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, 2019

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	Trading Symbol	Name of each exchange on which registered
Common Stock, One-tenth of One Cent ($0.001) Par Value Per Share	CSII	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
None.

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

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

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	☐
Emerging growth company	☐						

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

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, 2018, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $964.5 million based on the closing sale price as reported on The Nasdaq Stock Market LLC.

The number of shares of the registrant's common stock outstanding as of August 16, 2019 was 35,268,093.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the registrant's 2019 Annual Meeting of Stockholders are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Form 10-K.

Table of Contents

Preliminary Notes

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, this Form 10-K.

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

This Form 10-K 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 Form 10-K 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 Form 10-K. You should read this Form 10-K 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.

We have received federal registrations in the U.S. Patent and Trademark Office ("USPTO") of certain marks, including "CSI®" (a first and second), "CSI® (Stylized)" (a first and second), "CSIQ®", "CSIQ® (Stylized)", "DIAMONDBACK®", "DIAMONDBACK 360®" (a first and second), "DIAMONDBACK 360® (Stylized)", "GLIDEASSIST®", "STAY A STEP AHEAD OF PAD®", "STEALTH 360®", "TAKE A STAND AGAINST AMPUTATION®", "TAKE A STAND AGAINST AMPUTATION® (Stylized), "VIPERWIRE®", "VIPERWIRE ADVANCE®", "VIPERWIRE ADVANCE® (Stylized)", "VIPERSLIDE®", VIPERSLIDE® (Stylized)", "VIPERTRACK®", "VIPERTRACK® (Stylized)", "ZILIENT®", and "ZILIENT® (Stylized)". We have applied for federal trademark registration with the USPTO of certain marks, including "VIPERCATH" and "STEALTH 360® (Stylized). All other trademarks, trade names and service marks appearing in this Form 10-K are the property of their respective owners.

PART I

Item 1. *Business.*

Corporate Information

Cardiovascular Systems, Inc. ("CSI") was incorporated in Delaware in 2000. Our principal executive office is located at 1225 Old Highway 8 Northwest, St. Paul, Minnesota 55112. Our telephone number is (651) 259-1600, and our website is *www.csi360.com*. The information contained in or accessible through our website is not incorporated by reference into, and should not be considered part of, this Form 10-K.

Business Overview

We are a medical technology company leading the way in the effort to successfully treat patients suffering from peripheral and coronary artery diseases, including those with arterial calcium, the most difficult form of 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 the lives of patients facing this difficult disease state. We have developed a patented orbital atherectomy systems ("OAS") for both peripheral and coronary commercial applications. The primary base of our business is catheter-based platforms capable of treating a broad range of vessel sizes and plaque types, including calcified plaque, which address many of the limitations associated with other treatment alternatives. To date, more than 450,000 patients have been treated with our OAS devices and we continue to expand our footprint to serve more patients with cardiovascular disease.

Peripheral

Our peripheral artery disease ("PAD") products are catheter-based platforms capable of treating a broad range of plaque types in leg arteries both above and below the knee, including calcified plaque, and address many of the limitations associated with other existing surgical, catheter and pharmacological treatment alternatives. The micro-invasive devices use small access sheaths that can provide procedural benefits and allow physicians to treat PAD patients in even the small and tortuous vessels located below the knee and facilitate access through alternative sites in the ankle, foot and wrist, as well as in the groin.

The United States Food and Drug Administration ("FDA") granted 510(k) clearance for various OAS device products as a therapy in patients with PAD. We refer to these products in this Form 10-K as the "Peripheral OAS." In addition to our Peripheral OAS, we also offer support products within the peripheral space. Peripheral sales in the United States during the fiscal year ended June 30, 2019 represented 72% of revenue.

Coronary

Our coronary artery disease ("CAD") product, the Diamondback 360 Coronary OAS ("Coronary OAS"), is a catheter-based platform designed to facilitate stent delivery in patients with CAD who are acceptable candidates for percutaneous transluminal coronary angioplasty or stenting due to *de novo*, severely calcified coronary artery lesions. The Coronary OAS design is similar to technology used in our Peripheral OAS, customized specifically for the coronary application. In addition to the Coronary OAS, we also offer support products within the coronary space as we expand treatment to a broader patient population with complex coronary artery disease.

In October 2013, we received premarket approval ("PMA") from the FDA to market the Coronary OAS as a treatment for severely calcified coronary arteries and we commenced a commercial launch that same month. Coronary sales in the United States during the fiscal year ended June 30, 2019 represented approximately 25% of revenue.

International

In February 2018, the Coronary OAS Micro Crown received reimbursement approval in Japan, followed by the first commercial sales in Japan. This represented the first international market for any of our products, and more importantly, an opportunity to provide physicians in Japan a cost-effective treatment option for the difficult-to-treat patient population with severely calcified coronary lesions. In January 2019, Japan's Ministry of Health, Labor and Welfare ("MHLW") approved our Coronary OAS Classic Crown and the ViperWire Advance Guidewire with FlexTip, and in the third quarter of fiscal 2019, sales of this product commenced in Japan. Sales of our products in Japan are made through our exclusive Japan distributor, Medikit Co., Ltd.

In October 2014, we received CE Mark for our Stealth 360 Peripheral OAS, and in fiscal 2019, we commenced sales of this product in certain countries in Southeast Asia, Europe and the Middle East and of our Coronary OAS in Southeast Asia and the Middle East. Sales of our products in the rest of the world are made through our exclusive international distributor, OrbusNeich®.

International sales during the fiscal year ended June 30, 2019 represented approximately 3% of revenue.

Market Overview

Peripheral Artery Disease ("PAD")

Peripheral artery disease is widespread and can be life threatening. The disease is characterized by narrowed, hardened arteries in the legs, limiting blood flow to the legs and feet. If left untreated, PAD may continue to progress to Critical Limb Ischemia ("CLI"), a condition in which the amount of oxygenated blood being delivered to the limb is insufficient to keep the tissue viable. CLI may lead to non-healing ulcers, infections, gangrene, limb amputation or death. 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 patient and physician awareness. Emphasis on PAD education from industry, medical associations, insurance companies and other groups, coupled with publications in medical journals and public news channels, is increasing physician and patient awareness of PAD risk factors, symptoms, and treatment options. Physicians manage a significant portion of the PAD diagnosed population by recommending lifestyle changes, such as diet and exercise, and by prescribing prescription drugs, such as statins. While medications, diet and exercise may improve blood flow, they do not treat the underlying vascular occlusions, and many patients have difficulty maintaining lifestyle changes. As a result of these challenges, many medically managed patients develop more severe symptoms that require procedural intervention.

Coronary Artery Disease ("CAD")

Coronary artery disease is the most common type of heart disease in the United States and is a life-threatening condition. CAD occurs when a fatty material called plaque builds up on the walls of arteries that supply blood to the heart. The plaque buildup causes the arteries to harden and narrow (atherosclerosis), reducing blood flow. The risk of calcific CAD increases with age and if a person has one or more of the following: high blood pressure, abnormal cholesterol levels, diabetes, or family history of early heart disease. 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.

Our Peripheral OAS and Coronary OAS

Our orbital atherectomy systems represent a unique and innovative approach to the treatment of PAD and CAD that provide physicians and patients with a procedure that addresses many of the limitations of other treatment alternatives. The Peripheral OAS and Coronary OAS devices are single-use catheters that incorporate a control handle and flexible drive shaft with an eccentrically mounted diamond-coated crown. The peripheral device is often used for vessel preparation to enable low pressure percutaneous transluminal angioplasty, including the use of drug-coated balloons, and results in lower use of bailout stents. The coronary device is similarly used to prepare a vessel by treating severe calcium prior to stent delivery to help facilitate vessel access and stent expansion and prevent malapposition of stent struts for optimal stent performance.

The OAS treats atherosclerotic plaque, which is harder than a normal vessel wall. The OAS is designed to differentiate between hard, diseased plaque and healthy, compliant arterial tissue, a concept that we refer to as "differential sanding." The diamond-coated crown preferentially engages and sands away harder material, but is designed not to damage more compliant parts of the artery, which flex away from the crown. Physicians position the crown at the site of a lesion containing arterial plaque and orbit the crown against it to sand away the superficial, or surface, plaque and create a smooth lumen, or channel, in the vessel. In addition, the crown's rotating eccentric mass and orbital motion deliver pulsatile mechanical energy into the vessel wall. These pulsatile forces may break up deeper plaque and contribute to improving the compliance change of the diseased segment of the artery.

Multiple Applications

The unique OAS mechanism of action used in both the Peripheral OAS and Coronary OAS can be used to treat multiple anatomic locations.

- *Below-the-Knee and Behind-the-Knee Peripheral Artery Disease.* Arteries below and behind the knee are smaller in diameter and may be diffusely stenosed, calcified or both. Reaching and treating these small vessels requires a low profile, which most competitive devices do not offer. Behind-the-knee, or popliteal, lesions also present challenges if a stent is used because stents frequently fracture in this area due to the forces exerted on the vessels when the knee bends or flexes. The Peripheral OAS is effective in treating those vessels. The Peripheral OAS offers a shorter shaft length (60cm), a smaller profile and a more flexible shaft than the predecessors for improved ease of use, and includes a 4-Fr catheter that enables physicians to access lesions below-the-knee using retrograde access through arteries in 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. Our newest Peripheral OAS innovation includes the addition of extended length OAS that can treat above-the-knee disease through trans-radial access (access through the radial artery in the wrist). The ability to treat the larger above-the-knee arteries with OAS via the small trans-radial access sites is made possible by the unique features of the OAS including its small crossing profile and ability to orbit at higher speeds for treatment of larger vessels.

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

We believe the strong safety profile and proven efficacy of our OAS, stemming from the design of the product and demonstrated through key clinical trials offers additional benefits to patients. Furthermore, the short set-up time and short procedure time offer an easy to use and cost efficient treatment option for physicians.

Our Supporting Products

In addition to our OAS, we offer additional products aimed at supporting procedures that use our OAS.

- *Guidewires*. The ViperWire guide wires are required for using the OAS and were designed to offer the ability to maneuver through tortuous, twisting blood vessels and cross challenging lesions. The OAS travels over this wire to the lesion and operates on this wire. Our ZILIENT Peripheral guidewires further expand our low-profile endovascular portfolio and feature TWISTER® Core Wire Technology, a proprietary stainless steel core design that offers strong support with navigation and torque response. The ZILIENT guidewires are designed to get to and across lesions and includes four tip load choices across two diameters.

- *Catheters*. We sell OrbusNeich Teleport Microcatheters in the United States through an exclusive distribution agreement with OrbusNeich. We also sell our ViperCath XC Peripheral Exchange Catheter, which is the only 200 cm exchange catheter available to address the need for an extended length catheter when performing procedures with a radial access point.

- *Balloons*. We sell the OrbusNeich Sapphire semi compliant ("SC") and Sapphire non-compliant ("NC") balloon portfolio in the United States, which includes the only 1.0mm SC balloon on the United States market. Sapphire SC balloons are optimized for lesion entry and crossing with stainless steel hypo-tube for increased pushability and kink resistance. Sapphire NC balloons are optimized for robustness under high pressure and reliable sizing.

- *Other OAS Support Products*. Our OAS uses a small, portable saline infusion pump that bathes the OAS shaft and crown and provides an electric power supply for the operation of the catheter. We also sell ViperSlide Lubricant designed to optimize the smooth operation of the OAS.

Our Strategy

Our goal is to be the leading provider of solutions for the treatment of PAD and CAD. We intend to broaden our product offering and expand to new international markets. The key elements of our strategy include:

- *Drive Adoption through Our Direct U.S. Sales Organization, Medical Education and Key Opinion Leaders.* We expect to continue to drive adoption of the OAS in both hospital and office-based lab settings through the strong support of a clinically knowledgeable direct U.S. sales force focused on the needs of interventional cardiologists, vascular surgeons, interventional radiologists and their cath lab teams. A key element of our strategy is a focus on educating and training physicians about disease states, our clinical data, and proper use and application of OAS technology through programs delivered via physician faculty, our direct sales force and seminars where physician industry leaders discuss case studies and treatment techniques using the devices.

- *Build a Strong Portfolio of Clinical Evidence on Safety, Effectiveness and Economic Benefits of the OAS.* Physicians and payors are increasingly interested in clinical and economic evidence to support decisions regarding optimal treatment of patients. We are focused on conducting robust clinical studies that provide insight into and demonstrate the effectiveness of the OAS in treating complex peripheral and coronary artery disease. We believe that demonstrating the clinical advantages and cost-effectiveness of our OAS technology is critical to support physician adoption of the OAS, drive best clinical practice, and sustain ongoing reimbursement coverage for our devices.

- *Enhance OAS and Expand Product Portfolio within the Market for Treatment of Peripheral and Coronary Arteries.* In addition to continued innovation and product development on our peripheral and coronary OAS platforms, we are growing our product portfolio to offer new accessories and devices that improve outcomes and expand the patient population we can treat. See “Pursue Strategic Acquisitions and Partnerships” and “Research and Development Activities - Development Activities” for descriptions of new products in development.

- *Expand Internationally.* In February 2018, we announced reimbursement approval and our first commercially treated patient in Japan. This represented our first entry into the international market, and most importantly, an opportunity to provide physicians in Japan with a cost-effective treatment option for the difficult-to-treat patient population with severely calcified coronary lesions. In January 2019, Japan’s MHLW approved our Coronary OAS Classic Crown, and in the third quarter of fiscal 2019, sales of this product commenced in Japan.

  In October 2014, we received CE Mark for our Stealth 360 Peripheral OAS and in fiscal 2019, we commenced sales of our products in certain countries in Southeast Asia, Europe and the Middle East.

- *Pursue Strategic Acquisitions and Partnerships*. In addition to adding to our product portfolio through internal development efforts, we are opportunistically seeking ways to expand our portfolio through acquisitions, distribution agreements, licensing transactions, manufacturing agreements and other strategic partnerships to add new product lines and technologies that leverage our sales expertise and footprint or complement our strategic objectives. We have an exclusive U.S. distribution agreement with OrbusNeich to offer their full line of semi-compliant, non-compliant and specialty balloons and the Teleport Microcatheter. In addition, we have entered into an agreement with Integer Holdings Corporation to manufacture our ZILIENT™ peripheral guidewires, and we are co-developing a new laser atherectomy device in collaboration with Aerolase Corporation. Finally, in August 2019, we acquired the WIRION Embolic Protection System and related assets from Gardia Medical Ltd., a wholly owned Israeli subsidiary of Allium Medical Solutions Ltd. This device is a distal embolic protection filter used to capture debris that can be associated with all types of peripheral vascular intervention procedures. We plan to commercialize the WIRION System in the United States following the transfer of manufacturing from Gardia Medical, which we expect to be completed after a 12 to 15 month transition period. Gardia Medical has retained the rights to the WIRION System for angioplasty and stenting procedures in the carotid arteries.

Research and Development Activities

Clinical Studies Summary

We study the most challenging patient populations and are committed to providing relevant clinical evidence that enables physicians to select and utilize the best treatment options for their patients. A total of 6,674 subjects (4,794 PAD and 1,880 CAD) have been enrolled in our clinical studies as of June 30, 2019. Our clinical studies incorporate rigorous long-term clinical and healthcare economic data that are critical to improving patient care and ongoing healthcare changes.

PAD Studies

The following PAD clinical studies were completed or in process during fiscal 2019:

- REACH-PVI. This prospective, observational, single-arm, multi-center post-market study conducted in the United States is designed to evaluate acute clinical outcomes of orbital atherectomy via transradial access for treatment of PAD in lower extremity lesions. Approximately 50 subjects will be enrolled in REACH-PVI and will be followed post-procedure through the first standard of care follow-up visit (7 to 45 days post-procedure).

- LIBERTY 360°. This prospective, observational, multi-center clinical study is evaluating the procedural and long-term clinical, quality of life and economic outcomes of endovascular device interventions, including orbital atherectomy, for the treatment of PAD. We expect the results from this study to increase our understanding of the clinical and economic outcomes of endovascular treatment for PAD patients, including those with the most advanced form of the disease, Rutherford Class 6. Enrollment of 1,204 subjects at 51 sites in the United States was completed in February 2016.

  LIBERTY 360° one-year data were published in the *Journal of Endovascular Therapy* in April 2019. Additionally, two-year economic data and 2.5-year clinical data were presented at New Cardiovascular Horizons in May 2019 and at the International Symposium on Endovascular Therapy in January 2019, respectively. The majority of devices used in the study were balloons and/or atherectomy, and the Peripheral OAS was the most frequently used atherectomy device. Initial treatment costs and total 2-year costs varied significantly according to symptom burden and clinical and lesion-level characteristics. After adjustment for censoring, cumulative 2-year costs were substantially higher among patients with at least one chronic total occlusion, longer lesion length, severe calcification, greater lesion complexity, and more distal lesion location. The LIBERTY 360° data through 2.5 years demonstrate that peripheral interventions can be used successfully across all Rutherford Classes, including the most challenging Rutherford Class 6 subjects. An orbital atherectomy subanalysis of the LIBERTY 360° data indicated high freedom from major amputation at 2.5 years in all Rutherford Classes (RC2-3, 100.0%; RC4-5, 95.3%; and RC6, 88.6%). Overall, the results of this novel all-comers PAD study suggest that peripheral vascular intervention ("PVI") is an alternative to "primary amputation" in Rutherford Class 6 patients. Additionally, data from the LIBERTY 360° study provide further evidence to support PVI treatment in Rutherford Class 2-5 patients.

CAD Studies

We have conducted two clinical studies to evaluate the safety and efficacy of the Coronary OAS Classic Crown device: the ORBIT I feasibility study and the ORBIT II pivotal study. The safety and efficacy of the Coronary OAS Micro Crown device were evaluated in the COAST study.

The following CAD clinical study was in process during fiscal 2019:

- ECLIPSE. This post-market, randomized one-to-one, multi-center trial is designed to evaluate vessel preparation with Coronary OAS Classic Crown compared to conventional angioplasty technique prior to drug-eluting stent implantation for the treatment of severely calcified lesions. Approximately 2,000 subjects will be enrolled at approximately 150 sites in the United States and subjects will be followed for up to two years. The co-primary endpoints of acute minimum stent area (assessed by optical coherence tomography in a subset of equally randomized 500 subjects) and one-year target vessel failure are powered to demonstrate superiority of OAS vessel preparation vs. conventional angioplasty.

Our clinical portfolio is expanding as we develop future studies to answer difficult questions about PAD and CAD treatment. Our clinical research continues to highlight the safety and efficacy of the OAS and current and new research illustrates our versatility in the emerging vascular market.

