form of Non-Qualified Stock Option Agreement under the Amended and Restated 2007 Equity Incentive Plan. <sup>(7)</sup>
10.17†	Form of Restricted Stock Agreement under the Amended and Restated 2007 Equity Incentive Plan. <sup>(13)</sup>
10.18†	Form of Restricted Stock Unit Agreement under the Amended and Restated 2007 Equity Incentive Plan. <sup>(13)</sup>
10.19†	Form of Performance Share Award under the Amended and Restated 2007 Equity Incentive Plan. <sup>(7)</sup>
10.20†	Form of Performance Unit Award under the Amended and Restated 2007 Equity Incentive Plan. <sup>(7)</sup>
10.21†	Form of Stock Appreciation Rights Agreement under the Amended and Restated 2007 Equity Incentive Plan. <sup>(7)</sup>
10.22†	2003 Stock Option Plan of Cardiovascular Systems, Inc., a Minnesota corporation, as amended. <sup>(3)</sup>
10.23†	Form of Incentive Stock Option Agreement under the 2003 Stock Option Plan of Cardiovascular Systems, Inc., a Minnesota corporation. <sup>(3)</sup>

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Exhibit No.	Description
10.24†	Form of Nonqualified Stock Option Agreement under the 2003 Stock Option Plan of Cardiovascular Systems, Inc., a Minnesota corporation. <sup>(3)</sup>
10.25†	Cardiovascular Systems, Inc. Amended and Restated 2006 Employee Stock Purchase Plan. <sup>(6)</sup>
10.26	Corporate Job Creation Agreement between Pearland Economic Development Corporation and Cardiovascular Systems, Inc., dated June 17, 2009. <sup>(4)</sup>
10.27	Build-To-Suit Lease Agreement between Pearland Economic Development Corporation and Cardiovascular Systems, Inc., dated September 9, 2009. <sup>(4)</sup>
10.28	Letter Agreement between Silicon Valley Bank and Cardiovascular Systems, Inc., dated September 9, 2009. <sup>(4)</sup>
10.29	Amended and Restated Loan and Security Agreement, dated March 29, 2010, by and between Cardiovascular Systems, Inc. and Silicon Valley Bank. <sup>(8)</sup>
10.30	Loan and Security Agreement, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P. <sup>(8)</sup>
10.31	Intellectual Property Security Agreement, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P. <sup>(8)</sup>
10.32	Copyright Collateral Agreement and Notice, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P. <sup>(8)</sup>
10.33	Domain Rights Collateral Agreement and Notice, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P. <sup>(8)</sup>
10.34	Patent Collateral Agreement and Notice, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P. <sup>(8)</sup>
10.35	Trademark Collateral Agreement and Notice, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P. <sup>(8)</sup>
10.36	Letter Agreement, dated April 14, 2010, by and between Cardiovascular Systems, Inc. and Partners for Growth III, L.P. <sup>(8)</sup>
10.37	Modification No.1 dated August 23, 2011 to Loan and Security Agreement with Partners for Growth III, L.P. <sup>(11)</sup>
10.38	First Amendment to Loan and Security Agreement, dated as of December 27, 2011, by and between the Company and Silicon Valley Bank. <sup>(12)</sup>
10.39	Modification No. 2 to Loan and Security Agreement, dated as of December 27, 2011, by and between the Company and Partners for Growth III, L.P. <sup>(12)</sup>
10.40	Fourth Amendment to Lease, dated March 23, 2012, by and between the Company and Industrial Equities Group LLC. <sup>(13)</sup>
10.41	Second Amendment to Loan and Security Agreement, dated June 29, 2012, by and between the Company and Silicon Valley Bank. <sup>(14)</sup>
10.42	Modification No. 3 to Loan and Security Agreement, dated as of June 30, 2012, by and between the Company and Partners for Growth III, L.P. <sup>(14)</sup>
10.43	Amendment to Corporate Job Creation Agreement, dated effective July 2, 2012, by and between the Company and Pearland Economic Development Corporation. <sup>(14)</sup>
10.44†	Amendment to Employment Agreement, dated December 31, 2012, by and between the Company and David L. Martin. <sup>(15)</sup>
10.45†	Amendment to Employment Agreement, dated December 31, 2012, by and between the Company and Laurence L. Betterley. <sup>(15)</sup>
10.46†	Amendment to Employment Agreement, dated December 31, 2012, by and between the Company and Kevin J. Kenny. <sup>(15)</sup>

