

**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 December 31, 2019

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Transition Period From _____ to _____
Commission file number: 001-38677

Ra Medical Systems, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2070 Las Palmas Drive
Carlsbad, California
(Address of principal executive offices)

38-3661826
(I.R.S. Employer
Identification No.)

92011
(Zip Code)

(760) 804-1648

(Registrant's telephone number, including area code)

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

Title of each class
Common Stock, \$0.0001 par value

Trading Symbol
RMED

Name of the exchange on which registered
New York Stock Exchange

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 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, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|-------------------------|-------------------------------------|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| | | Emerging growth company | <input checked="" type="checkbox"/> |

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

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of a share of common stock on June 30, 2019 as reported by the New York Stock Exchange on such date was approximately \$29.8 million. Shares of the registrant's common stock held by each executive officer, director and other persons who may be deemed an affiliate of the registrant have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 6, 2020, the registrant has 13,770,349 shares of common stock, par value \$0.0001, outstanding.

RA MEDICAL SYSTEMS, INC.

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PART I

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available. This section should be read in conjunction with our audited financial statements and related notes included in Part II, Item 8 of this report. The statements contained in this Annual Report on Form 10-K that are not historical facts are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended.

Forward-looking statements can be identified by words such as "believe," "anticipate," "may," "might," "can," "could," "continue," "depends," "expect," "expand," "forecast," "intend," "predict," "plan," "rely," "should," "will," "may," "seek," or the negative of these terms and other similar expressions, although not all forward-looking statements contain these words. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including, but not limited to, those described in "Risk Factors." These forward-looking statements reflect our beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report on Form 10-K and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled "Risk Factors" included in Part I, Item 1A and elsewhere in this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We qualify all of the forward-looking statements in this Annual Report on Form 10-K by these cautionary statements. 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 any forward-looking statements, whether as a result of new information, future events or otherwise.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources.

ITEM 1.**BUSINESS****Overview**

Ra Medical Systems, Inc. (“we,” “us” or “our”) is a commercial-stage medical device company leveraging our advanced excimer laser-based platform for use in the treatment of vascular and dermatological immune-mediated inflammatory diseases. We believe our products enhance patients’ quality of life by restoring blood-flow in arteries and clearing chronic skin conditions. The DABRA laser system and single-use catheter, together referred to as DABRA, is cleared by the U.S. Food and Drug Administration, or FDA, as a device for crossing chronic total occlusions, or CTOs, in patients with symptomatic infrainguinal lower extremity vascular disease and with an intended use for ablating a channel in occlusive peripheral vascular disease. DABRA is used as a tool in the treatment of peripheral artery disease, or PAD, a form of peripheral vascular disease, which commonly occurs in the legs. We currently are pursuing an atherectomy indication for use, which the FDA currently defines to include a prespecified improvement in luminal patency, or a prespecified increase in the openness of the artery at a pre-defined time point. To satisfy the FDA’s data requirements to support an atherectomy indication, we are performing a pivotal study designed to allow the FDA to evaluate the DABRA atherectomy procedure. We received final Investigational Device Exemption, or IDE, approval in January 2020 and enrolled the first patient in the study in February 2020. DABRA was also granted CE mark approval in Europe in September 2016 for the endovascular treatment of infrainguinal arteries via atherectomy and for crossing total occlusions.

In the fourth quarter of 2018 and into 2019, we experienced inconsistencies in our DABRA catheter performance. After collecting field data and performing internal testing, we observed that while catheters can perform satisfactorily up to one year, catheters that were more than two months from sterilization, had a significantly higher rate of non-calibration than catheters that were within two months from sterilization. As a result, in September 2019, we initiated a voluntary recall of our catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters.

In addition, in the third quarter of 2019, we implemented certain operational efficiency and cost-savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives included targeted workforce reductions of our sales and marketing teams. We reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to five clinical specialists as of December 31, 2019. In the near term, we are focusing on servicing core accounts while we prioritize remedying the inconsistencies in our DABRA catheter performance. We are encouraged by the results, as we have seen significant decreases in the rates of non-calibrations following the voluntary recall.