Development Activities

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

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

Specific to the peripheral vascular disease market, we will continue our commitment to patients suffering from CLI through a breadth of above-the-knee and below-the-knee differentiated products that treat or uniquely expand the ability of our devices to treat obstructive lesions throughout the leg and foot. Most recently, we launched a next generation platform of our Diamondback 360 OAS, the Exchangeable Series. The Exchangeable Series offers multiple new features and benefits, notably the ability to use multiple crowns with one handle unit for those most challenging multi-level disease CLI patients. The system also includes GlideAssist, which was launched in the Coronary OAS in 2018. GlideAssist enables smooth tracking of the device catheter to and from target lesions when distal, tortuous and/or small vessels must be traversed.

Within the coronary vascular disease market, we are building a portfolio of differentiated products that are used to treat complex CAD. We launched the Coronary OAS Classic Crown in Japan in early 2019 along with a new ViperWire Advance Guidewire with FlexTip. The FlexTip guidewire utilizes a Nitinol core versus the stainless steel core of the first generation coronary ViperWire. The new core material, combined with a softer spring tip, enables OAS access to more challenging lesions and anatomy, especially when tortuosity or angulation is present. The FlexTip guidewire is currently under review with the FDA.

In July 2018 we announced our agreement with Aerolase Corp. for the co-development of a new laser atherectomy device. We are also developing a new percutaneous ventricular assist device. We continue to focus our efforts on other new organic technologies and devices that are aimed at addressing unmet or under-met clinical or technical needs in our target markets.

Sales and Marketing

We market and sell the majority of our products through a direct sales force in the United States, with direct shipments to hospitals or clinics. 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 directional or laser atherectomy. Professional education is also a key element of our sales strategy.

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

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

We are party to a purchasing agreement with HealthTrust Purchasing Group, L.P. (“HPG”), which was renewed effective May 1, 2018 and expires on July 31, 2021. HPG acts as a group purchasing organization for the healthcare providers belonging to HPG as participants. Under the purchasing agreement, all of HPG’s participants located in the United States or its territories are eligible to purchase our OAS and related products at prices set forth in the purchasing agreement. The purchasing agreement may be terminated at any time, without cause, by HPG upon at least 60 days’ prior written notice to us. Either party may terminate the purchasing agreement upon the occurrence of a material breach by the other party that goes uncured within 30 days following receipt of written notice of such breach. If the purchasing agreement with HPG were to be terminated, our financial results will be materially adversely affected.

Sales of our products in Japan are through our exclusive Japan distributor, Medikit. Outside of the United States and Japan, sales are made through the current sales and distribution network of OrbusNeich, our exclusive distributor for the rest of the world.

We have observed some degree of seasonality in our business, as there tends to be a lower number of procedures that use our products during the three months ending September 30. Interventional procedure volume usually grows throughout the course of the fiscal year, with the quarter ending June 30 usually representing the highest volume of cases and, therefore, the highest amount of revenue generated by us during the course of the fiscal year.

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. Single source supplier risk is mitigated by regularly assessing quality and capacity of suppliers, implementing supply and quality agreements, appropriate inventory level management and duplication of production capacity, where possible.

We are located in a leased 125,000-square-foot corporate headquarters in Minnesota. This custom-designed building has space for more than 500 employees and contains dedicated research and development, training and education, and manufacturing facilities. Depending on staffing, the facility has the annual capacity to produce in excess of 75,000 devices per shift. The finished goods storage has capacity for approximately 20,000 devices and more than 500 saline infusion pumps, as well as other accessory products.

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

We are registered with the FDA as a medical device manufacturer and comply with the FDA's Quality System Regulation ("QSR"). We have opted to maintain a Quality Management System 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 13485:2016 certified, and our renewal is due in December 2021. Under these registrations, our plants are audited by the FDA and our Notified Body. The Stealth 360 Peripheral OAS has received CE Mark. We are registered as a Foreign Medical Device Manufacturer in Japan and our registration certificate renewal is due in June 2021.

Third-Party Reimbursement and Pricing

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

CMS establishes Medicare reimbursement coverage policy and payment rates for physician and facility healthcare services, including procedures using atherectomy products. Obtaining and maintaining coding, coverage and payment for our products is critical for commercial success. 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 from private insurers, that is adequate to cover the costs of the OAS, associated materials, and physician's services.

Outside of the United States, in January 2019, we received reimbursement approval for our Coronary OAS Classic Crown in Japan. In connection with our international distribution agreement with OrbusNeich, we and OrbusNeich will seek reimbursement approvals in other countries in connection with the commercial introductions of our products, to the extent that reimbursement is available and subject to local rules and regulations.

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. Competitors in the stent, balloon angioplasty and microcatheter market segments include Abbott Laboratories, Boston Scientific, Medtronic, Cook Medical, Johnson & Johnson, Becton Dickinson, Terumo, Asahi, Teleflex and Cordis. We also compete against manufacturers of atherectomy catheters and other products designed to treat vascular disease, including Medtronic, Philips/Spectranetics, Boston Scientific, Ra Medical, Eximo Medical, Shockwave and Avinger, 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.

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

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

We are aware of a company, Cardio Flow, Inc., developing an atherectomy system that could potentially compete with our products. On August 27, 2012, we entered into a Settlement Agreement with Lela Nadirashvili, the widow of Dr. Leonid Shturman, our founder, relating to the ownership of certain patents invented by Dr. Shturman. We believe that Ms. Nadirashvili assigned her rights under the Settlement Agreement, including the right to utilize certain patents, to Cardio Flow. On April 6, 2018, we filed a breach of contract action against Cardio Flow, alleging that Cardio Flow has developed or is in the process of developing an atherectomy device that incorporates elements belonging exclusively to us, in violation of the Settlement Agreement. We are seeking damages and a permanent injunction preventing Cardio Flow from taking further steps to develop or attempt to develop an atherectomy device that incorporates the elements that belong exclusively to us. We are pursuing our claims against Cardio Flow vigorously.

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. Our U.S. and foreign issued patents and patent applications relate primarily to the design and operation of interventional atherectomy devices, including the Peripheral OAS and Coronary OAS. These patents and applications include claims covering key aspects of orbital atherectomy devices, including the design, manufacture and therapeutic use of certain atherectomy abrasive heads, drive shafts, control systems, handles and couplings. As we continue to research and develop our atherectomy technology, we intend to file additional U.S. and foreign patent applications related to the design, manufacture and therapeutic uses of atherectomy devices. As described at the beginning of this Form 10-K within the “Preliminary Notes,” we also have numerous registered trademarks throughout various geographies.

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 United States at the federal, state and local levels and in other countries extensively regulate, among other things, the development, testing, manufacture, labeling, promotion, advertising, distribution, marketing and export and import of medical devices such as the Peripheral OAS and Coronary OAS.

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

United States

The Federal Food, Drug, and Cosmetic Act (“FDCA”) and the FDA’s implementing regulations govern medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post market surveillance. Medical

devices and their manufacturers are also subject to inspection by the FDA. The FDCA, supplemented by other federal and state laws, also provides civil and criminal penalties for violations of its provisions.

Unless an exemption applies, each medical device we wish to commercially distribute in the United States 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.

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 have received 510(k) clearances for the Peripheral OAS products.

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 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 the data submitted in an amendment to the PMA application. Even if PMA is issued, 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.

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 Investigational Device Exemption ("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.

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 are not in compliance with these requirements, it can shut down our manufacturing operations, require recall of our products, refuse to clear or approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees. Any such action by the FDA would have a material adverse effect on our business.

Fraud and Abuse

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

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 June 28, 2016, we entered into a Settlement Agreement with the U.S. government, acting through the U.S. Attorney's Office for the Western District of North Carolina (the "DOJ") and on behalf of the Office of Inspector General of the Department of Health and Human Services (the "OIG") and Travis Thams to resolve the DOJ investigation of whether we violated the False Claims Act. In connection with the resolution of this matter, we entered into a five-year corporate integrity agreement (the "Corporate Integrity Agreement") with the OIG. The Corporate Integrity Agreement requires that we maintain our existing compliance programs and imposes certain expanded compliance-related requirements during the term of the Corporate Integrity Agreement, including establishment of specific procedures and requirements regarding consulting activities, co-marketing activities and other interactions with healthcare professionals and healthcare institutions and the sale and marketing of our products; ongoing monitoring, reporting, certification and training obligations; and the engagement of an independent review organization to perform certain auditing and reviews and prepare certain reports regarding our compliance with federal health care programs.

The federal Physician Payments Sunshine Act (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. While harmonization of global regulations has been pursued, requirements continue to differ significantly among countries. We expect this global regulatory environment will continue to evolve, which could impact the cost, the time needed to approve, and, ultimately, our ability to maintain existing approvals or obtain future approvals for our products. Regulations of the FDA and, as we continue our international expansions, regulatory agencies outside the United States, may impose extensive compliance and monitoring obligations on us and our operations. Additionally, 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. The new European Medical Device Regulation (the "EU MDR") will come into effect in May 2020, which will substantially expand the applicable premarket and postmarket requirements in Europe.

As part of our Japan commercialization process we are subject to the requirements of the Japanese Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (the "PMD Act"). Our quality management system and products are subject to review and examination by Japan's Pharmaceuticals and Medical Devices Agency and subject to approval and enforcement by Japan's MHLW. The critical suppliers named in our application are also subject to this review and examination for the activities they perform for us. Non-compliance with the PMD Act could result in revocation or suspension of our license, revocation of approvals, and criminal sanctions such as fines and/or imprisonment.

In connection with the introduction of our products in other countries, we will need to seek regulatory approvals under the rules and regulations applicable in each such country and we will be required to comply with ongoing requirements, which may be varied and require us to expend substantial resources.

In addition, our international expansion, operations, distribution and sales 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, as well as foreign tax laws; employment, immigration and labor laws; local intellectual property laws, which may not protect intellectual property rights to the same extent as the United States; and privacy laws such as the European General Data Protection Regulation.

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, 2019, we had 731 full-time employees. None of our employees are represented by a labor union or are parties to a collective bargaining agreement. We conduct an annual employment engagement survey and we believe that our employee relations are good.

Information About our Executive Officers

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

Name	Age	Position
Scott R. Ward	59	Chairman, President and Chief Executive Officer
Ryan D. Egeland	44	Chief Medical Officer
John M. Hastings	39	Vice President of Manufacturing and Operations
Jeffrey S. Points	42	Chief Financial Officer
Rhonda J. Robb	51	Chief Operating Officer
Alexander Rosenstein	47	General Counsel and Corporate Secretary
Sandra M. Sedo	55	Chief Compliance Officer
David S. Whitescarver	61	Vice President of Corporate Development and Intellectual Property

Scott R. Ward, Chairman President and Chief Executive Officer. Mr. Ward has been a member of our Board of Directors since November 2013 and has served as its Chairman since November 2014. Mr. Ward served as our Interim President and Chief Executive Officer beginning November 30, 2015, and on August 15, 2016, Mr. Ward was appointed as our President and Chief Executive Officer. Since 2013, Mr. Ward has been one of the Managing Directors at SightLine Partners. Following his appointment as our President and Chief Executive Officer, Mr. Ward continues to be a Managing Director of Sightline Opportunity Management Fund II, LLC and may provide limited advisory and consulting services to Sightline Partners in this capacity. From 1981 to 2010, Mr. Ward was employed by Medtronic, Inc. and held a number of senior leadership positions. Mr. Ward was Senior Vice President and President of Medtronic's CardioVascular business from May 2007 to November 2010. Prior to that he was Senior Vice President and President of Medtronic's Vascular business from May 2004 to May 2007, Senior Vice President and President of Medtronic's Neurological and Diabetes business, from February 2002 to May 2004, and President of Medtronic's Neurological business from January 2000 to January 2002. He was Vice President and General Manager of Medtronic's Drug Delivery business from 1995 to 2000. Prior to that, Mr. Ward led Medtronic's Neurological Ventures in the successful development of new therapies. Mr. Ward serves on the boards of several private companies. Until April 2016, Mr. Ward was the Chairman of the Board of Creganna Medical. Mr. Ward served as a member of the Board of Surmodics, Inc. from September 2010 to March 2015.

Ryan D. Egeland, Chief Medical Officer. Dr. Egeland joined us in November 2017. Prior to joining us, he held several roles in marketing, medical affairs and business development at Covidien and Medtronic from April 2012 to November 2017, most recently as Senior Director of Business Development & Licensing for Medtronic Surgical Innovations from February 2015 to November 2017. Prior to these roles, Dr. Egeland trained as a plastic and reconstructive surgeon at Northwestern Memorial Hospital and received an MD with honors from Harvard Medical School. Dr. Egeland also holds a PhD in biochemistry and engineering from the University of Oxford, where he also completed a MBA as a Rhodes Scholar.

John M. Hastings, Vice President of Manufacturing and Operations. Mr. Hastings joined us in October 2017. Prior to joining us, he held several leadership positions at St. Jude Medical and Abbott Laboratories from June 2005 to March 2010 and July 2012 to September 2017, most recently as a Senior Site Director, Operations from March 2014 to September 2017. Mr. Hastings also served as Director of Engineering at American Medical Systems from May 2010 to July 2012.

Jeffrey S. Points, Chief Financial Officer. Mr. Points joined us in September 2007 as Corporate Controller, became Senior Director and Controller in July 2013, Corporate Controller and Treasurer in January 2015, Vice President, Corporate Controller and Treasurer in May 2017 and was promoted to Chief Financial Officer in February 2018. From July 2005 to September 2007, Mr. Points was Assistant Controller at Empi, a manufacturer and provider of non-invasive medical products for pain management and physical rehabilitation. From January 1998 to July 2005, Mr. Points held various leadership positions at CliftonLarsonAllen, a national public accounting firm. Mr. Points also serves as a member of the Board of Directors for The Phoenix Residence, Inc.

Rhonda J. Robb, Chief Operating Officer. Ms. Robb joined us as Chief Operating Officer in January 2018. Prior to joining us, she held several positions at Medtronic, most recently as Vice President and General Manager of the Heart Valve Therapies Business from 2014 to 2018. From 2009 to 2014, Ms. Robb was Vice President and General Manager for Medtronic's Catheter Based Therapies business. Ms. Robb was employed by Medtronic since 1990 and has served in several other leadership roles, including Vice President of Global Marketing, Coronary and Peripheral; Director Global Marketing, Heart Failure/High Power Therapies; and Director US Marketing, Cardiac Rhythm & Disease Management.

Alexander Rosenstein, General Counsel and Corporate Secretary. Mr. Rosenstein joined us in September 2014 as Corporate Legal and Compliance Counsel, became Corporate Secretary in November 2014, and was promoted to General Counsel in March 2015. From October 2005 to September 2014, Mr. Rosenstein was an attorney at Fredrikson & Byron, P.A., which provides legal services to us from time to time, and from September 1998 to September 2005, he was an attorney practicing in New York City.

Sandra M. Sedo, Chief Compliance Officer. Ms. Sedo joined us in June 2016 as Corporate Compliance Officer and was promoted to Chief Compliance Officer in July 2017. Prior to joining us, Ms. Sedo consulted for medical device companies in the legal and compliance areas. From 2005 to 2015, Ms. Sedo was employed by Medtronic, Inc. in various legal and compliance roles, and prior to that was a partner at Dorsey & Whitney LLP, which provides legal services to us from time to time.

David S. Whitescarver, Vice President of Corporate Development and Intellectual Property. Mr. Whitescarver joined us in June 2017. From August 2011 to August 2016, he was Vice President, Chief Legal Officer and Secretary of the Van Andel Institute. Prior to that, Mr. Whitescarver held senior leadership positions at Medtronic and other organizations in the biomedical and technology industries and was a practicing attorney.

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 may continue to incur losses.

We were profitable in fiscal 2018 but have incurred net losses in each prior fiscal year since our formation in 1989 and most recently in fiscal 2019. For the years ended June 30, 2019, 2018, and 2017, we had net income (losses) of $(0.3) million, $1.7 million, and $(1.8) million, respectively. As of June 30, 2019, we had an accumulated deficit of approximately $329.5 million. We commenced commercial sales of the Peripheral OAS in September 2007 and the Coronary OAS in October 2013, and our short commercialization experience makes it difficult for us to predict future performance. We expect to continue to incur significant expenses for sales and marketing, research and development, and manufacturing as we expand our product offering, launch our business in international markets and continue to commercialize the Peripheral OAS and the Coronary OAS and develop and commercialize future versions of the Peripheral OAS, the Coronary OAS, and any future products. Additionally, we expect that our general and administrative expenses will increase to support business growth. If we are unable to balance revenue growth and cost management, our operating losses may continue.

We may be unable to sustain our historical revenue growth.

Other than a 4.9% decline in revenue from sales of our Peripheral OAS during fiscal 2016, our revenue from sales of our OAS devices has grown in each of the fiscal years since we began commercialization in September 2007. Our ability to increase our revenues in future periods will depend on our ability to increase sales of the OAS and other 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.

The Peripheral OAS, the Coronary OAS, and other products may never achieve broad market acceptance.

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

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

Our customers may not be able to achieve adequate reimbursement for using the Peripheral OAS, the Coronary OAS or other products, which could affect the acceptance of our products and cause our business to suffer.

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

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

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

In addition, in June 2016, we entered into a Settlement Agreement with the U.S. government, acting through the U.S. Attorney for the Western District of North Carolina (the "DOJ") and on behalf of the Office of Inspector General of the Department of Health and Human Services (the "OIG"), and Travis Thams, and a five-year Corporate Integrity Agreement with the OIG. In the event of a breach of the Settlement Agreement or the Corporate Integrity Agreement, we could be excluded from participation in federal health care programs. If third-party coverage and reimbursement for our products is limited or not available, the acceptance of our products and, consequently, our business will be substantially harmed.

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

Because our technology is relatively new in the treatment of PAD and CAD, we have performed clinical trials only with limited patient populations. The long-term effects of using the Peripheral OAS and the Coronary OAS in a large number of patients have not been studied and the results of short-term clinical use of the Peripheral OAS or the Coronary OAS do not necessarily predict long-term clinical benefits or reveal long-term adverse effects. We are conducting and developing several clinical trials, and there are substantial risks and uncertainties involved in these trials. We must devote substantial resources to our clinical trials, clinical trials often take several years to develop and conduct, there are difficulties involved in locating sites and patients to participate in our clinical trials, and the results of every trial are uncertain until the trial is completed. Furthermore, our active and future clinical trials may take substantially longer than we anticipate to develop, enroll, conduct and complete.

These uncertainties could adversely impact our financial results, our reputation and the reputation of our products.