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Exhibit No.	Description
10.47†	Amended and Restated Executive Officer Severance Plan. <sup>(22)</sup>
10.48	Third Amendment to Loan and Security Agreement, dated May 10, 2013, by and between the Company and Silicon Valley Bank. <sup>(16)</sup>
10.49	Modification No. 4 to Loan and Security Agreement, dated as of May 10, 2013, by and between the Company and Partners for Growth III, L.P. <sup>(16)</sup>
10.50†	Cardiovascular Systems, Inc. Deferred Compensation Plan. <sup>(17)</sup>
10.51†	Transition Agreement between Cardiovascular Systems, Inc. and James Flaherty. <sup>(18)</sup>
10.52+	Purchasing Agreement, effective August 1, 2014, between Cardiovascular Systems, Inc. and Healthtrust Purchasing Group, L.P. <sup>(19)</sup>
10.53	Fourth Amendment to Loan and Security Agreement, dated June 26, 2014, by and between Cardiovascular Systems, Inc. and Silicon Valley Bank. <sup>(19)</sup>
10.54	Development Services Agreement, dated June 11, 2014, by and between Cardiovascular Systems, Inc. and Ryan Companies US, Inc. <sup>(19)</sup>
10.55	Contract for Private Redevelopment, dated June 11, 2014, by and among Cardiovascular Systems, Inc., Ryan Companies US, Inc. and The City of New Brighton. <sup>(19)</sup>
10.56	Design Build Cost Plus Construction Contract, dated June 11, 2014, by and between Cardiovascular Systems, Inc. and Ryan Companies US, Inc. <sup>(19)</sup>
10.57	Fifth Amendment to Loan and Security Agreement, dated September 29, 2014, by and between Cardiovascular Systems, Inc. and Silicon Valley Bank. <sup>(20)</sup>
10.58	Separation Agreement and Release, dated September 30, 2014, between Cardiovascular Systems, Inc. and James Flaherty. <sup>(20)</sup>
10.59†*	Cardiovascular Systems, Inc. 2014 Equity Incentive Plan, as amended.
10.60†	Form of Restricted Stock Agreement for Time-Based Awards under the 2014 Equity Incentive Plan. <sup>(21)</sup>
10.61†	Form of Restricted Stock Agreement for Performance-Based Awards under the 2014 Equity Incentive Plan. <sup>(21)</sup>
10.62	Amendment No. 2 to Employment Agreement, dated February 4, 2015, by and between Cardiovascular Systems Inc. and Kevin J. Kenny. <sup>(22)</sup>
10.63	Cardiovascular Systems, Inc. Amended Executive Officer Severance Plan. <sup>(22)</sup>
10.64	Form of Restricted Stock Unit Agreement for Directors under the 2014 Equity Incentive Plan. <sup>(22)</sup>
10.65	Form of Restricted Stock Agreement with Immediate Vesting under the 2014 Equity Incentive Plan. <sup>(22)</sup>
23.1*	Consent of PricewaterhouseCoopers LLP.
24.1*	Power of Attorney (included on the signature page).
31.1*	Certification of principal executive officer required by Rule 13a-14(a).
31.2*	Certification of principal financial officer required by Rule 13a-14(a).
32.1**	Section 1350 Certification of principal executive officer.
32.2**	Section 1350 Certification of principal financial officer.
101**	Financial statements from the annual report on Form 10-K of the Company for the year ended June 30, 2015, formatted, in XBRL: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Changes in Stockholders' Equity (Deficiency) and Comprehensive Loss, (iv) the Consolidated Statements of Cash Flows, and (v) the Notes to Financial Statements.
*	Filed herewith.
**	Furnished herewith.
†	Compensatory plan or agreement.
+	Confidential treatment has been granted for certain portions omitted from this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

(1)

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Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Current Report on Form 8-K filed on March 18, 2009.

(2) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Current Report on Form 10-Q filed on May 8, 2014.

- (3) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from CSI Minnesota, Inc.'s Registration Statement on Form S-1, File No. 333-148798.
- (4) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Annual Report on Form 10-K filed on September 29, 2009.
- (5) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Registration Statement on Form S-8, File No. 333-158755.
- (6) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Registration Statement on Form S-8, File No. 333-158987.
- (7) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
- (8) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed on May 14, 2010.
- (9) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Annual Report on Form 10-K filed on September 28, 2010.
- (10) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Annual Report on Form 10-K filed on September 12, 2011.
- (11) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed on November 8, 2011.
- (12) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed on February 9, 2012.
- (13) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed on May 8, 2012.
- (14) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Annual Report on Form 10-K filed September 10, 2012.
- (15) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed February 8, 2013.
- (16) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Annual Report on Form 10-K filed September 11, 2013.
- (17) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Current Report on Form 8-K filed December 17, 2013.
- (18) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed May 8, 2014.
- (19) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Annual Report on Form 10-K filed August 26, 2014.
- (20) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed November 7, 2014.
- (21) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Current Report on Form 8-K filed November 14, 2014.
- (22) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Quarterly Report on Form 10-Q filed May 8, 2015.
- (23) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company's Current Report on Form 8-K filed May 21, 2015.