Our business strategy is focused on continuing to service our core accounts while we complete initiatives that are key to relaunching DABRA to the broader market. Key components of our DABRA relaunch strategy include:

- A longer shelf life;
- A braided overjacket designed to reduce kinking, and that will also allow the physician to apply more pressure when advancing the DABRA catheter;
- A rapid exchange designed to allow physicians to use more standard techniques, including a guidewire, to navigate the vasculature more easily; and
- An atherectomy indication for use.

When these initiatives are at or near completion, we intend to begin expanding our sales force to prepare for a commercial relaunch.

In the future, we may pursue additional uses for DABRA, including seeking regulatory clearance or approval for the use of DABRA as a tool for the treatment of vascular blockages associated with coronary artery disease, or CAD, in-stent restenosis, and other vascular-related indications. However, there can be no assurance that DABRA will receive the necessary clearances for these additional indications. The DABRA laser system is based on the same core technology and utilizes a similar excimer laser as Pharos, a medical device that we have marketed as a tool for the treatment of proliferative skin conditions since October 2004. Pharos is designed for use in the treatment of inflammatory skin conditions and is FDA cleared as a tool used in the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. Because DABRA and Pharos are both based on our core excimer laser technology platform and deploy similar mechanisms of action, we benefit from economies of scale in product development, manufacturing, quality assurance and distribution.

DABRA. DABRA (Destruction of Arteriosclerotic Blockages by laser Radiation Ablation) is our minimally-invasive excimer laser and single-use catheter system that is used by physicians as a tool in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease, a form of PAD, both above- and below-the-knee, by breaking down plaque to its fundamental chemistry, such as proteins, lipids and other chemical compounds, to eliminate blockages by essentially dissolving them without generating potentially harmful particulates. The accumulation of plaque in arteries, which is a result of lower extremity vascular disease, most commonly occurs in the pelvis and legs. Plaque accumulation, known as atherosclerosis, causes the narrowing of arteries, thereby reducing the flow of oxygenated blood to tissue and organs. If vascular blockages are left untreated, they can increase the risk of heart attack, stroke, amputation or death. Major risk factors for PAD include age, smoking, diabetes and obesity. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including CAD, in part because up to half of the PAD population is asymptomatic, or shows no symptoms, and many dismiss symptoms as normal signs of aging. Recent analysis suggests that 17.6 million people in the U.S. However, only 20-30% of PAD patients are actively being treated.

Current treatments for vascular blockages associated with PAD are largely endovascular and include angioplasty, stenting and atherectomy. Bypass surgery, which was frequently used in the past, is costly and often results in complications, including high levels of post-surgery pain and lengthy hospital stays and recovery times. Endovascular treatments employ catheter-based products for the displacement or removal of plaque. These treatments also have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease. We believe one of the main contributing factors to high restenosis, or the re-accumulation of blockages, rates for PAD patients treated with endovascular technologies is the amount of vascular injury that occurs during an intervention. Angioplasty balloons, invented in the 1970's, held a great deal of promise, but the trauma due to their inflation often causes the vessel to reocclude either immediately or over time. Stents, invented in the 1980's, were developed to help keep the arteries open. However, stents can also promote re-occlusion and are susceptible to fractures. Devices that remove plaque, including the excimer laser, invented in the 1990's, were developed to overcome the drawbacks of angioplasty balloons and stents, which merely push the plaque to the side of the vessel. DABRA was designed to remove the plaque with less trauma, which we believe helps to improve patient outcomes when compared to other competing devices.

DABRA is a novel technology for use in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease. We believe that our liquid-filled, full aperture ratio catheter allows for a less traumatic endovascular treatment for the removal of vascular blockages and offers significant benefits over competing treatments and therapies. DABRA is easy to use with proper physician training and can cross and debulk, or reduce or remove, a broad range of plaque types. DABRA is predominantly used as an adjunct therapy with angioplasty balloons, drug-coated balloons, stents, and other endovascular treatments. DABRA employs photoablation, or the removal of body tissue by using photons, to remove blockages by breaking the bonds of the obstructing plaque directly. Unlike many treatments for PAD and other vascular diseases that may damage the arterial wall, DABRA dissolves plaque quickly and with minimal vascular trauma. DABRA is minimally invasive and is designed to not stretch the arterial walls or penetrate the layers of arterial tissue known as the subintimal space, which can lead to dissection, or a tear in the inner lining of the vessel wall, or perforation, or a hole or a break in the vessel wall, although these events may still occur with DABRA and other competing products. We believe that endovascular treatments using DABRA may be more durable and longer lasting than treatments using other devices because of the reduced mechanical trauma, thermal trauma, and barometric trauma, or trauma due to change in pressure inside the vessel.