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

We face significant competition, must innovate to stay competitive, and may be unable to sell the Peripheral OAS, the Coronary OAS or any other products 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, companies that provide products used by surgeons in peripheral and coronary bypass procedures, and other companies that develop and sell other products or devices for the treatment of vascular disease. 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, worldwide distribution channels, and the novelty and effectiveness of their products.

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;
- sell their products at lower prices than we do; or
- develop more effective or less expensive products or technologies that render our technology or products obsolete or non-competitive.

We have encountered and expect to continue to encounter potential customers who, due to existing relationships with our competitors, are committed to or prefer the products offered by these competitors. In addition, increased consolidation in the healthcare industry has resulted in companies with greater market power, which increases competition for goods and services.

We experience significant competition on the pricing of our products and expect to continue to experience pressure from our customers to lower our prices. Our customers may require lower pricing in connection with contract renewals or otherwise for us to continue to sell our products to them. In addition, if our purchasing agreement with HealthTrust Purchasing Group, L.P. is terminated, our financial results will be materially adversely affected.

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.

Our efforts to develop new products may not be successful or the new products may not provide the revenue we expect.

We have been and are substantially dependent on the sales of the Peripheral OAS and the Coronary OAS and seek to diversify our product portfolio. We plan to add to our product portfolio through both internal development efforts and through acquisitions, distribution agreements, licensing transactions, manufacturing agreements and other strategic partnerships. For example, in 2018 we entered into an agreement with Aerolase Corp. for the co-development of a new vascular laser device for physicians to use in more effectively treating multiple forms of arterial disease and we are developing a new temporary hemodynamic support pump. We have several other products in development, and we have also entered into distribution agreements for the sale of OrbusNeich products by us in the United States and the sale of our products in Japan by Medikit and in the rest of the world by OrbusNeich.

These new products and technologies may fail to reach the market or may only have limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, clinical trial requirements and results, inability to obtain necessary regulatory approvals, limited scope of approved uses, excessive costs to manufacture, failure to establish or maintain intellectual property rights, or infringement of the intellectual property rights of others. Development of new products may take substantially longer than we anticipate. Even if we successfully develop or introduce new products or enhancements or new generations of our existing products, they may be quickly rendered obsolete by changing customer preferences,

changing industry standards, or competitors' innovations. Innovations may not be accepted quickly in the marketplace because of, among other things, entrenched patterns of clinical practice or uncertainty over third-party reimbursement. We cannot provide certainty as to when or whether any of our products under development will be launched, whether we will be able to develop, license, or otherwise acquire compounds or products, or whether any products will be commercially successful. Failure to launch successful new products or technologies, or new indications or uses for existing products, may cause our products or technologies to become obsolete, causing our revenues and operating results to suffer.

Growth in the office-based lab site of service for PAD procedures could adversely affect our business.

We have observed a shift in the number of PAD procedures that are performed in office-based labs ("OBLs") in the United States as compared to PAD procedures performed in hospitals. These OBLs tend to have more price sensitivity than hospitals, as they are often established and managed by individual physicians and are subject to different reimbursement payments than hospitals. As a result, our sales to OBLs could result in lower pricing than sales of similar products to hospitals. To the extent that the OBL site of service continues to grow, we may experience increasing pricing pressure and be forced to lower our prices in order to retain existing business and gain new business with OBL customers. We may not be able to increase the volumes of our products sold overall in order to offset any pricing pressure we experience in sales to OBLs, which would result in our revenues declining or not growing as fast as we anticipate, which would adversely affect our business.

We have limited commercial manufacturing experience and could experience difficulty in producing the Peripheral OAS and the Coronary OAS and other products or may need to depend on third parties to manufacture the products.

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

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

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

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

We rely on third-party suppliers to provide us with certain components of our products and to provide key components or supplies to our customers for use with our products. We rely on single source suppliers for certain components of the Peripheral OAS and the Coronary OAS, including the diamond-grit-coated crown, and for our ViperSlide Lubricant. In some cases, we do not have long-term supply agreements with, or guaranteed commitments from, our suppliers, including single source suppliers. We depend on our suppliers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand and our customers' demands. These suppliers may cease producing the components we purchase from them or otherwise decide to cease doing business with us.

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

Currently, substantially all of our revenues are in the United States. In fiscal 2018, commercial sales of certain of our products commenced in Japan, which became the first international market for our products, and in fiscal 2019, we commenced sales in certain countries in Southeast Asia, Europe and the Middle East under our distribution agreement with OrbusNeich. Our ability

to sell our products outside of the United States through our distributors is and will continue to be subject to foreign regulatory requirements, and we may incur substantial time and expense in seeking these approvals. Although our products have been cleared or approved by the FDA, regulatory authorities in other countries may not approve the same products for sale in their countries. Attempting to obtain these foreign approvals could result in significant delays and expenses for us and require additional clinical trials. We will be subject to substantial requirements relating to our international expansion, including differing regulatory, import, marketing and distribution requirements and different levels and structures of reimbursement and payment. There can be no guarantee that we will receive approval to sell our products in any additional countries or that any of our approvals will be maintained, nor can there be any guarantee that any sales would result even if such approval is received. We will be substantially reliant upon Medikit and OrbusNeich for our international sales, and any failure of such distributors to effectively sell our products could have a material adverse effect on our international efforts and harm our financial position. In addition, we will incur substantial expenses in connection with international expansion, particularly with respect to our efforts to train physicians on the safe and effective use of our products. Our inability to successfully enter international markets and manage business on a global scale could negatively affect our financial results.

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

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

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

We have significantly expanded the size of our organization over the past three years, particularly in the number of sales and marketing personnel, and may need to do so in the future. The growth we may experience in the future may provide challenges to our organization, requiring us to also rapidly expand other aspects of our business, including our manufacturing operations. Rapid expansion in personnel may result in less experienced people producing and selling our products, which could result in unanticipated costs and disruptions to our operations. If we cannot scale and manage our business appropriately, our anticipated growth may be impaired and our financial results will suffer.

We 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 face a risk of non-compliance with the financial covenants in our loan and security agreement with Silicon Valley Bank.

We are party to a loan and security agreement with Silicon Valley Bank. This agreement requires us to maintain, among other things, either (i) minimum unrestricted cash at Silicon Valley Bank and unused availability on our line of credit of at least $10.0 million or (ii) minimum trailing three-month Adjusted EBITDA of $1.0 million and contains customary events of default, including, among others, the failure to comply with certain covenants or other agreements. Upon the occurrence and during the continuation of an event of default, amounts due under the agreements may be accelerated by Silicon Valley Bank. If we are unable to meet the financial or other covenants under the current loan and security agreement or negotiate future waivers or amendments of such covenants, events of default could occur under the agreement. Upon the occurrence and during the continuance of an event of default under the agreement, Silicon Valley Bank has available a range of remedies customary in these circumstances, including declaring all outstanding debt, together with accrued and unpaid interest thereon, to be due and payable, foreclosing on the assets securing the agreement and/or ceasing to provide additional loans under our line of credit, which could have a material adverse effect on us.

The restrictive covenants under this agreement could limit our ability to obtain future financing, withstand a future downturn in

our business or the economy in general or otherwise conduct necessary corporate activities. The financial and restrictive covenants contained in this agreement could also adversely affect our ability to respond to changing economic and business conditions and place us at a competitive disadvantage relative to other companies that may be subject to fewer restrictions. Transactions that we may view as important opportunities, such as acquisitions, may be subject to the consent of Silicon Valley Bank, which consent may be withheld or granted subject to conditions specified at the time that may affect the attractiveness or viability of the transaction.

We lease our corporate headquarters, which subjects us to ongoing payment obligations and compliance with certain covenants.

On March 30, 2017, we completed the sale of our corporate headquarters. In connection with such sale, we entered into a lease agreement for our corporate headquarters, which has an initial term of fifteen years, with four consecutive renewal options of five years each. Under this lease, we are obligated to pay a base annual rent in the first year of $1,637,500 with annual escalations of 3%. If we are unable to make such rent payments or comply with the other covenants contained in the lease, the landlord could take certain actions against us, up to and including termination of the lease, which could have an adverse impact on our business, results of operations or financial conditions.

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 $25.26 and as high as $43.66 per share during the 12-month period ended June 30, 2019. Factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

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

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

We rely on information and communication systems in our manufacturing and in the conduct of our business. If there is any

failure or interruption of these systems, such an incident could cause failures or disruptions in our customer relationship systems or product manufacturing. In addition, we could be subject to a cyber incident, such as an intentional attack or an unintentional event that involves a third party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data, or result in release of our confidential information. Although we have systems and processes designed to detect and prevent security breaches, the technology used by parties seeking unauthorized access to our systems is rapidly changing and we may not be able to timely and adequately detect and prevent any breaches. The occurrence of any failures, interruptions or cyber incidents could cause a loss of business or damage to our reputation and have a material effect on our business, financial condition, results of operations and cash flows.

The effects of hurricanes, flooding and other natural disasters may impact our sales, inventories and supply availability, which could adversely affect our financial condition and results of operations.

In August and September 2017, Hurricanes Harvey and Irma made landfall along the Texas Gulf Coast and in the State of Florida, respectively, bringing high winds, unprecedented rain and extreme flooding to those areas. A significant portion of our sales is generated from these areas. Procedure volumes in the Houston area and in Florida decreased during the pendency and immediate aftermath of the hurricanes and flooding, which decreased the number of our products used during this time. Any sustained decrease in procedure volumes from hurricanes and other natural disasters that affect any areas in which our customers are located will result in decreased sales in these areas and could have a material adverse effect on our financial condition and results of operations.

In addition, we maintain a 46,000-square foot production facility in Pearland, Texas, which is just outside of Houston in southeast Texas. The storm and its aftermath did not cause damage to our Pearland facility. However, any future loss of operations at the Pearland facility as a result of natural disasters eliminates an alternate production source in the event that our manufacturing capacity at the Minnesota facility is disrupted for any reason.

Any disruptions in our ability to timely manufacture and supply our products to our customers could cause us to experience delays in recognizing revenue or even to lose sales altogether, and any additional hurricanes, flooding or other natural disasters affecting areas in which our products are sold could result in decreased numbers of cases using our products. Any of these events could have a material adverse effect on our financial condition and results of operations.

We may acquire new products, technologies, businesses or companies and if we are unable to successfully complete these acquisitions or to integrate acquired businesses, we may fail to realize expected benefits or harm our existing business.

On August 5, 2019, we completed the acquisition of the WIRION Embolic Protection System and may seek to acquire additional products, technologies, businesses or companies in the future. We may not be able to successfully integrate newly acquired products, technologies, businesses or companies into our operations, and the process of integration could be expensive and time consuming, and may strain our resources. Furthermore, we may not be successful in commercializing acquired products or technologies. Other risks associated with acquisitions may include:

- the business culture of the acquired business may not match well with our culture;
- technological and product synergies, economies of scale and cost reductions may not occur as expected;
- we may acquire or assume unexpected liabilities;
- we may fail to retain, motivate and integrate key management and other employees of the acquired business;
- higher than expected finance costs may arise due to unforeseen changes in tax, trade, environmental, labor, safety, payroll or pension policies in any jurisdiction in which the acquired business conducts its operations;
- we may experience problems in retaining suppliers or customers of the acquired business;
- we may not be able to effectively integrate internal control processes of the acquired business into our business; and
- we may not be able to operate acquired businesses profitably.

Consequently, we may not achieve anticipated benefits of the acquisitions, which could harm our existing business. In addition, future acquisitions could result in potentially dilutive issuances of equity securities or the incurrence of debt, contingent liabilities or expenses, or other charges such as in-process research and development, any of which could harm our business and affect our financial results or cause a reduction in the price of our common stock.

Risks Related to Government Regulation

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

We received FDA 510(k) clearances in the United States for use of the Peripheral OAS as a therapy in patients with PAD, and we received PMA to use the Coronary OAS as a therapy in patients with severely calcified CAD. These general clearances and approvals restrict our ability to market or advertise the Peripheral OAS and the Coronary OAS beyond these uses and could affect our growth.

If we determine to market our orbital technology in the United States 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 also developing several new products, all of which will require clearances or approvals from the FDA. Such clearances or approvals will be conditioned on, in some cases, clinical trials relating to such products. There is no assurance that we will be able to obtain such clearances or approvals.

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.

We are also seeking to sell our current and future products in other countries, which have their own requirements for the development, approval and sale of products in their countries. There is no assurance we will be able to obtain approvals in other countries for the sale of our products, and failure to comply with applicable foreign laws and regulations may result in seizures, injunctions or other types of enforcement actions and the inability of our products to be sold.

Our promotion of our current and future products is closely controlled by the FDA and other regulatory agencies in the United States and internationally, and enforcement activities could limit our ability to inform potential customers of the features of the products.

Our products may in the future be subject to product recalls that could harm our reputation and product liability claims that could exceed the limits of available insurance coverage.

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. For example, since commercialization of the Peripheral OAS, we have had instances of recalls, including the OAS saline infusion pump recall discussed below. 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 any of our products is defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation by our customers or their patients. The use, misuse or off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business. We cannot prevent a physician from using any of our products 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.

Additional issues following the recall of our saline infusion pumps could adversely affect our business and financial results, harm our reputation and result in legal claims against us.

In April 2017, we initiated a voluntary recall of one type of our saline infusion pumps. While we have made design changes to this pump and have launched a next generation pump to address the issues that led to the recall, it is possible that we did not adequately assess the cause and effect of these issues and we may not have adequately modified the pump design in order to prevent these issues from happening in the future. Any additional problems with our pumps could cause delays in the ability of our customers to perform procedures using our devices and prevent us from adding new customers who may not have access to other pumps that can be used in procedures, which could harm our reputation with customers, adversely affect our ability to generate revenue, and have an adverse effect on our financial condition and results of operations. Any future pump recall would harm our reputation and divert managerial and sales force attention and financial resources from other aspects of our business and would require us to incur substantial expense.

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

Our products and related manufacturing processes, clinical data, adverse events, recalls and 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.

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

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

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

We are subject to 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 and foreign 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 Sunshine Act requires us to collect and report certain data on payments and other transfers of value to physicians and teaching hospitals. In addition, foreign countries in which are products are or will be sold may have similar disclosure requirements.

Public reporting under the Sunshine Act and implementing Open Payments regulations has resulted in increased scrutiny of the financial relationships between industry, physicians and teaching hospitals. These anti-kickback, public reporting and aggregate spend laws and the fraud and abuse laws affect our sales, marketing, promotional and clinical activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers or users of medical devices. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales offerings, including discount practices, customer support, education and training programs, physician consulting and other service arrangements, and clinical trials. If we were to offer or pay inappropriate inducements to purchase our products, we could be subject to a claim under the federal healthcare program Anti-Kickback Statute or similar state and foreign laws. If we fail to comply with particular reporting requirements, we could be subject to penalties under applicable federal or state laws. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payments to Medicare, Medicaid or other third-party payors that are false or fraudulent, or for items or services that were not provided as claimed. Although we do not submit claims directly to government healthcare programs or other payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by providing inaccurate billing or coding information to customers, by providing improper financial inducements, or through certain other activities.
In providing billing and coding information to customers, we make every effort to ensure that the billing and coding information furnished is accurate and that treating physicians understand that they are responsible for all treatment decisions. Nevertheless, we cannot provide assurance that the government will regard any billing errors that may be made as inadvertent or that the government will not examine our role in providing information to our customers and physicians concerning the benefits of therapy with our devices. Likewise, our financial relationships with customers, physicians, or others in a position to influence the purchase or use of our products may be subject to government scrutiny or be alleged or found to violate applicable fraud and abuse laws. False claims laws prescribe civil, criminal and administrative penalties for noncompliance, which can be substantial. Moreover, an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business and results of operations.

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

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

On June 28, 2016, we entered into a five-year Corporate Integrity Agreement with the OIG. The Corporate Integrity Agreement requires that we maintain our existing compliance programs and imposes certain expanded compliance-related requirements during the term of the Corporate Integrity Agreement, including establishment of specific procedures and requirements regarding consulting activities, co-marketing activities and other interactions with healthcare professionals and healthcare

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

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

In February 2018, Medikit, our exclusive distributor in Japan, commenced sales of our Coronary OAS Micro Crown, and, in July 2018, we entered into an exclusive Distribution Agreement with OrbusNeich to sell our Peripheral and Coronary OAS outside of the United States and Japan. Sales by OrbusNeich commenced in certain countries in Southeast Asia, Europe and the Middle East during the year ended June 30, 2019. Movement into these and other international markets subjects us and our products to different and increased laws and regulations, including foreign medical device regulations; tax laws; employment, immigration and labor laws; local intellectual property laws, which may not protect intellectual property rights to the same extent as the United States; increased financial accounting and reporting burdens and complexities; import and export laws; privacy laws such as the European General Data Protection Regulation; 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, distributors 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. Medikit and OrbusNeich may appoint sub-distributors of our products and we will have limited ability to control the actions of these sub-distributors, but we may be held responsible by governmental authorities for the actions of these sub-distributors. 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. Furthermore, geopolitical developments in international markets, such as the recent demonstrations in Hong Kong, where OrbusNeich is headquartered, could have a negative effect on the ability or us or our distributors to operate and sell our products or disrupt the supply chain for our suppliers and products, all of which would negatively affect our business.

New regulatory requirements will impose additional burdens on us, and our business could be adversely affected if we are unable to satisfy all applicable new requirements in a timely fashion.

New regulations impacting our products are periodically adopted. These regulations may require us to change our existing product designs in order to continue marketing our products, which could result in increased expenditures and in risks that we may be unable to successfully change our designs to satisfy the new requirements. For example, IEC 60601-1-2 (4th Edition) was published in July 2014 and updates the performance requirements with respect to electromagnetic interference for medical devices. In the United States, the 4th Edition requirements went into effect on December 31, 2018 for new devices and devices that have undergone substantial changes. We took steps to ensure that our products sold in the United States are compliant with the 4th Edition requirements, but if it is determined that our products do not meet the 4th Edition standards, we may be delayed in launching new products or selling existing products that require material changes, including, for example, as a result of a change of supplier or quality issues. In addition, the new EU MDR will come into effect in May 2020. We have taken steps to ensure our compliance with EU MDR but we could experience unforeseen delays, which could delay or prevent our ability to sell products in the European market. Any delays in selling our products resulting from non-compliance with 4th Edition, EU MDR and other new regulatory requirements could have a material adverse effect on our business.

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 (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. The U.S. Congress has in the past considered legislation to repeal, modify or replace the Patient Act. We cannot predict the outcome of these efforts and, as a result, we cannot predict the effect that any such repeal, modification or replacement will have on our business and results of operations.