In May 2017, we received FDA 510(k) clearance to market the DABRA laser system and single-use DABRA catheter in the U.S. for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease and with an intended use for ablating a channel in occlusive peripheral vascular disease. We are initially focused on placing DABRA in outpatient-based laboratories, or OBLs, and subsequently we intend to expand into the hospital catheterization laboratory market. Reimbursement claims for DABRA procedures are typically submitted by the provider to Medicare or another third-party payor using established Current Procedural Terminology, or CPT, codes. DABRA was also granted CE mark approval in Europe in September 2016 for the endovascular treatment of infrainguinal arteries via atherectomy and for crossing total occlusions. As noted above, we are currently pursuing an atherectomy indication in the U.S.

Pharos. Pharos is our excimer laser device that emits highly concentrated ultraviolet light and is used as a tool in the treatment of dermatological skin disorders. Physicians use Pharos by applying 308 nanometer ultraviolet light to the skin. The FDA has granted 510(k) clearance to market Pharos in the U.S. for psoriasis, vitiligo, atopic dermatitis, and leukoderma. Pharos was granted CE mark approval in Europe in September of 2016 for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma by the application of UVB ultraviolet light. We have also received clearance to market Pharos from the China Food and Drug Administration, or CFDA. We believe Pharos offers significant benefits to patients. The targeted nature of our treatment allows the operator to spare healthy tissue from exposure to the ultraviolet light making the treatment faster and safer than some other forms of phototherapy, or light therapy. The light induces T-cell apoptosis which we believe may produce an immunosuppressant effect. For instance, Pharos is not contraindicated for children and pregnant women, allowing for their treatment. Treatment with Pharos differs from topical treatments, such as steroids and vitamin D derivatives, which may require frequent ongoing application. Treatment with Pharos also differs from pharmaceutical treatments, which may be associated with systemic side effects.

Psoriasis is a chronic autoimmune disorder that causes cells to build up rapidly and affects the surface of the skin. The National Psoriasis Foundation reports that psoriasis affects more than 8 million people in the U.S. Psoriasis often develops between the ages of 15 to 35, but can develop at any age. Vitiligo is an autoimmune condition in which the skin turns white due to the loss of melanocytes, cells that produce the pigment melanin, which gives skin color. Vitiligo affects approximately 1% of the population globally. Atopic dermatitis, more commonly known as eczema, is a chronic eczematous skin disease. There are more than 18 million adults in the U.S. suffering from atopic dermatitis, according to the National Eczema Association. Leukoderma is the localized loss of pigment in the skin due to several causes including vitiligo.

Vascular Disease

Vascular disease refers to diseases of the blood vessels located throughout the body. The most common cause of vascular disease is atherosclerosis. Atherosclerosis is a progressive, degenerative condition in which plaque, consisting of lipids, cholesterol, calcium and other substances found in the blood stream, accumulates on the vascular wall. Plaque occurs in several different forms and may be located throughout the arterial system. Plaque varies in composition, with portions that are hard and brittle, referred to as calcified plaque, and other portions that are fatty or fibrous. Endovascular treatments for atherosclerosis are performed in a catheterization laboratory located in an OBL or hospital. These patients are diagnosed by their primary care physician, podiatrist, or other specialist, and then treatment is performed by an interventional cardiologist, interventional radiologist, or vascular surgeon.

PAD is atherosclerosis of the extremities, most commonly in the legs. Smoking, genetic predisposition, diabetes, aging, and obesity may significantly increase the risk of developing PAD. Plaque build-up reduces blood-flow to the surrounding tissue, causing claudication, pain or cramping in the leg, the most common early symptom of PAD. Symptoms may progress to include numbness, tingling or weakness in the legs and, in severe cases, burning or aching pain in the feet or toes.