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

The imposition of the 2.3% medical device excise tax enacted as part of the Patient Act has adversely affected our financial results and has required, and will continue to require, us to identify ways to reduce spending in other areas or raise additional capital to offset the increased expense. Although the excise tax has been suspended by Congress until the end of 2019, its status is unclear for subsequent years. We have not been able to pass along the cost of the tax to our customers or offset the cost of the tax through higher sales volumes resulting from the expansion of health insurance coverage and do not expect to be able to do so in the future. Ongoing implementation of this legislation could have a material adverse effect on our results of operations and cash flows.

Failure to comply with data privacy and security laws could have a material adverse effect on our business.

We are subject to state, federal and foreign laws relating to data privacy and security in the conduct of our business, including state breach notification laws, the Health Insurance Portability and Accountability Act, and the European Union's General Data Protection Regulation. These laws affect how we collect and use data of our employees, consultants, customers and other parties. Furthermore, these laws impose substantial requirements that require the expenditure of significant funds and employee time to comply, and additional states and countries are enacting new data privacy and security laws, which will require future expansion of our compliance efforts. We also rely on third-parties to host or otherwise process some of this data, and any failure by a third party to prevent security breaches could have adverse consequences for us. We will need to expend additional resources and make significant investments to comply with data privacy and security laws. Our failure to comply with these laws or prevent security breaches of such data could result in significant liability under applicable laws, cause disruption to our business, harm our reputation and have a material adverse effect on our business.

Our failure to comply with environmental and health safety laws may result in liabilities, expenses and restrictions on our operations.

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. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. Our manufacturing and research and development operations use hazardous substances and are subject to federal, state, local and foreign environmental laws and regulations relating to hazardous substances. We have policies and procedures relating to the use and disposal of hazardous substances, and the instructions for use of our products, which are disposable, contain information on the proper disposal of the products after use, but the use of hazardous substances in our business nevertheless exposes us to risks of damages and liabilities relating to these hazardous substances. We cannot provide assurances that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. If we violate environmental or health and safety laws, we could be liable for damages and fines that could exceed our existing insurance coverage, damage our reputation and have a material adverse effect on our business.

The impact of restrictive trade policies in the United States and the potential corresponding actions by other countries could adversely affect our financial performance.

The U.S. federal government has recently implemented tariffs on certain products imported into the United States from China, and the Chinese government has responded with retaliatory tariffs on certain products, including medical devices, exported from the United States to China. The Trump Administration has also threatened to impose tariffs with respect to goods imported from other countries. We cannot predict whether the United States will implement additional trade restrictions with respect to China or other countries and how such countries would respond to such trade restrictions. If these tariffs continue or are expanded, they would make it more difficult to sell our products in China or other markets outside of the United States, if we seek to expand into the Chinese or other markets in the future, and they may increase the costs of procuring component parts for our products from China or other countries. Restrictive trade policies may also harm the United States and global economies generally, which would adversely affect our business in a variety of ways, including reducing the market for our products, causing a downturn in the trading price of our common stock, and restricting access to credit if we seek it for future

growth.

The Tax Cuts and Jobs Act of 2017 may have a significant impact on our financial condition and results of operations.

The Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law on December 22, 2017. The Tax Act made numerous changes to U.S. federal corporate tax law and is expected to reduce our effective tax rate for the year ended June 30, 2018 and future periods. Effective January 1, 2018, the Tax Act lowers the U.S. corporate tax rate from 35% to 21% and prompts various other changes to U.S. federal corporate tax law. We have assessed the impact the Tax Act with our professional advisors which resulted in the remeasurement of our deferred tax assets and valuation allowance. The impact the Tax Act will have on us in future periods is uncertain and may adversely affect our financial condition and results of operations.

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 be assured that any of our pending patent applications will result in the issuance of patents to us. Further, if any patents we obtain or license are deemed invalid and unenforceable, or have their scope narrowed, it could impact our ability to commercialize or license our technology and achieve competitive advantages.

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

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

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

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

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

The medical technology industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. The likelihood that patent infringement or misappropriation claims may be brought against us increases as we achieve more visibility in the marketplace and introduce products to market. We are aware of numerous patents issued to third parties that relate to the manufacture and use of medical devices for the treatment of vascular disease. The owners of each of these patents could assert that the manufacture, use or sale of our products infringes one or more claims of their patents. There could also be existing patents of which we are unaware that one or more aspects of our technology may inadvertently infringe. In some cases, litigation may be threatened or brought by a patent-holding company or other adverse patent owner who has no relevant product revenues and against whom our patents may provide little or no deterrence.

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

Item 1B. ***Unresolved Staff Comments.***

None.

Item 2. ***Properties.***

Our principal executive offices are located in our headquarters, a 125,000 square foot facility in St. Paul, Minnesota, which contains dedicated research and development, training and education, and manufacturing facilities, and our central administrative offices. In March 2017, we sold the Minnesota facility and entered into an agreement to lease the facility through March 2032.

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

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

Item 3. ***Legal Proceedings*****.**

None.

Item 4. ***Mine Safety Disclosures.***

None.

PART II

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

We trade on the Nasdaq Global Select Market under the symbol "CSII." The number of record holders of our common stock on August 16, 2019 was approximately 120. No cash dividends have been previously paid on our common stock and none are anticipated during the year ending June 30, 2020.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

The following table presents the information with respect to purchases made by us of our common stock during the fourth quarter of fiscal 2019:

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased under the Plans or Programs
April 1 to April 30, 2019	—	—	N/A	N/A
May 1 to May 31, 2019[(1)]	2,076	$ 39.79	N/A	N/A
June 1 to June 30, 2019	—	—	N/A	N/A
	2,076	$ 39.79		

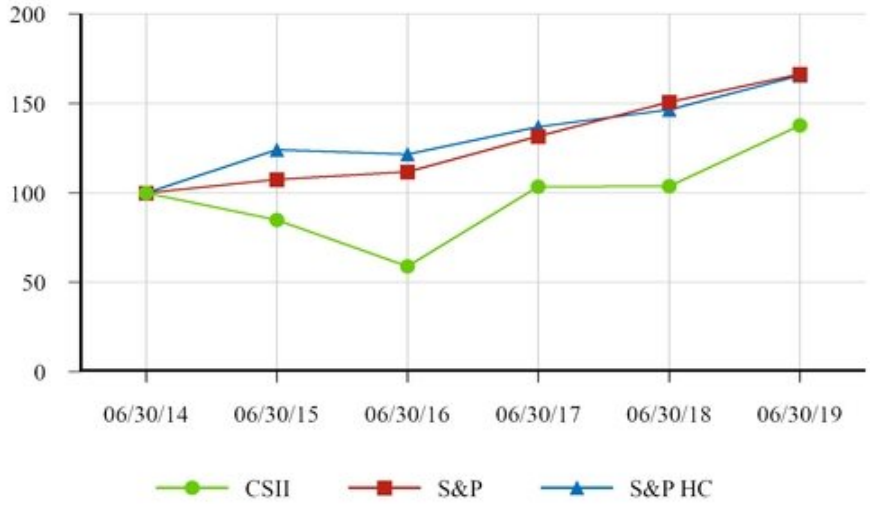
[(1)] Comprised of shares withheld pursuant to the terms of restricted stock awards under our stock-based compensation plans to offset tax withholding obligations that occur upon vesting and release of shares. The value of the shares withheld is the closing price of our common stock on the date the relevant transaction occurs.

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, 2014 through June 30, 2019. The comparisons assume $100 was invested on June 30, 2014 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)

	2019	2018	2017	2016	2015
SUMMARY OF OPERATIONS FOR THE FISCAL YEAR:					
Net revenues	$ 248,017	$ 217,043	$ 204,906	$ 178,184	$ 181,544
Income (loss) from operations	$ (825)	$ 2,234	$ (1,542)	$ (56,077)	$ (32,637)
Net income (loss)	$ (255)	$ 1,712	$ (1,792)	$ (56,024)	$ (32,822)
Basic and diluted earnings per share	$ (0.01)	$ 0.05	$ (0.06)	$ (1.72)	$ (1.04)
Cash dividends declared per share	$ —	$ —	$ —	$ —	$ —
FINANCIAL POSITION AT YEAR END:					
Total assets	$ 218,577	$ 203,352	$ 193,940	$ 142,406	$ 171,328
Total long-term liabilities	$ 28,288	$ 31,422	$ 34,459	$ 6,010	$ 2,005
Stockholders' equity	$ 147,944	$ 134,470	$ 118,389	$ 100,897	$ 139,435

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 technology company leading the way in the effort to successfully treat patients suffering from peripheral and coronary artery diseases, including those with arterial calcium, the most difficult form of 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 these difficult disease states.

Peripheral

Our peripheral artery disease ("PAD") products are catheter-based platforms capable of treating a broad range of plaque types in leg arteries both above and below the knee, including calcified plaque, and address many of the limitations associated with other existing surgical, catheter and pharmacological treatment alternatives. The micro-invasive devices use small access sheaths that can provide procedural benefits and allow physicians to treat PAD patients in even the smaller and tortuous vessels located below the knee and facilitate access through alternative sites in the ankle, foot and wrist, as well as in the groin.

The United States Food and Drug Administration ("FDA") granted 510(k) clearances for various OAS device products as a therapy in patients with PAD. We refer to these products in this Form 10-K as the "Peripheral OAS." In addition to our Peripheral OAS, we also offer support products within the peripheral space.

Coronary

Our coronary artery disease ("CAD") product, the Diamondback 360 Coronary OAS ("Coronary OAS"), is a catheter-based platform designed to facilitate stent delivery in patients with CAD who are acceptable candidates for percutaneous transluminal coronary angioplasty or stenting due to *de novo*, severely calcified coronary artery lesions. The Coronary OAS design is similar to technology used in our Peripheral OAS, customized specifically for the coronary application. In addition to the Coronary OAS, we also offer support products within the coronary space as we expand treatment to a broader patient population with complex coronary artery disease.

In October 2013, we received premarket approval ("PMA") from the FDA to market the Coronary OAS as a treatment for severely calcified coronary arteries and we commenced a commercial launch that same month.

International

In February 2018, the Coronary OAS Micro Crown received reimbursement approval in Japan, followed by the first commercial sales in Japan. This represented the first international market for any of our products. In January 2019, Japan's MHLW approved our Coronary OAS Classic Crown and the Viperwire Advance Guidewire with FlexTip, and in the third quarter of fiscal 2019, sales of these products commenced in Japan.

In October 2014, we received CE Mark for our Stealth 360 Peripheral OAS and in fiscal 2019, we commenced sales of this product in certain countries in Southeast Asia, Europe and the Middle East and our coronary OAS in Southeast Asia and the Middle East.

FINANCIAL OVERVIEW

Net Revenues. We derive substantially all of our revenues from the sale of the Peripheral OAS, the Coronary OAS and other products in the United States. The Peripheral OAS and the Coronary OAS each use a disposable, single-use, low-profile catheter that travels over our proprietary ViperWire guide wire. The OAS uses a saline infusion pump as a power supply for the operation of the catheter. Additional ancillary products include catheters, guidewires, balloons, and other OAS support devices.

We have observed some degree of seasonality in our business, as there tends to be a lower number of procedures that use our products during the three months ending September 30. Interventional procedure volume usually grows throughout the course of the fiscal year, with the quarter ending June 30 usually representing the highest volume of cases and, therefore, the highest amount of revenue generated by us during the course of the fiscal year.

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. Balloons, guide wires, and certain catheters are purchased from third-party suppliers. Our cost of goods sold consists primarily of raw materials, direct labor, manufacturing overhead, and purchased finished goods.

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 and facilities overhead. Other significant expenses include bad debt expense, travel, marketing costs, professional fees and professional education.

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

Other (Income) and Expense, Net. Other (income) and expense, net primarily includes interest expense from amounts owed under the lease of our headquarters facility and DOJ settlement and interest income from money market funds and other investments in marketable securities.

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, 2019, we had net operating loss carryforwards for federal and state income tax reporting purposes of approximately $269.4 million, which will expire at various dates through fiscal 2037.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations is 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, deferred revenue 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 our peripheral and coronary products to customers through a direct sales force in the United States and through distributors internationally. We have no material concentration of credit risk or significant payment terms extended to customers and, therefore, we do not adjust the promised amount of consideration for the effects of a significant financing component. Sales, use, value-added, and other excise taxes are not recognized in revenue. We have elected to present revenue net of sales taxes and other similar taxes.

Performance Obligations

The majority of our revenues are from customer arrangements containing a single performance obligation to transfer peripheral and coronary products, and thus revenue is recognized at a point in time when control is transferred. This generally occurs upon shipment or upon delivery to the customer site, based on the contract terms. Shipping and handling activities are considered to be fulfillment activities and are not considered to be a separate performance obligation. We do not assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer and we do not disclose the value of unsatisfied performance obligations for contracts with an original expected length of one year or less.

Significant Judgments

We have an exclusive distribution agreement with Medikit to sell our Coronary and Peripheral OAS in Japan. To secure exclusive distribution rights, Medikit made an upfront payment of $10.0 million, which is partially refundable based on the occurrence of certain events during the term of the agreement. The payment is classified as current or long-term based on its expectation of when revenue will be recognized and this expectation is re-evaluated on a quarterly basis. Medikit also provides advance payments for orders under the terms of the agreement, and, therefore, deferred revenue is recorded until products are accepted by Medikit.

Revenue is recognized at the transaction price to which we expect to be entitled. We offer customers certain volume-based rebates, discounts, and incentives. Estimates of variable consideration from these items are taken into account using the most-likely amount method based on contractual provisions, our historical experience, and forecasted customer buying patterns. These items are recognized as a reduction to revenue in the period the revenue is recognized and recorded as a liability.

Return and warranty obligations vary by the specific terms of agreements with customers. We generally do not provide customers with a right of return. We have a limited warranty provision for goods that are nonconforming or defective at the time of shipment, which is estimated based on historical experience.

Contract Costs

Commissions are earned by our direct sales force based on booked orders. We apply the practical expedient and recognize commissions as an expense when incurred because the amortization period of the asset that we would have otherwise recognized is one year or less.

Stock-Based Compensation. We have stock-based compensation plans that include nonvested share awards and an employee stock purchase plan. 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. Fair value of shares purchased under the employee stock purchase plan are estimated on the grant date, which is the first date in the six-month purchase period. Stock-compensation expense is recognized over the purchase period based on the anticipated amount of shares to be purchased. Management's key assumptions are developed with input from independent third-party valuation advisors. During the years ended June 30, 2019, 2018 and 2017, we recorded stock-based compensation expense of $11.3 million, $10.3 million, and $10.4 million, respectively.

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

RESULTS OF OPERATIONS

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

Comparison of Fiscal Year Ended June 30, 2019 with Fiscal Year Ended June 30, 2018

	Year Ended June 30,			
	2019	2018	Change	Percent Change
Net revenues	$ 248,017	$ 217,043	$ 30,974	14.3 %
Cost of goods sold	47,680	39,484	8,196	20.8
Gross profit	200,337	177,559	22,778	12.8
Gross margin	80.8%	81.8%	(1.0)%	(1.2)
Expenses:				
Selling, general and administrative	167,700	148,569	19,131	12.9
Research and development	33,462	26,756	6,706	25.1
Total expenses	201,162	175,325	25,837	14.7
Income (loss) from operations	(825)	2,234	(3,059)	(136.9)
Other (income) and expense, net	(760)	390	(1,150)	(294.9)
(Loss) income before income taxes	(65)	1,844	(1,909)	(103.5)
Provision for income taxes	190	132	58	43.9
Net (loss) income	$ (255)	$ 1,712	$ (1,967)	(114.9)

Net Revenues. Net revenues increased by $31.0 million, or 14.3%, from $217.0 million for the year ended June 30, 2018 to $248.0 million for the year ended June 30, 2019. Revenues from our peripheral products increased $17.5 million, or 10.8%, due to an increase in customer accounts, growth in both the hospital and office based lab sites of service, international expansion, and additional product offerings within the peripheral space. Revenues from our coronary products increased by approximately $13.5 million, or 24.2%, due to an increase in customer accounts, international expansion, and additional product offerings in the coronary space. Revenue growth in both peripheral and coronary was partially offset by modest average selling price declines. In fiscal 2019, we also had $7.9 million of revenue from international sales of our OAS and related products, compared to $1.8 million of revenue in the prior fiscal year.

Historically, all of our revenues have been in the United States; however, international sales through Medikit commenced in February 2018 when we first received reimbursement approval in Japan. In July 2018, we entered into an exclusive Distribution Agreement with OrbusNeich to sell our Peripheral and Coronary OAS outside of the United States and Japan and began selling our products through OrbusNeich in certain countries in Southeast Asia, Europe and the Middle East commencing in September 2018. 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 such as the Sapphire balloons, Teleport Microcatheter, and ZILIENT guidewires; generate additional clinical data; and continue expansion into new geographies, partially offset by potential decreases in average selling prices.

Cost of Goods Sold. Cost of goods sold increased 20.8%, from $39.5 million for the year ended June 30, 2018 to $47.7 million for the year ended June 30, 2019. These amounts represent the cost of materials, labor and overhead for single-use catheters, guide wires, pumps, and other ancillary products. The increase in cost of goods sold was due to greater unit volumes as we added new accounts, expanded into international markets, and offered other support products. The increase in cost of goods sold was partially offset by lower costs per unit driven by manufacturing efficiencies and cost reductions in the current year ended June 30, 2019. Gross margin decreased to 80.8% for the year ended June 30, 2019 from 81.8% for the year ended June 30, 2018 due to increased sales of lower margin products and a greater percentage of sales into international markets. Cost of goods sold for the years ended June 30, 2019 and 2018 includes $346,000 and $275,000, respectively, for stock-based compensation. We expect that gross margin for the year ending June 30, 2020 will decrease slightly compared to the year ended June 30, 2019, as an increasing amount of revenue will be derived from lower margin products and international markets. Quarterly margin fluctuations could occur based on production volumes, timing of new product introductions, sales mix, pricing changes, or other unanticipated circumstances.

Selling, General and Administrative Expenses. Selling, general, and administrative expenses increased by $19.1 million, or 12.9%, from $148.6 million for the year ended June 30, 2018 to $167.7 million for the year ended June 30, 2019. The increase was primarily due to the expansion of clinical specialists in our sales organization, investments in medical education to support international expansion and higher incentive compensation due to company performance. Selling, general, and administrative expenses for the years ended June 30, 2019 and 2018 include $9.6 million and $9.1 million, respectively, for stock-based compensation. We expect our selling, general and administrative expenses to increase as revenue grows in fiscal 2020, but at a rate less than the rate of revenue growth.

Research and Development Expenses. Research and development expenses increased by $6.7 million, or 25.1%, from $26.8 million for the year ended June 30, 2018 to $33.5 million for the year ended June 30, 2019. 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 and support products to our Peripheral and Coronary OAS, as well as PAD and CAD clinical studies. The increase was primarily due to increased activity on the ECLIPSE clinical study and new development projects, including our percutaneous ventricular assist device. Research and development expenses for the years ended June 30, 2019 and 2018 include $1.3 million and $1.0 million, respectively, for stock-based compensation. We generally expect to incur higher research and development expenses in fiscal 2020 than amounts incurred for the year ended June 30, 2019 as we continue to progress in the ECLIPSE clinical study and make further investments in expanding our product portfolio. Fluctuations could occur based on the number of projects and studies and the timing of expenditures.

Please refer to Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended June 30, 2018 for a comparative discussion of our financial results for the fiscal year ended June 30, 2018 as compared with the fiscal year ended June 30, 2017.

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 GAAP measure expressed as dollar amounts (in thousands):

	Year Ended June 30,	
	2019	**2018**
Net (loss) income	$ (255)	$ 1,712
Less: Other (income) and expense, net	(760)	390
Less: Provision for income taxes	190	132
(Loss) income from operations	(825)	2,234
Add: Stock-based compensation	11,266	10,302
Add: Depreciation and amortization	3,446	3,934
Adjusted EBITDA	$ 13,887	$ 16,470

Adjusted EBITDA declined as compared to the prior year due to the loss from operations.

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 depreciation and amortization expense and non-cash charges such as stock-based compensation. 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. Additionally, our management is partially evaluated on the basis of Adjusted EBITDA when determining achievement of their incentive compensation performance targets. Management does not use this Adjusted EBITDA measure as a liquidity measure or in the calculation of our financial covenants under the revolving credit facility with Silicon Valley Bank.

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*. Our management believes that excluding this item from our non-GAAP results is useful to investors to understand the application of stock-based compensation guidance and its impact on our operational performance and ability to make additional investments in our company, and it allows for greater transparency to certain line items in our financial statements.
- *Depreciation and amortization expense*. Our management believes that excluding these items from our non-GAAP results is useful to investors to understand our operational performance and ability to make additional investments in our 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 $74.2 million and $116.3 million at June 30, 2019 and 2018, respectively. As of June 30, 2019, we had an accumulated deficit of $329.5 million. The increase in cash and cash equivalents was primarily attributable to net cash provided by our operating and financing activities during the year ended June 30, 2019.

A summary of our cash flow activities is as follows:

	Year Ended June 30,		
	2019	**2018**	**2017**
Net cash provided by operating activities	$ 10,208	$ 9,674	$ 19,588
Net cash used in investing activities	(54,352)	(5,095)	(1,779)
Net cash provided by financing activities	2,121	3,769	29,465
Net change in cash and cash equivalents	$ (42,023)	$ 8,348	$ 47,274

Changes in Liquidity

Operating Activities

Net cash provided by operating activities was $10.2 million for the year ended June 30, 2019, primarily due to positive cash flow when the net loss of $255,000 is adjusted for non-cash expenditures such as stock-based compensation, depreciation and amortization. Contributing to positive cash flows from operations was the timing of cash payments on payables, as well as increased accrued liabilities associated with higher accruals for incentive compensation and commissions. These positive cash flows were partially offset by the timing of collections on receivables, increased use of cash as we build inventory and diversify our products, and the effects of recognizing previously deferred revenue.

Net cash provided by operating activities was $9.7 million for the year ended June 30, 2018, primarily due to the net income of $1.7 million contributing to higher cash flows when adjusted for non-cash expenditures such as stock-based compensation, depreciation and amortization, as well as the timing of prepaid expenses. These positive cash flows were partially offset by the timing of collections on receivables, the use of cash for payouts of previously accrued bonuses and commissions and a litigation settlement payment.

Investing Activities

Net cash used in investing activities was $54.4 million for the year ended June 30, 2019, primarily due to purchases of available-for-sale debt securities made with our excess cash balance. Also contributing to cash flows used in investing activities was a combined $3.6 million related to capital expenditures and patent costs and an additional $3.1 million equity investment.

Net cash used in investing activities was $5.1 million for the year ended June 30, 2018. Contributing to this was a combined $3.1 million of capital expenditures and patent costs and a $2.5 million equity investment made in June 2018, partially offset by the collection of a note receivable.

Financing Activities

Net cash provided by financing activities was $2.1 million for the year ended June 30, 2019, primarily from proceeds of $3.8 million from the employee stock purchase plan and a small amount of cash proceeds from stock option exercises. These amounts were partially offset by $1.8 million of payroll tax payments we made on behalf of our employees, associated with the vesting of employee restricted stock.

Net cash provided by financing activities was $3.8 million for the year ended June 30, 2018, primarily from proceeds of $3.8 million from the employee stock purchase plan and a small amount of cash proceeds from stock option exercises.

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 business operations, 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, potential strategic transactions (including the potential acquisition of, or investments in, businesses, technologies and products), international expansion, and the existence, defense and resolution of legal proceedings. As of June 30, 2019, we believe our current cash and marketable securities will be sufficient to fund working capital requirements and operations for the foreseeable future, including at least the next 12 months, including anticipated capital expenditures, strategic investments, development programs and potential legal activities. We intend to retain any future earnings to support operations and to finance the growth and development of our business. We do not anticipate paying any dividends in the foreseeable future.

Facility Sale and Lease

On December 29, 2016, we entered into a Purchase and Sale Agreement, as subsequently amended (collectively, the “Sale Agreement”), with Krishna Holdings, LLC (the “Buyer”), providing for the sale to Buyer of our headquarters facility in St. Paul, Minnesota (the “Facility”) for a cash purchase price of $21.5 million. On March 30, 2017, the sale of the Facility under the Sale Agreement closed. We received proceeds of approximately $20.9 million ($21.5 million less $556,000 of transaction expenses). See Notes 2 and 4 to our Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional discussion.

Revolving Credit Facility

On March 31, 2017, we entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank ("SVB"). The Loan Agreement provides for a senior, secured revolving credit facility (the "Revolver") of $40.0 million (the "Maximum Dollar Amount").

Advances under the Revolver may be made from time to time up to the Maximum Dollar Amount, subject to certain borrowing limitations. The Revolver has a maturity date of March 31, 2020 and bears interest at a floating per annum rate equal to the Wall Street Journal prime rate, less 0.25%. Interest on borrowings is due monthly and the principal balance is due at maturity. Borrowings up to $10.0 million are available on a non-formula basis. Borrowings above $10.0 million are based on (i) 85% of eligible domestic accounts receivable, and (ii) the lesser of 50% of eligible inventory or $5.0 million, subject to adjustment as defined in Loan Agreement. Upon the Revolver's maturity, any outstanding principal balance, unpaid accrued interest, and all other obligations under the Revolver will be due and payable. We will incur a fee equal to 1% of the Maximum Dollar Amount upon termination of the Loan Agreement or the Revolver for any reason prior to the maturity date, unless refinanced with SVB.

Our obligations under the Loan Agreement are secured by certain of our assets, including, among other things, accounts receivable, deposit accounts, inventory, equipment, general intangibles and records pertaining to the foregoing. The collateral does not include our intellectual property, but we agreed not to encumber our intellectual property without the consent of SVB. The Loan Agreement contains customary covenants limiting our ability to, among other things, incur debt or liens, make certain investments and loans, enter into transactions with affiliates, undergo certain fundamental changes, dispose of assets, or change the nature of its business. In addition, the Loan Agreement contains financial covenants requiring us to maintain, at all times when any amounts are outstanding under the Revolver, either (i) minimum unrestricted cash at SVB and unused availability on the Revolver of at least $10.0 million or (ii) minimum trailing three-month Adjusted EBITDA of $1.0 million. If we do not comply with the various covenants under the Loan Agreement, the interest rate on outstanding amounts will increase by 5% and SVB may, subject to various customary cure rights, decline to provide additional advances under the Revolver, require the immediate payment of all amounts outstanding under the Revolver, and foreclose on all collateral.

Under the Loan Agreement, we paid SVB a non-refundable commitment fee of $80,000, which will be amortized to interest expense over the term of the Loan Agreement. We are required to pay a fee equal to 0.35% per annum on the unused portion of the Revolver, payable quarterly in arrears. SVB's obligations to advance funds under the Revolver are subject to an initial collateral examination to be completed within 90 days of the effective date of the Loan Agreement. We are not obligated to draw any funds under the Revolver and no amounts are outstanding as of June 30, 2019. We currently do not have plans of borrowing under the Loan Agreement.

Contractual Cash Obligations. Our contractual obligations and commercial commitments as of June 30, 2019 are summarized below:

	Payments Due by Period (in thousands)				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**3-5 Years**	**More Than 5 Years**
Operating leases[1]	$ 441	$ 392	$ 47	$ 2	$ —
Financing obligation[2]	26,698	1,750	3,660	3,883	17,405
Purchase commitments[3]	24,136	24,136	—	—	—
Legal settlement[4]	467	467	—	—	—
Other[5]	144	107	37	—	—
Total	$ 51,886	$ 26,852	$ 3,744	$ 3,885	$ 17,405

(1) The amounts represent future minimum payments under a non-cancellable operating lease for our Texas production facility along with equipment leases.
(2) The amounts represent future minimum payments due under the capital lease related to the sale leaseback of our Facility.
(3) The amount represents open purchase orders as of June 30, 2019.
(4) Consists of payments and related interest associated with the previously disclosed Department of Justice settlement.
(5) Other includes service agreements and severance arrangements.

Due to the uncertainty with respect to the timing of future cash flows associated with our unrecognized tax benefits at June 30, 2019, we are unable to make reasonably reliable estimates of the period of cash settlement with the respective taxing authority. Therefore, $611,000 of unrecognized tax benefits have been excluded from the contractual obligations table above.

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 February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, "Leases." The guidance requires lessees to recognize the assets and liabilities that arise from leases on the balance sheet. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, and should be applied using a modified retrospective approach. The guidance was effective for us on July 1, 2019.

We have elected the prospective transition method with the effects of adoption recognized as a cumulative effect adjustment to the opening balance of retained earnings in our fiscal 2020 financial statements, with no restatement of comparative periods. We have also elected the package of three practical expedients permitted under the transition guidance within the new standard, which among other things, allows us to carry forward the historical lease classification.

We have assessed the impact of adopting this guidance on our consolidated financial statements and related disclosures and do not expect a material impact to our results of operations and cash flows. We will record our operating leases on our consolidated balance sheet as right of use assets and lease liabilities, but due to the makeup of our current operating lease portfolio, we do not expect a material amount to be recognized on the consolidated balance sheet.

In June 2016, the FASB issued ASU 2016-13, "Measurement of Credit Losses on Financial Instruments," which revises guidance for the accounting for credit losses on financial instruments within its scope. The new standard introduces an approach, based on expected losses, to estimate credit losses on certain types of financial instruments and modifies the impairment model for available-for-sale debt securities. The new approach to estimating credit losses (referred to as the current expected credit losses model) applies to most financial assets measured at amortized cost and certain other instruments, including trade and other receivables, loans, held-to-maturity debt securities, net investments in leases and off-balance-sheet credit exposures. ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted and should be applied as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. The guidance is effective for us on July 1, 2020. 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, but not limited to, (i) the expectation of selling our products, including recently approved products, future products and products we distribute, domestically and internationally in the future, the timing and structure of our plans to do so, and the specific countries and products to be sold, either by us or through distributors; (ii) our strategy; (iii) the competitive benefits of our products; (iv) potential strategic acquisitions and partnerships; (v) the expected timing of the manufacturing transfer and commercialization of the WIRION system; (vi) our products in development; (vii) seasonality in our business; (viii) reimbursement of our products; (ix) our intention to expand our product portfolio through internal development and external relationships; (x) our plan to balance revenue growth with a pathway to profitability and positive cash flow; (xi) our current and anticipated clinical studies, including the results and timing of such studies; (xii) our expectation that our revenue will increase; (xiii) our expectation of increased selling, general and administrative expenses and the rate of such growth; (xiv) our expectation that gross margin in fiscal 2020 will decrease slightly compared to fiscal 2019; (xv) our expectation that our current facilities will be adequate for the foreseeable future; (xvi) our plans to continue to expand our sales and marketing efforts as well as our product portfolio and clinical studies; (xvii) our intention to file additional patents and our efforts to protect our intellectual property; (xviii) our expectation that we will incur research and development expenses in fiscal 2020 higher than the amounts incurred for fiscal 2019; (xix) 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, as well as to fund certain other anticipated expenses; (xx) our intention to retain any future earnings to support operations and to finance the growth and development of our business; (xxi) our dividend

expectations; (xxii) our ability to obtain regulatory approvals to market our products; (xxiii) our plan not to borrow under our loan and security agreement; and (xxiv) the anticipated impact of adoption of recent accounting pronouncements on our 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,” or the negative of 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, clearances and approvals; approval of our products for distribution in foreign countries; approval of products for reimbursement and the level of reimbursement in the U.S., Japan and other foreign countries; dependence on market growth; agreements with third parties to sell their products; the ability of OrbusNeich to successfully launch our products outside of the United States and Japan; our ability to maintain third-party supplier relationships and renew existing purchase agreements; our ability to maintain our relationships with Medikit and OrbusNeich; the experience of physicians regarding the effectiveness and reliability of the products we sell; 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; our ability to comply with the financial covenants in our loan and security agreement and to make payments under and comply with the lease agreement for our corporate headquarters; unanticipated developments affecting our estimates regarding expenses, future revenues and capital requirements; the difficulty of successfully managing operating costs; our ability to manage our sales force strategy; actual research and development efforts and needs, including the timing of product development programs; our ability to obtain and maintain intellectual property protection for product candidates; fluctuations in results and expenses based on new product introductions, sales mix, unanticipated warranty claims, and the timing of project expenditures; our ability to manage costs; our actual financial resources and our ability to obtain additional financing; investigations or litigation threatened or initiated against us; court rulings and future actions by the FDA and other regulatory bodies; international trade developments; the impact of federal corporate tax reform on our business, operations and financial statements; shutdowns of the U.S. federal government; unanticipated developments during the manufacturing transfer process for the WIRION system; and general economic conditions.

These and additional risks and uncertainties are described more fully in Part I, 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, United States government securities, certain bank obligations and highly rated corporate bonds, asset-backed securities and municipal obligations.

Our cash and cash equivalents as of June 30, 2019 include liquid money market accounts. Additionally, we have certain available-for-sale marketable securities. See Notes 1 and 5 to our Consolidated Financial Statements included in Part II, Item 8 of this Form 10-K for additional information on these available-for-sale marketable securities. Due to the short-term nature of these investments, we believe that there is no material exposure to interest rate risk.

Item 8. ***Financial Statements and Supplementary Data.***

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

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

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Cardiovascular Systems, Inc. and its subsidiaries (the "Company") as of June 30, 2019 and 2018, and the related consolidated statements of operations, comprehensive income, changes in stockholders' equity and cash flows for each of the three years in the period ended June 30, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of June 30, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of June 30, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2019 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, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated 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 the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. 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.

Definition and Limitations of Internal Control over Financial Reporting

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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Performance-Based Restricted Stock Awards with Market Conditions

As described in Notes 1 and 6 to the consolidated financial statements, the Company granted performance-based restricted stock awards with market conditions that vest based on the Company's total shareholder return relative to total shareholder return of a peer group, as measured by the closing prices of the stock of the Company and its peer group for the period as defined in the award agreement, which resulted in the Company recognizing stock-based compensation expense of $3.5 million for the year ended June 30, 2019. With the assistance of a specialist, management determined the fair value of the performance-based restricted stock awards with market conditions using the Monte Carlo simulation model.

The principal considerations for our determination that performing procedures relating to performance-based restricted stock awards with market conditions is a critical audit matter are there was significant judgment by management, including the use of a specialist, to determine the fair value of these stock awards using the Monte Carlo simulation model. This in turn led to a high degree of auditor subjectivity and judgment to evaluate the audit evidence obtained related to the valuation of the stock awards. The audit effort involved the use of professionals with specialized skill and knowledge to assist in evaluating the audit evidence obtained from these procedures.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the valuation of the performance-based restricted stock awards with market conditions, including management's method, assumptions, and data. These procedures also included, among others, developing an independent estimate of the fair value of a sample of performance-based restricted stock awards with market conditions and comparing to management's estimate to evaluate the reasonableness of the estimate. The independent estimate was calculated by (i) developing an independent Monte Carlo simulation model of the Company's expected total shareholder return relative to total shareholder return of a peer group as defined in the award agreement and (ii) testing the completeness and accuracy of historical stock prices and volatilities of the Company and the peer group data used in the Monte Carlo simulation model by utilizing data obtained from an independent third-party source. Professionals with specialized skill and knowledge were used to assist in developing the independent Monte Carlo simulation model and evaluating the audit evidence.

/s/ PricewaterhouseCoopers LLP
Minneapolis, Minnesota
August 22, 2019

We have served as the Company's auditor since at least 2003, which includes periods before the Company became subject to SEC reporting requirements.

Cardiovascular Systems, Inc.

Consolidated Balance Sheets
(Dollars in thousands, except per share and share amounts)

	June 30, 2019	June 30, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 74,237	$ 116,260
Marketable securities	48,435	544
Accounts receivable, net	36,015	31,225
Inventories	18,058	16,605
Prepaid expenses and other current assets	3,330	2,977
Total current assets	180,075	167,611
Property and equipment, net	27,324	27,744
Patents, net	5,105	5,231
Other assets	6,073	2,766
Total assets	$ 218,577	$ 203,352
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	11,194	10,441
Accrued expenses	29,387	25,776
Deferred revenue	1,764	1,243
Total current liabilities	42,345	37,460
Long-term liabilities		
Financing obligation	20,972	21,064
Deferred revenue	6,541	8,946
Other liabilities	775	1,412
Total liabilities	70,633	68,882
Commitments and contingencies		
Common stock, $0.001 par value; authorized 100,000,000 common shares; issued and outstanding 34,934,569 at June 30, 2019 and 33,360,032 at June 30, 2018	34	33
Additional paid in capital	477,368	461,927
Accumulated other comprehensive income	78	101
Accumulated deficit	(329,536)	(327,591)
Total stockholders' equity	147,944	134,470
Total liabilities and stockholders' equity	$ 218,577	$ 203,352

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

Cardiovascular Systems, Inc.