As PAD progresses, additional symptoms may develop on the legs and feet, including cooling, color changes, or ulcers or wounds that do not heal. Left untreated, PAD can progress into critical limb ischemia, or CLI, the end stage of the disease where there is not enough oxygenated blood being delivered to the lower limbs to keep the tissue alive. As of June 2017, the SAGE Group reported that conservatively 22 to 30 million people suffer from CLI worldwide. If untreated, CLI may result in ulceration, infection, or gangrene in the feet and legs and eventually limb amputation or death.

Market Overview

PAD affects approximately 17.6 million people in the U.S. However, only 20-30% of PAD patients are actively being treated. Despite its prevalence and poor outcomes, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including CAD, in part because up to half of the PAD population is asymptomatic and many dismiss symptoms as normal signs of aging.

Without treatment, the disease can result in severe complications including amputation or death. The most common reason for amputation today is PAD. Despite the relative under diagnosis and treatment of PAD, the 2018 global atherectomy market was estimated to be \$1.1 billion and is estimated to grow at a CAGR of 6.6% by 2026. Higher diagnosis and intervention rates resulting from greater physician and patient awareness of PAD, as well as higher prevalence, are helping drive the market opportunity for PAD treatments.

We believe that the following factors are contributing to a growing diagnosed patient population:

- **Increased Awareness.** Recent emphasis on PAD education from medical associations, insurance companies and online medical communities, as well as publication in medical journals is increasing public and physician awareness of PAD risk factors, symptoms and treatment options.
- **Evolving Physician Practice Patterns.** Given that many patients with CAD also have PAD, we believe that interventional cardiologists and vascular surgeons are increasingly screening patients for both diseases. As a result, we believe that physicians are diagnosing more cases of PAD. In addition, we believe that heightened awareness of PAD, its symptoms and treatment options is leading to increased referrals.

Conventional Means of Treatment and Their Limitations

Physicians typically treat patients with mild to moderate PAD through non-invasive management, including exercise and prescription medication, and, if symptoms worsen, may recommend interventional or surgical procedures. Some patients who initially are diagnosed with severe PAD are treated immediately through interventional or surgical procedures.

Non-Invasive Management. For many diagnosed cases of PAD in the U.S., lifestyle changes, including improved diet, regular exercise and smoking cessation, as well as drug treatment are often prescribed. Although these measures can be effective, many people do not sustain them. In addition, these measures may reduce the symptoms, but do not treat the underlying causes of the disease. Physicians may also prescribe medications that lower cholesterol and reduce blood pressure. These drug therapies are generally prescribed for the life of the patient and do not treat the obstruction, making them an ineffective treatment for many patients. As a result, many of these patients will ultimately require more aggressive treatments.

Interventional Procedures. When PAD progresses beyond claudication, physicians may advise intervention, often beginning with minimally-invasive procedures. Minimally invasive endovascular treatments include balloon angioplasty, stents, and plaque removal devices. These treatments have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease. We believe that there are over 500,000 annual endovascular procedures for the treatment of PAD in the U.S. Angioplasty and stenting are the most commonly performed minimally-invasive interventional treatments.

- **Angioplasty.** In an angioplasty procedure, a long, thin tube, or catheter, with a balloon tip is inserted into the blocked or narrowed part of the artery over a previously positioned guidewire that directs the catheter to the affected area. The balloon is then inflated, compressing the plaque and stretching the arterial wall. While angioplasty catheters are relatively easy to use, they stretch the arterial wall, often leading to dissections of, and damage to, the arterial walls. Angioplasty does not remove the plaque, which remains in the artery. In addition, angioplasty is not well suited to treat highly calcified lesions, lesions concentrated on one side of the arterial wall, or lesions that occur at bifurcations, all common manifestations of PAD in the leg. Also, most angioplasty procedures for PAD are performed with the additional use of a stent.

- **Stenting.** Stenting is generally performed in tandem with angioplasty. A stent is a wire-mesh tube that acts as a scaffold inside the artery to keep it open. Stents are currently available in a wide range of varieties, including drug-coated stents. Despite their widespread use, stents may cause injury and inflammation to the arterial wall during placement and continued trauma post-procedure. Stents placed in the legs are subject to force and compression that may fracture or crush them, leading to reduced blood-flow and further vessel trauma. Once a stent is implanted, it cannot be removed, which may limit future treatment options such as angioplasty, additional stenting, atherectomy and bypass.
- **Plaque Removal Devices.** Procedures to remove plaque are often referred to in the medical field as atherectomy procedures. There are several types of atherectomy devices, including directional, rotational and laser, each with different mechanisms of action to remove plaque. Atherectomy treatments are frequently used with a stent or balloon. Atherectomy technologies can damage the vessel walls, which may increase the risk of restenosis. For example, cutting devices, such as directional or rotational devices, introduce significant mechanical trauma and other commercial laser devices have a significant thermal component due to the arrangement of the delivery catheter, both of which can cause trauma to the artery.