Consolidated Statements of Operations
(Dollars in thousands, except per share and share amounts)

	Year Ended June 30,		
	2019	**2018**	**2017**
Net revenues	$ 248,017	$ 217,043	$ 204,906
Cost of goods sold	47,680	39,484	39,441
Gross profit	200,337	177,559	165,465
Expenses:			
Selling, general and administrative	167,700	148,569	144,096
Research and development	33,462	26,756	22,911
Total expenses	201,162	175,325	167,007
(Loss) income from operations	(825)	2,234	(1,542)
Other (income) expense, net:			
Interest expense	1,684	1,717	500
Interest income and other, net	(2,444)	(1,327)	(336)
Total other (income) expense, net	(760)	390	164
(Loss) income before income taxes	(65)	1,844	(1,706)
Provision for income taxes	190	132	86
Net (loss) income	$ (255)	$ 1,712	$ (1,792)
Basic earnings per share	$ (0.01)	$ 0.05	$ (0.06)
Diluted earnings per share	$ (0.01)	$ 0.05	$ (0.06)
Basic weighted average shares outstanding	33,535,759	33,145,140	32,373,709
Diluted weighted average shares outstanding	33,535,759	33,614,260	32,373,709

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

Cardiovascular Systems, Inc.

Consolidated Statements of Comprehensive Income
(Dollars in thousands, except per share and share amounts)

	Year Ended June 30,		
	2019	**2018**	**2017**
Net (loss) income	$ (255)	$ 1,712	$ (1,792)
Other comprehensive income:			
Unrealized gain on available-for-sale securities	78	35	66
Adjustment for net gain realized and included in interest income and other, net	—	(34)	(6)
Total change in unrealized gain on available for sale securities	78	1	60
Comprehensive (loss) income	$ (177)	$ 1,713	$ (1,732)

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

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	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
Balances at June 30, 2016	$ 33	$ 428,235	$ 40	$ (327,411)	$ 100,897
Stock-based compensation related to restricted stock awards, net	—	9,412	—	—	9,412
Exercise of stock options at $7.90-$12.15 per share	—	5,362	—	(100)	5,262
Employee stock purchase plan activity	—	4,550	—	—	4,550
Unrealized gain on marketable securities	—	—	66	—	66
Net gain reclassified from accumulated other comprehensive income	—	—	(6)	—	(6)
Net loss	—	—	—	(1,792)	(1,792)
Balances at June 30, 2017	$ 33	$ 447,559	$ 100	$ (329,303)	$ 118,389
Stock-based compensation related to restricted stock awards, net	—	9,546	—	—	9,546
Exercise of stock options at $7.90-$12.15 per share	—	514	—	—	514
Employee stock purchase plan activity	—	4,308	—	—	4,308
Unrealized gain on marketable securities	—	—	35	—	35
Net gain reclassified from accumulated other comprehensive income	—	—	(34)	—	(34)
Net income	—	—	—	1,712	1,712
Balances at June 30, 2018	$ 33	$ 461,927	$ 101	$ (327,591)	$ 134,470
Impact from adoption of ASU 2016-01 (See Note 5)	—	—	(101)	101	—
Stock-based compensation related to restricted stock awards, net	1	10,355	—	—	10,356
Shares withheld for payroll taxes	—	—	—	(1,791)	(1,791)
Exercise of stock options at $8.75 per share	—	196	—	—	196
Employee stock purchase plan activity	—	4,890	—	—	4,890
Unrealized gain on available-for-sale debt securities	—	—	78	—	78
Net loss	—	—	—	(255)	(255)
Balances at June 30, 2019	$ 34	$ 477,368	$ 78	$ (329,536)	$ 147,944

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

Cardiovascular Systems, Inc.

Consolidated Statements of Cash Flows
(Dollars in thousands)

	Year Ended June 30,		
	2019	**2018**	**2017**
Cash flows from operating activities			
Net (loss) income	$ (255)	$ 1,712	$ (1,792)
Adjustments to reconcile net (loss) income to net cash provided by operating activities			
Depreciation of property and equipment	3,150	3,730	3,917
Provision for (recovery of) doubtful accounts (including note receivable)	125	(225)	465
Amortization of patents	296	204	218
Write-off of patent costs	800	497	733
Stock-based compensation	11,266	10,302	10,354
Accretion of discount on marketable securities	(55)	—	—
Loss on disposal of property and equipment and other	42	16	296
Changes in assets and liabilities			
Accounts receivable	(4,915)	(2,878)	(5,809)
Inventories	(1,453)	292	543
Prepaid expenses and other assets	(393)	2,308	(1,823)
Accounts payable	566	104	1,761
Accrued expenses and other liabilities	2,918	(6,577)	725
Deferred revenue	(1,884)	189	10,000
Net cash provided by operating activities	10,208	9,674	19,588
Cash flows from investing activities			
Expenditures for property and equipment	(2,665)	(1,956)	(981)
Purchases of long-term investments	(3,055)	(2,538)	—
Purchases of marketable securities	(47,892)	—	—
Sales of marketable securities	150	194	46
Costs incurred in connection with patents	(890)	(1,113)	(844)
Proceeds from convertible note receivable	—	318	—
Net cash used in investing activities	(54,352)	(5,095)	(1,779)
Cash flows from financing activities			
Proceeds from the employee stock purchase plan	3,752	3,242	3,254
Payment of employee taxes related to vested restricted stock	(1,791)	—	—
Exercise of stock options	196	513	5,263
Proceeds from financing	—	—	20,944
Other	(36)	14	4
Net cash provided by financing activities	2,121	3,769	29,465
Net change in cash and cash equivalents	(42,023)	8,348	47,274
Cash and cash equivalents			
Beginning of period	116,260	107,912	60,638
End of period	$ 74,237	$ 116,260	$ 107,912
Supplemental cash flow information			
Interest paid	$ 1,684	$ 1,717	$ 500

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

1. Summary of Significant Accounting Policies

Company Description

Cardiovascular Systems, Inc. (the "Company"), based in St. Paul, Minn., is a medical technology company focused on developing and commercializing innovative solutions for treating vascular and coronary disease. The Company's Orbital Atherectomy Systems ("OAS") treat calcified and fibrotic plaque in arterial vessels throughout the leg and heart in a few minutes of treatment time, and address many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives.

Principles of Consolidation

The consolidated balance sheets and statements of operations, comprehensive income, 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.

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.

Marketable Securities

The Company's marketable securities consist predominately of available-for-sale debt securities and were valued in accordance with the fair value measurement guidance. Available-for-sale debt securities are carried at fair value with unrealized gains and losses reported as a component of stockholders' equity as accumulated other comprehensive income, 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 equity securities are carried at fair value with any unrealized gains or losses reported in earnings.

Available-for-sale securities are reviewed for possible impairment at least quarterly, or more frequently if circumstances arise that 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.

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, which is an estimate 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
Balance at June 30, 2016	$ 712
Provision for doubtful accounts	465
Write-offs	(313)
Balance at June 30, 2017	864
Provision for doubtful accounts	125
Write-offs	(189)
Balance at June 30, 2018	800
Provision for doubtful accounts	125
Write-offs	(312)
Balance at June 30, 2019	$ 613

Inventories

Inventories are stated at the lower of cost or net realizable value, 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. The Company writes down its inventories as it becomes aware of any situation where the carrying amount exceeds the estimated realizable value based on assumptions about future demands and market conditions.

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 years 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 that 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.

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.

Financing Obligation

In March 2017, the Company entered into an agreement to lease its Minnesota facility. The lease agreement has an initial term of fifteen years, with four consecutive renewal options of five years each at the Company's option. As the lease terms resulted in a capital lease classification, the Company accounted for the sale and leaseback of its Minnesota facility as a financing transaction where the assets remain on the Company's balance sheet and a financing obligation was recorded for $20,944. As lease payments are made, they will be allocated between interest expense and a reduction of the financing obligation, resulting in a value of the financing obligation that is equivalent to the net book value of the assets at the end of the lease term. At the end of the lease (including any renewal option terms), the Company will remove the assets and financing obligation from its balance sheet.

Revenue Recognition

Effective July 1, 2018, the Company adopted Accounting Standards Codification ("ASC") Topic 606 - Revenue from Contracts with Customers using the modified retrospective adoption method. Adoption did not have a material impact on the Company's financial statements.

The Company sells its peripheral and coronary products to customers through a direct sales force in the United States and through distributors internationally and has no material concentration of credit risk or significant payment terms extended to customers and, therefore, the Company does not adjust the promised amount of consideration for the effects of a significant financing component. Sales, use, value-added, and other excise taxes are not recognized in revenue. The Company has elected to present revenue net of sales taxes and other similar taxes.

Performance Obligations

The majority of the Company's revenues are from customer arrangements containing a single performance obligation to transfer peripheral and coronary products, and thus revenue is recognized at a point in time when control is transferred. This generally occurs upon shipment or upon delivery to the customer site, based on the contract terms. Shipping and handling activities are considered to be fulfillment activities and are not considered to be a separate performance obligation. The Company does not assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer. The Company does not disclose the value of unsatisfied performance obligations for contracts with an original expected length of one year or less. The Company did not recognize any material revenue in the current reporting period for performance obligations that were fully satisfied in previous periods.

Significant Judgments

The Company has an exclusive distribution agreement with Medikit to sell the Company's coronary and peripheral OAS in Japan. To secure exclusive distribution rights, Medikit made an upfront payment of $10,000 to the Company, which is partially refundable based on the occurrence of certain events during the term of the agreement. The Company has classified the payment as current or long-term based on its expectation of when revenue will be recognized and this expectation is re-evaluated on a quarterly basis. Medikit also provides advance payments for orders under the terms of the agreement, and, therefore, deferred revenue is recorded until products are accepted by Medikit.

Revenue is recognized at the transaction price to which the Company expects to be entitled. The Company offers customers certain volume-based rebates, discounts, and incentives. Estimates of variable consideration from these items are taken into account using the most-likely amount method based on contractual provisions, the Company's historical experience, and forecasted customer buying patterns. These items are recognized as a reduction to revenue in the period the revenue is recognized and recorded as a liability.

Return and warranty obligations vary by the specific terms of agreements with customers. The Company generally does not provide customers with a right of return. The Company has a limited warranty provision for goods that are nonconforming or defective at the time of shipment, which is estimated based on historical experience.

Contract Costs

Commissions are earned by the Company's direct sales force based on sales of the Company's OAS and other products. The Company applies the practical expedient and recognizes commissions as an expense when incurred because the amortization period of the asset that the Company would have otherwise recognized is one year or less.

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
Balance at June 30, 2016	$ 145
Provision	1,733
Claims	(1,361)
Balance at June 30, 2017	517
Provision	328
Claims	(713)
Balance at June 30, 2018	132
Provision	502
Claims	(501)
Balance at June 30, 2019	$ 133

Litigation and Contingent Liabilities

The Company and its operations from time to time are, and in the future may be, parties to or targets of lawsuits, claims, investigations, and proceedings, which are handled and defended in the ordinary course of business. The Company accrues a liability for such matters when it is probable that a liability has been incurred and the amount can be reasonably estimated. When a single amount cannot be reasonably estimated but the cost can be estimated within a range, the Company accrues an amount based on management's best estimate considering all facts and circumstances. The Company expenses legal costs, including those expected to be incurred in connection with a loss contingency, as incurred.

Medical Device Excise Tax

The Patient Protection and Affordable Care Act of 2010 imposed a medical device excise tax on medical device manufacturers on their sales in the United States of certain devices, which was effective January 1, 2013. The excise tax is 2.3% of the taxable base and applied to a substantial majority of the Company's sales. Effective January 1, 2016, the excise tax was suspended until the end of 2017, and in January 2018, another temporary two year suspension of the tax was passed, extending the suspension to December 31, 2019.

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 rules on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

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 and fees, 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.

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.

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

As of June 30, 2019, 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 4 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 and these differences could be material.

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.

Subsequent Event

On August 5, 2019, the Company acquired the WIRION Embolic Protection System and related assets from Gardia Medical Ltd., a wholly owned Israeli subsidiary of Allium Medical Solutions Ltd. Upon closing, the Company made an initial $5,600 cash outlay and issued Gardia 31,493 shares of Common Stock of the Company valued at $1,400. Following the successful completion of the manufacturing transfer of the WIRION system to the Company, the Company has agreed to pay Gardia an additional $10,000, half of which may be paid by the Company through an additional issuance of shares of Common Stock. In addition, the Company has agreed to make a performance milestone payment to Gardia equal to $3,000 for each $10,000 in net revenues recognized by the Company from sales of the WIRION system for applications above-the-knee in excess of $30,000 during the 36 month period beginning on the earlier of the first commercial sale of the system by the Company or six months following successful manufacturing transfer. The initial accounting for this acquisition will be completed in the first quarter of fiscal 2020.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-02, “Leases.” The guidance requires lessees to recognize the assets and liabilities that arise from leases on the balance sheet. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, and should be applied using a modified retrospective approach. The guidance is effective for the Company on July 1, 2019.

The Company will elect the prospective transition method with the effects of adoption recognized as a cumulative effect adjustment to the opening balance of retained earnings in the Company's fiscal 2020 financial statements, with no restatement of comparative periods. The Company will also elect the package of three practical expedients permitted under the transition guidance within the new standard, which, among other things, allows the Company to carry forward the historical lease classification.

The Company has assessed the impact of adopting this guidance on its consolidated financial statements and related disclosures and does not expect a material impact to its results of operations and cash flows. The Company will record its operating leases on its consolidated balance sheet as right of use assets and lease liabilities, but due to the makeup of its current operating lease portfolio, does not expect a material amount to be recognized on the consolidated balance sheet.

In June 2016, the FASB issued ASU 2016-13, “Measurement of Credit Losses on Financial Instruments,” which revises guidance for the accounting for credit losses on financial instruments within its scope. The new standard introduces an approach, based on expected losses, to estimate credit losses on certain types of financial instruments and modifies the impairment model for available-for-sale debt securities. The new approach to estimating credit losses (referred to as the current expected credit losses model) applies to most financial assets measured at amortized cost and certain other instruments, including trade and other receivables, loans, held-to-maturity debt securities, net investments in leases and off-balance-sheet credit exposures. ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted and should be applied as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. The guidance is effective for the Company on July 1, 2020. The Company does not anticipate a material impact on its financial statements upon adoption.

2. Selected Consolidated Financial Statement Information

Accounts Receivable, Net

Accounts receivable consists of the following:

	June 30,	
	2019	2018
Accounts receivable	$ 36,628	$ 32,025
Less: Allowance for doubtful accounts	(613)	(800)
Accounts receivable, net	$ 36,015	$ 31,225

Inventories

Inventories consist of the following:

	June 30,	
	2019	2018
Raw materials	$ 5,547	$ 6,820
Work in process	1,415	1,315
Finished goods	11,096	8,470
Inventories	$ 18,058	$ 16,605

Property and Equipment, Net

Property and equipment consists of the following:

	June 30,	
	2019	2018
Land	$ 572	$ 500
Building	22,420	22,420
Equipment	17,517	16,510
Furniture	2,975	2,709
Leasehold improvements	540	438
Construction in progress	1,328	1,110
	45,352	43,687
Less: Accumulated depreciation	(18,028)	(15,943)
Total Property and equipment, net	$ 27,324	$ 27,744

On December 29, 2016, the Company entered into a Purchase and Sale Agreement, as subsequently amended (collectively, the "Sale Agreement"), with Krishna Holdings, LLC (the "Buyer"), providing for the sale to Buyer of the Company's headquarters facility in St. Paul, Minnesota (the "Facility"), for a cash purchase price of $21,500. On March 30, 2017, the sale of the Facility under the Sale Agreement closed. The Company received proceeds of approximately $20,944 ($21,500, less $556 of transaction expenses). The net proceeds are to be used for working capital and general corporate purposes. In connection with the sale, the Company recorded an impairment charge of $158.

Under the Sale Agreement, the Company entered into a Lease Agreement (the "Lease Agreement") with Krishna Holdings, LLC, Apex Holdings, LLC, Kashi Associates, LLC, Keva Holdings, LLC, S&V Ventures, LLC, Polo Group LLC, SPAV Holdings LLC, Star Associates LLC, and The Global Villa, LLC. As the lease terms resulted in a capital lease classification, the Company accounted for the sale and leaseback of the Facility as a financing transaction where the assets remain on the Company's balance sheet. See Note 4 for further discussion on future payment obligations under the Lease Agreement.

Patents, net

Patents, net consist of the following:

	June 30,	
	2019	2018
Patents	$ 6,093	$ 6,435
Less: Accumulated amortization	(988)	(1,204)
Total Patents, net	$ 5,105	$ 5,231

As of June 30, 2019, future estimated amortization of patents is as follows:

2020	$ 209
2021	209
2022	207
2023	201
2024	197
Thereafter	4,082
	$ 5,105

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, change in useful life or other events.

Accrued Expenses

Accrued expenses consist of the following:

	June 30,	
	2019	2018
Salaries and bonus	$ 11,105	$ 6,624
Commissions	6,829	7,234
Accrued vacation	4,230	3,557
Accrued excise, sales and other taxes	3,349	3,522
Clinical studies	2,092	1,422
Legal settlement	467	1,847
Other accrued expenses	1,315	1,570
Total Accrued expenses	$ 29,387	$ 25,776

Legal Settlement

On June 28, 2016, the Company entered into a Settlement Agreement (the "Settlement Agreement") with the United States of America, acting through the Department of Justice (the "DOJ") and on behalf of the Office of Inspector General of the Department of Health and Human Services, and Travis Thams, to resolve the investigation by the DOJ and the civil action underlying such investigation. Under the Settlement Agreement, the Company agreed to pay $8,000 (the "Settlement Amount"), as follows: an initial payment of $3,000, paid on July 1, 2016, with the remaining $5,000, which bears interest at 1.8% per annum, payable in 11 equal quarterly installments, beginning January 1, 2017. The final quarterly installment made on July 1, 2019 is included in accrued expenses (as noted in the table above). Under the Settlement Agreement, if the Company makes a single payment in excess of $2,000, which payment is not covered by an insurance policy, in settlement of any claims before paying the full Settlement Amount, the remaining unpaid balance of the Settlement Amount will become immediately due and payable, with interest accruing on the unpaid principal portion at an interest rate of 1.8% per annum.