Surgical Procedures. Most PAD patients are treated endovascularly. Many of these patients, including diabetics, are not candidates for surgical procedures. However, surgery is used when non-invasive management or interventional procedures have failed or if the patient is diagnosed when PAD has progressed to an advanced state.

- **Bypass Surgery.** More severe cases of PAD may be treated by surgeons with bypass surgery. The blood flow is diverted around the occluded area using a synthetic graft or harvested vessel. Bypass surgery is performed by physicians in an operating room with the patient under general anesthesia and requires multi-day hospital stays for healing and rehabilitation. General anesthesia and the potential for surgical infections make this approach less suitable for patients with conditions such as high blood pressure, heart failure, chronic obstructive pulmonary disease or poor kidney function.
- **Amputation.** CLI is a serious form of PAD caused by severe lack of blood flow to the legs. Physicians may recommend full or partial amputation of the leg or foot for patients with CLI. Up to 200,000 amputations occur annually in the U.S. as a result of PAD.

Our Solution

Strengths of Our Approach

DABRA includes a portable excimer laser system combined with proprietary, single-use catheters that together represent a competitive plaque removal solution for the minimally invasive endovascular treatment of blockages in the vasculature. DABRA represents a novel approach to the treatment of a broad range of vascular blockages that is safe and effective, easy to use, and competitively priced. We believe that the principal benefits of DABRA are:

- **Safety.** DABRA is designed to track the patient's true lumen, or the center of the artery, and not to penetrate between the layers of arterial structure known as the subintimal space. Damage or stretching of the arterial walls, which can lead to dissection or perforation, may be reduced. In our post-market surveillance, the most frequent complication reported to us has been clinically non-significant vessel perforation.
- **Efficacy.** Unlike many treatments for PAD that do not remove plaque, DABRA employs photoablation to disintegrate plaque by breaking its chemical bonds, thereby reducing the plaque to the components of its fundamental chemistry without generating potentially harmful particulates. We believe that eliminating plaque while minimizing injury to the arterial wall may minimize the rate of restenosis.
- **Utility.** DABRA enables physicians to remove plaque from long and calcified lesions in arteries located in the lower extremities both above- and below-the-knee. DABRA is able to cross and debulk a wide variety of plaque, removing vascular blockages. For example, in patients with a CTO, the physician may use DABRA to cross the CTO prior to alternative treatments consisting of balloon angioplasty and possibly stenting.

- **Ease of Use.** DABRA employs techniques similar to those used in angioplasty, which are familiar to the approximately 10,000 interventional cardiologists, vascular surgeons and interventional radiologists in the U.S. who are generally trained in endovascular techniques. In order to further the ease of use for physicians, we are working towards a braided shaft for the catheter, which may reduce kinking, and a rapid exchange, which will allow the physicians to employ existing techniques used with other devices on DABRA.
- **Cost and Time Efficient.** We believe that because our single-use DABRA catheters are priced competitively and because we provide the DABRA laser system for a nominal periodic fee without requiring the purchase of capital equipment, DABRA is a cost-effective solution for providers. Providers are also eligible for reimbursement for procedures that are performed using DABRA by using existing Current Procedural Terminology, or CPT, codes. The existence of a CPT code does not guarantee reimbursement, and payors impose restrictions on the use of codes. In addition, DABRA's easy setup and fast ablation speed reduce both treatment and fluoroscopy time, or x-ray exposure time, for the patient, physician, and staff, improving the providers' patient throughput. The average lasing time in our pivotal study was approximately two and a half minutes per procedure. Cost and time efficiencies can trigger Medicare payment reductions based on the resource based relative value payment methodology.