3. Revenue

A summary of the Company's accounting policies related to revenue recognition in accordance with ASC 606 can be found within Note 1 of these financial statements. The following table disaggregates the Company's net revenues by product category and geography for the following periods:

	Year Ended June 30,		
Product Category	**2019**	**2018**	**2017**
Peripheral	$ 178,896	$ 161,405	$ 153,716
Coronary	69,121	55,638	51,190
Total net revenues	$ 248,017	$ 217,043	$ 204,906
Geography			
United States	$ 240,114	$ 215,233	$ 204,906
International	7,903	1,810	—
Total net revenues	$ 248,017	$ 217,043	$ 204,906

Revenue of $1,312 was recognized in the year ended June 30, 2019 that was deferred as of June 30, 2018. As of June 30, 2019 and June 30, 2018, the Company had a liability of $1,958 and $1,398, respectively, related to estimates of variable consideration which are recorded within accounts payable on the consolidated balance sheet.

4. Debt

Revolving Credit Facility

On March 31, 2017, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank ("SVB"). The Loan Agreement provides for a senior, secured revolving credit facility (the "Revolver") of $40,000 (the "Maximum Dollar Amount").

Advances under the Revolver may be made from time to time up to the Maximum Dollar Amount, subject to certain borrowing limitations. The Revolver has a maturity date of March 31, 2020 and bears interest at a floating per annum rate equal to the Wall Street Journal prime rate, less 0.25%. Interest on borrowings is due monthly and the principal balance is due at maturity. Borrowings up to $10,000 are available on a non-formula basis. Borrowings above $10,000 are based on (i) 85% of eligible domestic accounts receivable, and (ii) the lesser of 50% of eligible inventory or $5,000, subject to adjustment as defined in the Loan Agreement. Upon the Revolver's maturity, any outstanding principal balance, unpaid accrued interest, and all other obligations under the Revolver will be due and payable. The Company will incur a fee equal to 1% of the Maximum Dollar Amount upon termination of the Loan Agreement or the Revolver for any reason prior to the maturity date, unless refinanced with SVB.

The Company's obligations under the Loan Agreement are secured by certain of the Company's assets, including, among other things, accounts receivable, deposit accounts, inventory, equipment, general intangibles and records pertaining to the foregoing. The collateral does not include the Company's intellectual property, but the Company has agreed not to encumber its intellectual property without the consent of SVB. The Loan Agreement contains customary covenants limiting the Company's ability to, among other things, incur debt or liens, make certain investments and loans, enter into transactions with affiliates, undergo certain fundamental changes, dispose of assets, or change the nature of its business. In addition, the Loan Agreement contains financial covenants requiring the Company to maintain, at all times when any amounts are outstanding under the Revolver, either (i) minimum unrestricted cash at SVB and unused availability on the Revolver of at least $10,000 or (ii) minimum trailing three-month Adjusted EBITDA of $1,000. If the Company does not comply with the various covenants under the Loan Agreement, the interest rate on outstanding amounts will increase by 5% and SVB may, subject to various customary cure rights, decline to provide additional advances under the Revolver, require the immediate payment of all amounts outstanding under the Revolver, and foreclose on all collateral.

Under the Loan Agreement, the Company paid SVB a non-refundable commitment fee of $80, which is being amortized to interest expense over the term of the Loan Agreement. The Company is required to pay a fee equal to 0.35% per annum on the unused portion of the Revolver, payable quarterly in arrears. SVB's obligations to advance funds under the Revolver are subject

to an initial collateral examination to be completed within 90 days of the effective date of the Loan Agreement. The Company is not obligated to draw any funds under the Revolver and no amounts were outstanding as of June 30, 2019 and 2018.

Financing Obligation

In connection with the sale of the Facility, the Company entered into a Lease Agreement to lease the Facility. The Lease Agreement has an initial term of 15 years, with four consecutive renewal options of 5 years each at the Company's option, with a base annual rent in the first year of $1,638 and annual escalations of 3% thereafter. Rent during subsequent renewal terms will be at the then fair market rental rate. The effective interest rate is 7.89%.

Future payments under the initial term of the Lease Agreement as of June 30, 2019 are as follows:

2020	$ 1,750
2021	1,803
2022	1,857
2023	1,913
2024	1,970
Thereafter	17,405
	$ 26,698

5. Marketable Securities & Fair Value Measurements

The Company's marketable securities at June 30, 2019 and 2018 are classified on the consolidated balance sheet as follows:

	June 30,	
	2019	2018
Short-term available-for-sale debt securities	$ 38,193	$ —
Long-term available-for-sale debt securities	9,832	—
Available-for-sale debt securities	48,025	—
Mutual funds	410	544
Total marketable securities	$ 48,435	$ 544

Effective July 1, 2018 the Company adopted the provisions of ASU 2016-01. Upon adoption, the Company recorded a cumulative-effect reclassification adjustment of $101 from accumulated other comprehensive income to the opening balance of retained earnings as of July 1, 2018. Unrealized gains and losses of marketable securities in equity investments, denoted as mutual funds, previously recognized in other comprehensive income, will now be recognized in net income as a component of other income.

Available-for-sale debt securities at June 30, 2019 are invested in the following financial instruments:

	As of June 30, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 14,277	$ —	$ —	$ 14,277
Corporate debt	26,466	64	—	26,530
Asset backed securities	7,204	14	—	7,218
Total available-for-sale debt securities	$ 47,947	$ 78	$ —	$ 48,025

The Company did not hold any available-for-sale debt securities at June 30, 2018. There were no other-than-temporary impairments during the years ended June 30, 2019 and 2018. During the year ended June 30, 2018 there was a realized gain of $34 that was recorded within interest income and other, net on the consolidated statement of operations associated with the mutual funds, prior to the adoption of ASU 2016-01.

The Company's marketable securities are measured at fair value on a recurring basis. The following tables set forth the Company's marketable securities measured at fair value by level within the fair value hierarchy as of June 30, 2019 and 2018:

		Fair Value Measurements as of June 30, 2019 Using Inputs Considered as		
	Fair Value	Level 1	Level 2	Level 3
Commercial paper	$ 14,277	—	14,277	$ —
Corporate debt	$ 26,530	—	26,530	$ —
Asset backed securities	$ 7,218	—	7,218	$ —
Mutual funds	$ 410	121	289	$ —
Total marketable securities	$ 48,435	121	48,314	$ —

		Fair Value Measurements as of June 30, 2018 Using Inputs Considered as		
	Fair Value	Level 1	Level 2	Level 3
Mutual funds	$ 544	199	345	$ —
Total marketable securities	$ 544	199	345	$ —

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy during the year ended June 30, 2019. Any transfers between levels are recognized on the date of the event or when a change in circumstances causes a transfer.

Non-Marketable Equity Investment

The Company holds an equity investment that does not have a readily determined fair value. The Company has elected to measure this investment at cost minus impairment, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. Impairment is reviewed each reporting period by performing a qualitative assessment considering impairment indicators to evaluate whether the investment is impaired. As of June 30, 2019 and 2018, the carrying value of the investment was $5,593 and $2,538, respectively. During the year ended June 30, 2019, no observable price changes or impairment indicators were noted. The investment is recorded within other long term assets on the consolidated balance sheet.

6. Stock-Based Compensation

On November 15, 2017, the Company's stockholders approved the 2017 Equity Incentive Plan (the "2017 Plan") for the purpose of granting equity awards to employees, directors, and consultants. The 2017 Plan replaced the 2014 Equity Incentive Plan (the "2014 Plan"), and no further equity awards may be granted under the 2014 Plan or the 2007 Equity Incentive Plan (the "2007 Plan") (the 2017 Plan, 2014 Plan and the 2007 Plan are collectively referred to as the "Plans").

The 2017 Plan allows for the granting of up to 3,607,523 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. As of June 30, 2019, there were 2,085,025 shares available for grant under the 2017 Plan.

Equity awards classified as restricted stock and performance-based restricted stock are treated as issued shares when granted; however, these shares are not included in the computation of basic weighted average shares outstanding. When shares vest, unless the holder elects to pay the payroll tax liability in cash or through a sale of shares, the Company withholds the appropriate amount of shares to settle the payroll tax liability, on behalf of the individual receiving the shares, as an adjustment to accumulated deficit.

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.

Stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price
Options outstanding at June 30, 2016	606,879	$ 10.14
Exercised	(519,297)	$ 10.33
Forfeited or expired	(9,381)	$ 8.83
Options outstanding at June 30, 2017	78,201	$ 9.07
Exercised	(55,880)	$ 9.20
Options outstanding at June 30, 2018	22,321	$ 8.75
Exercised	(22,321)	$ 8.75
Options outstanding at June 30, 2019	—	$ —

As of June 30, 2019, no options are outstanding. 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, 2019, 2018 or 2017.

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, 2019, 2018 and 2017, was $0, $527 and $1,811, respectively. The total aggregate intrinsic value of options exercised during the years ended June 30, 2019, 2018 and 2017, was $553, $1,095, and $7,955, respectively. Shares supporting option exercises are sourced from new share issuances.

Restricted Stock

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 time based restricted stock awards ranges from one year 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.

Restricted stock award activity is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at June 30, 2016	647,573	$ 23.24
Granted	258,346	$ 21.80
Forfeited	(103,140)	$ 22.11
Vested	(316,195)	$ 24.21
Outstanding at June 30, 2017	486,584	$ 21.26
Granted	290,856	$ 27.93
Forfeited	(68,499)	$ 22.76
Vested	(253,725)	$ 22.87
Outstanding at June 30, 2018	455,216	$ 24.77
Granted	262,727	$ 35.53
Forfeited	(27,143)	$ 29.05
Vested	(215,855)	$ 23.23
Outstanding at June 30, 2019	474,945	$ 31.36

Estimated pre-vesting forfeitures are considered in determining stock-based compensation expense. As of June 30, 2019, 2018 and 2017, the Company estimated its weighted average forfeiture rate at 18.0%, 15.2% and 17.1%, respectively. As of June 30, 2019, there was approximately $11,016 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 1.6 years.

Performance-Based Restricted Stock

The Company also grants performance-based restricted stock awards to certain executives and other management. Fiscal 2019 awards vest based on the Company's total shareholder return relative to total shareholder return of the peer group (a market condition), as measured by the closing prices of the stock of the Company and its peer group for the 90 trading days preceding July 1, 2018 compared to the closing prices for the 90 trading days preceding July 1, 2021. Fiscal 2018 awards vest based on the Company's total shareholder return relative to total shareholder return of the peer group (a market condition), as measured by the closing prices of the stock of the Company and its peer group for the 90 trading days preceding July 1, 2017 compared to the closing prices for the 90 trading days preceding July 1, 2020. Fiscal 2017 awards vest based on the Company's total shareholder return relative to total shareholder return of the peer group (a market condition), as measured by the closing prices of the stock of the Company and its peer group for the 90 trading days preceding July 1, 2016 compared to the closing prices for the 90 trading days preceding July 1, 2019. The aggregate maximum shares granted were as follows:

Performance Measurement	2019	2018	2017
Total shareholder return	225,325	278,889	336,826

Performance-based restricted stock award activity is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at June 30, 2016	310,111	$ 16.67
Granted	336,826	$ 11.97
Forfeited	(328,353)	$ 16.41
Outstanding at June 30, 2017	318,584	$ 11.97
Granted	278,889	$ 13.63
Forfeited	(66,295)	$ 13.17
Outstanding at June 30, 2018	531,178	$ 12.69
Granted	225,325	$ 22.33
Forfeited	(2,631)	$ 18.64
Outstanding at June 30, 2019	753,872	$ 15.20

Estimated pre-vesting forfeitures are considered in determining stock-based compensation expense. As of June 30, 2019, there was approximately $4,078 of total unrecognized compensation expense related to nonvested performance-based restricted stock awards, which is expected to be recognized over a weighted-average period of 1.8 years. Stock-based compensation expense associated with performance-based restricted stock was $3,497 for the year ended June 30, 2019.

Restricted Stock Units

The Company grants restricted stock units to members of its 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 occur within 30 days following the six month anniversary of the date that the director ceases to serve on the Board of Directors 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 units 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, 2016	304,816	$ 13.95
Granted	54,064	$ 21.21
Converted to common stock	(6,476)	$ 29.34
Forfeited	(2,974)	$ 21.01
Restricted stock units outstanding at June 30, 2017	349,430	$ 14.73
Granted	28,364	$ 31.02
Converted to common stock	(41,925)	$ 16.07
Restricted stock units outstanding at June 30, 2018	335,869	$ 15.94
Granted	21,162	$ 38.28
Converted to common stock	(2,855)	$ 21.01
Restricted stock units outstanding at June 30, 2019	354,176	$ 17.23

Employee Stock Purchase Plan

The Company maintains an employee stock purchase plan that was approved by the Company's stockholders in November 2015 ("2015 ESPP") and replaced the previous employee stock purchase plan that expired on May 31, 2016. The 2015 ESPP 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 155,394 shares at an average price of $24.14 per share during the year ended June 30, 2019. Shares reserved under the 2015 ESPP at June 30, 2019 totaled 1,530,037.

Stock-Based Compensation Expense

The following amounts were recognized as stock-based compensation expense in the consolidated statements of operations:

Year Ended June 30, 2019	Restricted Stock Awards	Restricted Stock Units	Employee Stock Purchase Plan	Total
Cost of goods sold	$ 281	$ —	$ 65	$ 346
Selling, general and administrative	7,899	810	905	9,614
Research and development	1,136	—	170	1,306
Total stock-based compensation expense	$ 9,316	$ 810	$ 1,140	$ 11,266

Year Ended June 30, 2018	Restricted Stock Awards	Restricted Stock Units	Employee Stock Purchase Plan	Total
Cost of goods sold	$ 207	$ —	$ 68	$ 275
Selling, general and administrative	7,462	750	848	9,060
Research and development	817	—	150	967
Total stock-based compensation expense	$ 8,486	$ 750	$ 1,066	$ 10,302

Year Ended June 30, 2017	Restricted Stock Awards	Restricted Stock Units	Employee Stock Purchase Plan	Total
Cost of goods sold	$ 588	$ —	$ 101	$ 689
Selling, general and administrative	6,568	1,024	1,065	8,657
Research and development	879	—	129	1,008
Total stock-based compensation expense	$ 8,035	$ 1,024	$ 1,295	$ 10,354

7. Income Taxes

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

	June 30,	
	2019	2018

Deferred tax assets		
Stock-based compensation	$ 3,803	$ 2,505
Deferred revenue	2,032	2,351
Accrued expenses and compensation	1,058	1,103
Other	1,062	1,022
Research and development credit carryforwards	5,161	5,048
Net operating loss carryforwards	65,628	64,101
Total deferred tax assets	78,744	76,130
Valuation allowance	(78,744)	(76,130)
Net deferred tax assets	$ —	$ —

On December 22, 2017, the United States enacted tax reform legislation commonly known as the Tax Cuts and Jobs Act (the "Act"), resulting in significant modifications to existing law. Accounting for the income tax effects of the Act which impacted the Company's tax provision has been completed as of the current year and included in the Company's financial statements as of June 30, 2018. As a result of the Act, the Company remeasured deferred tax assets and liabilities from 34% to 21%, but given the Company is in a full valuation allowance position, there was no tax expense impact.

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:

Balances at June 30, 2016	$	101,217
Reductions		(186)
Balance at June 30, 2017		101,031
Reductions		(24,901)
Balance at June 30, 2018		76,130
Additions		2,614
Balance at June 30, 2019	$	78,744

As of June 30, 2019 and 2018, the Company had federal tax net operating loss carryforwards of approximately $269,433 and $275,030, respectively. These net operating loss carryforwards are available to offset taxable income through 2037. The Company also had various state net operating loss carryforwards available to offset future state taxable income. These state net operating loss carryforwards typically have the same expirations as the Company's federal tax net operating loss carryforwards.

As of June 30, 2019 and 2018, the Company had approximately $4,314 and $4,244 of federal research and development credit carryforwards, respectively. As of June 30, 2019 and 2018, the Company had approximately $1,798 and $1,560 of state research and development credit carryforwards. The federal and state research and development credit carryforwards will expire through fiscal 2038 and 2033, 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 $611 and $597 at June 30, 2019 and 2018, 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 Company has not currently reserved for any interest or penalties for such reserves due to the Company being in an net operating loss 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:

Balances at June 30, 2016	$	545
Decreases related to prior year tax positions		(8)
Increases related to current year tax positions		33
Balances at June 30, 2017		570
Decreases related to prior year tax positions		(3)
Increases related to current year tax positions		30
Balance at June 30, 2018		597
Decreases related to prior year tax positions		(11)
Increases related to current year tax positions		25
Balance at June 30, 2019	$	611

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, 2019, 2018, 2017, and 2016. The Company is not currently under examination by any taxing jurisdiction.

8. Commitments and Contingencies

Operating Leases

The Company leases manufacturing space and equipment under lease agreements that expire at various dates through April 2024. Rental expenses were $540, $652, and $656, for the years ended June 30, 2019, 2018, and 2017, respectively.

Future minimum lease payments under the agreements as of June 30, 2019 are as follows:

2020	$ 392
2021	36
2022	8
2023	3
2024	2
Thereafter	—
	$ 441

Other Matters

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, 2019 that are probable or estimable, for which the outcome is reasonably possible of having a material adverse impact on its consolidated balance sheets or statements of operations.

9. Employee Benefits

The Company offers a 401(k) plan to its employees. Eligible employees may authorize up to $19 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, 2019, 2018, and 2017.

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. 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, 2019, $82 of the amount is included in accrued expenses and $328 is included in other liabilities on the consolidated balance sheet.

10. 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,		
	2019	2018	2017
Numerator			
Net income (loss)	$ (255)	$ 1,712	$ (1,792)
Income allocated to participating securities	—	(19)	—
Net income (loss) available to common stockholders	$ (255)	$ 1,693	$ (1,792)
Denominator			
Weighted average common shares outstanding — basic	33,535,759	33,145,140	32,373,709
Effect of dilutive stock options[1]	—	15,039	—
Effect of dilutive restricted stock units[2]	—	335,869	—
Effect of performance-based restricted stock awards [3]	—	118,212	—
Weighted average common shares outstanding — diluted	33,535,759	33,614,260	32,373,709
Earnings per common share — basic	$ (0.01)	$ 0.05	$ (0.06)
Earnings per common share — diluted	$ (0.01)	$ 0.05	$ (0.06)

(1) At June 30, 2018, and 2017; 22,321, and 78,201 stock options, respectively, were outstanding. 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 as of June 30, 2019, and 2017, because those shares are anti-dilutive. No stock options were outstanding at June 30, 2019.

(2) At June 30, 2019, 2018, and 2017; 354,176, 335,869 and 349,430 additional shares of common stock, respectively, were issuable upon the settlement of outstanding restricted stock units. The effect of the shares that would be issued upon settlement of these restricted stock units has been excluded from the calculation of diluted loss per share as of June 30, 2019, and 2017, because those shares are anti-dilutive.

(3) At June 30, 2019, 2018, and 2017; 753,872, 531,178, and 318,584 respectively, of performance-based restricted stock awards were outstanding. The effect of the shares that would be issued upon vesting of these awards has been excluded from the calculation of diluted loss per share as of June 30, 2019, and 2017, because those shares are anti-dilutive.

Unvested time-based restricted stock awards that contain nonforfeitable rights to dividends are participating securities and included in the computation of earnings per share pursuant to the two-class method. Under this method, earnings attributable to the Company are allocated between common stockholders and the participating awards, as if the awards were a second class of stock. During periods of net income, the calculation of earnings per share excludes the income attributable to participating

securities in the numerator and the dilutive impact of these securities from the denominator. In the event of a net loss, undistributed earnings are not allocated to participating securities and the denominator excludes the dilutive impact of these securities as they do not share in the losses of the Company. During the year ended June 30, 2018, undistributed earnings allocated to participating securities were based on 382,476 unvested time-based restricted stock awards.

11. 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, 2019 and 2018. 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).

	2019				
	Q1	Q2	Q3	Q4	Year Total
Net revenue	$ 56,266	$ 60,206	$ 63,311	$ 68,234	$ 248,017
Gross profit	$ 45,691	$ 48,729	$ 51,145	$ 54,772	$ 200,337
Net income (loss)	$ (2,888)	$ 492	$ 672	$ 1,469	$ (255)
Earnings per common share - basic[(1)]	$ (0.09)	$ 0.01	$ 0.02	$ 0.04	$ (0.01)
Earnings per common share - diluted[(1)]	$ (0.09)	$ 0.01	$ 0.02	$ 0.04	$ (0.01)

	2018				
	Q1	Q2	Q3	Q4	Year Total
Net revenue	$ 49,676	$ 52,628	$ 55,587	$ 59,152	$ 217,043
Gross profit	$ 40,474	$ 43,129	$ 45,618	$ 48,338	$ 177,559
Net income (loss)	$ (1,977)	$ (413)	$ 365	$ 3,737	$ 1,712
Earnings per common share - basic[(1)]	$ (0.06)	$ (0.01)	$ 0.01	$ 0.11	$ 0.05
Earnings per common share - diluted[(1)]	$ (0.06)	$ (0.01)	$ 0.01	$ 0.11	$ 0.05

(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 our 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 our 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, 2019. 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, our 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 us. 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 our internal control over financial reporting was effective as of June 30, 2019.

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 effectiveness of our internal control over financial reporting as of June 30, 2019, as stated in their 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, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. ***Other Information.***

None

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance.***

Other than the information included in this Form 10-K under the heading "Employees—Information About our Executive Officers," which is set forth at the end of Item 1 and incorporated herein by reference, 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 2019 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 2019 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 2019 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 2019 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 2019 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, 2019 and 2018
- Consolidated Statements of Operations for the years ended June 30, 2019, 2018 and 2017
- Consolidated Statements of Comprehensive Income for the years ended June 30, 2019, 2018 and 2017
- Consolidated Statements of Changes in Stockholders' Equity for the years ended June 30, 2019, 2018 and 2017
- Consolidated Statements of Cash Flows for the years ended June 30, 2019, 2018 and 2017
- 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.

Exhibit No.	Description
3.1	Restated Certificate of Incorporation, as amended (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 14, 2009).
3.2	Amended and Restated Bylaws (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 May 21, 2015).
4.1	Specimen Common Stock Certificate (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 3, 2009).
4.2	Registration Rights Agreement by and among Cardiovascular Systems, Inc. and certain of its stockholders, dated as of March 16, 2009 (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).
4.3*	Description of Capital Stock.
10.1†	Form of Standard Employment Agreement (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, filed January 22, 2008).
10.2†*	Fiscal 2020 Executive Officer Bonus Plan and Equity Compensation.
10.3†*	Fiscal Year 2020 Director Compensation Arrangements.
10.4†	Form of Director and Officer Indemnification Agreement (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 14, 2009).
10.5	Build-To-Suit Lease Agreement between Pearland Economic Development Corporation and Cardiovascular Systems, Inc., dated September 9, 2009 (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, 2009).
10.6	First Amendment of Lease, between Pearland Economic Development Corporation and Cardiovascular Systems, Inc., dated November 10, 2017 (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, 2018).
10.7+	Supply Agreement, between Cardiovascular Systems, Inc. and Fresenius Kabi AB, effective April 4, 2011 (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 13, 2011).
10.8†	Cardiovascular Systems, Inc. Deferred Compensation Plan (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).
10.9†	Cardiovascular Systems, Inc. 2014 Equity Incentive Plan, as amended (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 27, 2015).
10.10†	Form of Restricted Stock Agreement for Time-Based Awards under the 2014 Equity Incentive Plan (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 6, 2015).

10.11†	Form of Restricted Stock Agreement for Performance-Based Awards under the 2014 Equity Incentive Plan (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 6, 2015).
10.12†	Cardiovascular Systems, Inc. Executive Officer Severance Plan (restated August 22, 2018).
10.13†	Form of Restricted Stock Unit Agreement under the 2014 Equity Incentive Plan (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).
10.14†	Form of Restricted Stock Agreement under the 2014 Equity Incentive Plan (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).
10.15†	Cardiovascular Systems, Inc. 2015 Employee Stock Purchase Plan (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 19, 2015).
10.16	Amendment No. 1 to Supply Agreement, between Cardiovascular Systems, Inc. and Fresenius Kabi AB, effective March 17, 2016 (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 6, 2016).
10.17+	Amendment No. 1 to Product Schedule, between Cardiovascular Systems, Inc. and Fresenius Kabi AB, effective March 27, 2016 (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 6, 2016).
10.18	Settlement Agreement, among Cardiovascular Systems, Inc., the United States of America acting through the United States Attorney for the Western District of North Carolina and on behalf of the Office of Inspector General of the Department of Health and Human Services, and Travis Thams, dated June 28, 2016 (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 June 28, 2016).
10.19	Corporate Integrity Agreement, between Cardiovascular Systems, Inc. and the Office of Inspector General of the Department of Health and Human Services, dated June 28, 2016 (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 June 28, 2016).
10.20†	Form of Performance Unit Award (Cash Settled) under the 2014 Equity Incentive Plan (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 24, 2017).
10.21†	Form of Restricted Stock Agreement for Performance-Based Awards (3-year cliff vesting) under the 2014 Equity Incentive Plan (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 25, 2016).
10.22†	Employment Agreement, dated August 15, 2016, by and between Cardiovascular Systems Inc. and Scott R. Ward (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 25, 2016).
10.23	Lease Agreement, by and between Cardiovascular Systems, Inc. and Krishna Holdings, LLC, Apex Holdings, LLC, Kashi Associates, LLC, Keva Holdings, LLC, S&V Ventures, LLC, Polo Group LLC, SPAV Holdings LLC, Star Associates LLC, and The Global Villa, LLC, dated March 30, 2017 (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 5, 2017).
10.24	Loan and Security Agreement, by and between Cardiovascular Systems, Inc. and Silicon Valley Bank, dated March 31, 2017 (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 5, 2017).
10.25†	Cardiovascular Systems, Inc. 2017 Equity Incentive Plan (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 November 17, 2017).
10.26†	Form of Board Restricted Stock Award Agreement (in lieu of cash retainer) under 2017 Equity Incentive Plan (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 November 17, 2017).
10.27†	Form of Board RSU Agreement (annual) under 2017 Equity Incentive Plan (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 November 17, 2017).
10.28†	Form of Board RSU Agreement (in lieu of cash retainer) under 2017 Equity Incentive Plan (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 November 17, 2017).
10.29†	Form of Performance Unit Agreement (cash settled) under 2017 Equity Incentive Plan (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 November 17, 2017).
10.30†	Form of Performance-Vest Restricted Stock Award Agreement under 2017 Equity Incentive Plan (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 November 17, 2017).

10.31†	Form of Time-Vest Restricted Stock Award Agreement under 2017 Equity Incentive Plan (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 November 17, 2017).
10.32†	Offer Letter and Employment Agreement, dated January 12, 2018, by and between the Company and Rhonda Robb (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 4, 2018).
10.33†	Offer Letter and Employment Agreement, dated February 7, 2018, by and between the Company and Jeff Points (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 4, 2018).
10.34+	Purchasing Agreement, effective May 1, 2018, between Cardiovascular Systems, Inc. and Healthtrust Purchasing Group, L.P. (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 4, 2018).
10.35	Second Amendment of Lease, between Pearland Economic Development Corporation and Cardiovascular Systems, Inc., dated April 9, 2018
10.36†	Separation Agreement, dated August 15, 2018, by and between the Company and Laurence L. Betterley
10.37†	Consulting Agreement, dated August 16, 2018, by and between the Company and Laurence L. Betterley
10.38	Third Amendment of Lease, between Pearland Economic Development Corporation and Cardiovascular Systems, Inc., dated August 30, 2018
10.39†	Transition Agreement, dated January 9, 2019, by and between the Company and Laura J. Gillund.
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, 2019, formatted, in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Income, (iv) the Consolidated Statements of Changes in Stockholders' Equity, (v) the Consolidated Statements of Cash Flows, and (vi) the Notes to Consolidated 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.

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 22, 2019

By: /s/ Scott R. Ward
Scott R. Ward
Chairman, 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 Scott R. Ward and Jeffrey S. Points 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/ Scott R. Ward Scott R. Ward	Chairman, President and Chief Executive Officer (principal executive officer)	August 22, 2019
/s/ Jeffrey S. Points Jeffrey S. Points	Chief Financial Officer (principal financial and accounting officer)	August 22, 2019
/s/ Martha Goldberg Aronson Martha Goldberg Aronson	Director	August 22, 2019
/s/ Brent G. Blackey Brent G. Blackey	Director	August 22, 2019
/s/ Edward Brown Edward Brown	Director	August 22, 2019
/s/ William E. Cohn William E. Cohn	Director	August 22, 2019
/s/ Augustine Lawlor Augustine Lawlor	Director	August 22, 2019
/s/ Erik Paulsen Erik Paulsen	Director	August 22, 2019

Exhibit 4.3

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of June 30, 2019, Cardiovascular Systems, Inc. (the "Company") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): Common Stock.

Description of Common Stock

The following description of the Company's Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to the Company's Restated Certificate of Incorporation and Amended and Restated Bylaws, each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K to which this description is also an exhibit.

Authorized Capital Stock

The Company's Restated Certificate of Incorporation authorizes the Company to issue 100,000,000 shares of common stock, par value $0.001 per share (the "Common Stock") and 5,000,000 shares of preferred stock, par value $0.001 per share (the "Preferred Stock"). The outstanding shares of Common Stock are fully paid and nonassessable.

Voting Rights

The holders of Common Stock are entitled to one vote for each share on all matters voted on by Company stockholders, including elections of directors, and, except as otherwise required by law or provided in any resolution adopted by the Company's Board of Directors with respect to any series of Preferred Stock, the holders of such shares possess all voting power.

The Company has a classified Board of Directors, with three separate classes of directors each serving a three-year term. The Company's Restated Certificate of Incorporation does not provide for cumulative voting in the election of directors.

Dividend Rights

Subject to the rights of holders of outstanding shares of Preferred Stock, if any, the holders of Common Stock are entitled to receive dividends, if any, as may be declared from time to time by the Company's Board of Directors in its discretion out of funds legally available for the payment of dividends. No cash dividends have been previously paid on the Common Stock.

Liquidation Rights

Subject to any preferential rights of outstanding shares of Preferred Stock, holders of Common Stock will share ratably in all assets legally available for distribution to the Company's stockholders in the event of dissolution.

Other Rights and Preferences

The Common Stock has no sinking fund or redemption provisions or preemptive, conversion or exchange rights.

The rights, preferences and privileges of holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of Preferred Stock that the Company's Board of Directors may designate and issue in the future.

Transfer Agent and Registrar

The transfer agent and registrar for the Common Stock is Broadridge Corporate Issuer Solutions, Inc.

Listing

The Common Stock is listed on the Nasdaq Global Select Market under the symbol "CSII."

Anti-Takeover Effect of Delaware Law and Certain Charter and Bylaw Provisions

The Company's Restated Certificate of Incorporation and Amended and Restated Bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control of the Company. These provisions are as follows:

- special meetings of stockholders may be called only by the Chairman of the Board, the Chief Executive Officer, or by a majority of the Board of Directors;
- the Board of Directors is a classified board, with three separate classes of directors each serving a three-year term;
- only business brought before an annual meeting by the Board of Directors or by a stockholder who complies with the procedures set forth in the Amended and Restated Bylaws may be transacted at an annual meeting of stockholders;
- advance notice is required for specified stockholder actions, such as the nomination of directors and stockholder proposals; and
- the Company may issue, without stockholder approval, up to 5,000,000 shares of preferred stock that could adversely affect the rights and powers of the holders of our common stock.

The Company is subject to the provisions of Section 203 of the General Corporation Law of the State of Delaware, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a "business combination" includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an "interested stockholder" is a person who owns 15% or more of the voting stock of a corporation, or any affiliate or associate of a corporation who, within three years prior, did own 15% or more of the voting stock of that corporation.

Exhibit 10.2

FISCAL 2020 EXECUTIVE OFFICER BONUS PLAN AND EQUITY COMPENSATION

Bonus Plan

For the 12-month period ending June 30, 2020, each executive officer of Cardiovascular Systems, Inc. (the "Company") is eligible to receive cash incentive compensation pursuant to the Fiscal 2020 Executive Officer Bonus Plan (the "Bonus Plan"), based on the Company's achievement of revenue and Adjusted EBITDA financial goals for such period. Adjusted EBITDA is defined as EBITDA with stock compensation added back into the calculation. In addition, Adjusted EBITDA may be further adjusted by the Human Resources and Compensation Committee to include or exclude the events set forth in Section 7(b) of the Company's 2017 Equity Incentive Plan and other unforeseen expenses. Target bonus amounts are weighted 75% for the revenue goal and 25% for the Adjusted EBITDA goal. Target bonus levels as a percentage of base salary are 115% for the Chief Executive Officer, 100% for the Chief Operating Officer, 75% for the Chief Financial Officer and General Counsel, and 50% for the other executive officers. Depending upon the Company's performance against the goals, participants are eligible to earn up 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.

Long-Term Incentive Plan

Each executive officer of the Company received grants of restricted stock under the fiscal 2020 long-term incentive plan on August 9, 2019. The restricted stock grants were based on a target equity percentage of each executive officer's base salary, with 40% of such target amount allocated to time-vesting restricted stock and 60% of such target amount allocated to performance-vesting restricted stock; provided, that the performance-vesting restricted stock was granted to each executive officer at 200% of the target number of shares allocated to performance-vesting restricted stock, and any shares not earned will be forfeited upon confirmation of performance achievement. Target equity grants as a percentage of base salary are 450% for the Chief Executive Officer, 200% for the Chief Operating Officer, 150% for the Chief Financial Officer, and 125% for the other named executive officers.

The time-vesting restricted stock grants will vest in equal installments of 1/3 in August 2020, 2021 and 2022. The performance-vesting restricted stock grants will vest based on the Company's total shareholder return relative to total shareholder return of the Company's peer group (as determined by the Human Resources and Compensation Committee), as measured by the closing prices of the Company's stock and the stock of the peer group members for the 90 trading days preceding July 1, 2019 compared to the closing prices of the Company's stock and the stock of the peer group members for the 90 trading days preceding July 1, 2022. Vesting of the performance-vesting shares will be determined on the date that the Company's Form 10-K for the fiscal year ending June 30, 2022 is filed.

Exhibit 10.3

FISCAL 2020 DIRECTOR COMPENSATION ARRANGEMENTS

For the 12 month period ending June 30, 2020, each non-employee director of Cardiovascular Systems, Inc. will receive the following compensation:

- Retainers of $45,000 for service as a Board member; $22,000 for service as the chair of the Audit committee; $20,000 for service as a chair of a Board committee other than the Audit committee; $10,000 for service as a member of a Board committee; and $1,200 per Board or committee meeting attended in the event that more than 12 of such meetings are held during the period. Directors may irrevocably elect, in advance of the fiscal year, to receive these fees in cash, in common stock of the Company or a combination thereof, or in restricted stock units ("RSUs"). Each director electing to receive fees in RSUs shall at the time of such election also irrevocably select the date of settlement of the RSU. On the settlement date, RSUs may be settled, at the Company's discretion, in cash or in shares of common stock or a combination thereof.

- An RSU award with a value of $145,000 payable, in the Company's discretion, in cash or in shares of common stock. The Company will provide for the RSU payment, whether paid in cash or shares of common stock, to be made (in a lump sum if paid in cash) within 30 days following the six-month anniversary of the termination of the director's Board membership.

In addition, the Lead Independent Director of the Board receives an additional annual retainer of $40,000, and may irrevocably elect, in advance of the fiscal year, to receive this retainer in cash, in common stock of the Company or a combination thereof, or in RSUs. The non-employee members of the Board are also reimbursed for travel, lodging and other reasonable expenses incurred in attending Board or committee meetings.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-228686) and S-8 (No. 333-158755, 333-160609, 333-168682, 333-175703, 333-182668, 333-189856, 333-197348, 333-200214, 333-208137, and 333-221651) of Cardiovascular Systems, Inc. of our report dated August 22, 2019 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Minneapolis, Minnesota

August 22, 2019

Exhibit 31.1

CERTIFICATION UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott R. Ward, certify that:

1. I have reviewed this annual report on Form 10-K of Cardiovascular Systems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 22, 2019

/s/ Scott R. Ward

Scott R. Ward
Chairman, President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey S. Points, certify that:

1. I have reviewed this annual report on Form 10-K of Cardiovascular Systems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 22, 2019

/s/ Jeffrey S. Points

Jeffrey S. Points
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing of the Annual Report on Form 10-K for the year ended June 30, 2019 (the "Report") by Cardiovascular Systems, Inc. ("Registrant"), I, Scott R. Ward, the Chief Executive Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Dated: August 22, 2019

/s/ Scott R. Ward

Scott R. Ward
Chairman, President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing of the Annual Report on Form 10-K for the year ended June 30, 2019 (the "Report") by Cardiovascular Systems, Inc. ("Registrant"), I, Jeffrey S. Points, the Chief Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Dated: August 22, 2019

By: /s/ Jeffrey S. Points
Jeffrey S. Points
Chief Financial Officer