Our Strategy

Our goal is to become the leading medical device company marketing excimer lasers as tools for the treatment of endovascular diseases. Key components of our strategy to achieve this goal are:

- **Increasing the shelf life and improving the consistency of the DABRA catheter.** During the fourth quarter of 2018 and into 2019, we experienced high levels of non-calibration with our catheters, which we determined was due principally to the age of the catheter, as catheters more than two months post-sterilization experienced significantly higher rates of non-calibration. In the third quarter of 2019, we engaged in a voluntary recall of the catheters with a 12-month shelf life to replace them with catheters with a two-month shelf life. We have seen a significant decrease in the rate of non-calibration following the recall. We are working on solutions to extend the shelf life, as the two-month shelf life may make it difficult for customers to manage their inventory, and to increase sales significantly as we adopt the product enhancements discussed below.
- **Product enhancements.** We are working on two important design changes to the DABRA catheter. First, we are developing a braided overjacket designed to make the DABRA catheter less prone to kinking. Second, we are developing a rapid exchange, which will allow endovascular surgeons to use more standard techniques, including a guidewire, to navigate the vasculature more easily.
- **Atherectomy indication.** We commenced our atherectomy study by enrolling our first patient in February 2020, and believe that having the atherectomy indication will allow us to more effectively position DABRA in the marketplace, as many of our competitors have an atherectomy indication in the U.S.
- **Expanding DABRA sales.** As we accomplish some or all of the components listed above, we intend to expand our sales force to begin the relaunch of DABRA.

Products

The DABRA Product

DABRA combines a portable excimer laser console with proprietary, single-use catheters for the minimally invasive endovascular treatment of vascular blockages resulting from lower extremity vascular disease in both above- and below-the-knee lesions. We have significant expertise in excimer lasers gained from over a decade developing, manufacturing, testing, marketing, and servicing the Pharos excimer laser for dermatological diseases, and have leveraged this expertise in the design, development and manufacturing of DABRA.

The most important aspect of DABRA for the vascular market is the catheter, which conducts energy from the laser to the vascular blockage. The laser energy travels through the catheter and ablates the blockage, reducing it to chemicals that are found naturally in the bloodstream. The catheters are sterilized single-use only and specifically designed for our laser-based systems. The DABRA catheter uses a liquid-filled plastic tubing allowing for the efficient and precise delivery of the laser energy.

The DABRA catheter is a single-use, 5 French gauge catheter that currently does not use a guidewire to navigate vasculature and that typically stays within the normal area in which blood is flowing or true lumen, even while crossing blockages. It is a full aperture ratio forward cutter, delivering fast ablation of a wide variety of plaque, without the “dead-space” of fiber optic bundle catheters. It produces a high quality lumen while minimizing trauma to the vasculature. The DABRA catheter has a 1.5 millimeter blunt-tip design and a working length of 150 cm that tracks the true lumen, navigating the vascular curves. DABRA catheters have been used with a variety of introducers and guide catheters. They have been used in both above- and below-the-knee procedures, including axially, femorally, both antegrade and retrograde, from popliteal access and pedal access, both anterior tibial and posterior tibial. DABRA removes plaque by photoablation, limiting the vascular trauma caused by mechanical forces, acoustic or thermal energy, or vapor bubbles, which may occur when using competing products.

The DABRA excimer laser is the power source for DABRA catheters that generates a laser light by a software controlled 308 nanometer excimer laser source that produces 308 nanometer ultraviolet-B photons that are directed to the catheter through a lens to photoablate vascular blockages, reducing calcium, thrombus, and atheroma into their fundamental chemistry, minimizing downstream debris.

DABRA ablation produces fast treatment times and minimizes fluoroscopy time. The laser is small enough for most catheterization laboratories, weighs approximately 180 pounds, (including a gas bottle), and is easily portable around and between rooms. It is easy-to-use, features a simple and intuitive operator-interface, plugs into a standard 110-volt outlet, and does not require any pumps or fluids.



The DABRA Laser



The DABRA Catheter

The DABRA Procedure

During the procedure, the physician inserts the proximal end of the single-use DABRA catheter into the laser console. Using the buttons next to the screen of the console, the physician enters the calibration mode and inserts the distal end of the catheter into the calibration port of the console to perform the calibration. The physician sets the treatment settings on the touch screen. The physician then inserts the catheter into the support catheter and under fluoroscope, advances the catheter to the target lesion. The physician uses the footswitch to activate the laser unit and slowly advances the catheter to ablate the target lesion.

Depending upon the type of lesion, DABRA can cross blockages at a rate of up to one centimeter per second. The DABRA procedure is typically performed under local anesthesia in a catheterization laboratory. A patient treated in an OBL is discharged the same day.



Clinical Studies and Patient Data

Pre-Marketing Studies. We applied and received FDA IDE approval for our pivotal study. It was a non-randomized, single-arm, prospective, multi-site study that enrolled 64 subjects at four sites. The objective of the study was to evaluate plaque photoablation using DABRA in the endovascular treatment resulting from lower extremity vascular disease of patients with Rutherford categories 3, 4, 5 and 6. The primary efficacy endpoint was the successful crossing of the target lesion based on angiographic analysis at time of the procedure. The safety endpoint was device-related major adverse events at the time of the procedure. It was conducted at four centers including the California Heart and Vascular Center, an OBL in El Centro, California, Centro Medico Excel, a hospital in Tijuana, Mexico, the University of California, San Diego, a major teaching hospital in San Diego, California, and Merit Health Wesley, a hospital in Hattiesburg, Mississippi. As part of the inclusion criteria for the DABRA study, the target blockage must have been refractory to guidewire crossing. The average lasing time in our study was approximately two and a half minutes and the average lesion measured over seven centimeters, which is representative of a typical patient suffering from severe lower extremity vascular disease. The analyses pre- and post-treatment were performed using standard angiographic and ultrasonic tools which are commonly used in commercial catheterization laboratories.

The study was closed to enrollment on May 24, 2017 when we received 510(k) clearance for DABRA. 50 subjects were included in the FDA's data used to determine the 510(k) clearance. The final study results demonstrated 94% effectiveness with 0% reported device-related SAEs, both related to the 50 subjects included in the data submitted to the FDA and the 64 patients enrolled in the study. Furthermore, in our study, 64 lesions crossed were above the knee, or approximately 85%, and 11 lesions crossed were below-the-knee, or approximately 15%.

Atherectomy Study. In January 2020, we received final IDE approval to evaluate the safety and effectiveness of the DABRA laser system for use as an atherectomy device for the treatment of peripheral vascular stenoses.

The multicenter, open-label trial will enroll up to 100 patients with symptoms of PAD (Rutherford Class 2-4). Outcome measures include safety, acute technical success and clinical success. The trial's primary efficacy endpoint is the mean reduction in percent diameter stenosis in each patient's primary lesion as measured by angiography immediately following treatment with DABRA, before any adjunctive treatment. Major adverse events at 30 days and incidence of primary target lesion revascularization (TLR) at six months will be the safety and clinical success endpoints.

RESULTS Registry. In the fourth quarter of 2018, we announced the prospective long-term revascularization study of DABRA titled REvascularization RateS and Clinical OUtcomes with DABRA Laser. A Long-Term 2-year Study (RESULTS). This registry is being conducted to measure the benefit and the safety profile of DABRA over two years. The registry is still open, however, we have been prioritizing the atherectomy trial and have not yet had significant enrollment in the registry.

The Pharos Product

Pharos is a powerful, monochromatic, or single-wavelength, xenon-chlorine, 308 nanometer ultraviolet-B excimer laser used by physicians as a tool to treat chronic skin diseases, including psoriasis, vitiligo, atopic dermatitis, and leukoderma. We launched Pharos in 2004. Pharos does not use heat and does not ablate lesions, and treatments are generally painless. Pharos' proprietary hand piece features an integrated adjustable spot size and aiming beam that accurately targets only the diseased tissue while sparing the healthy skin from exposure. The laser beam is easily contoured to accommodate the shape of the lesion for fast and precisely targeted treatments with constant fluence, or stream of photons crossing a unit area. No templates or attachments are required. Its flat-top, no hot-spot beam profile delivers uniform dosing for optimal results. Pharos is small enough for most treatment rooms, intuitive to use, and uses a standard 110-volt outlet. In the third quarter of 2019, we launched Pharos, Optimized, which includes faster treatments and extended peak performance.



The Pharos Laser

The Pharos treatment is generally performed in a dermatology treatment room in an office, clinic or hospital. In most states and countries in which we have received regulatory approval, the treatment can be applied by a nurse or technician. The laser is calibrated, the desired dose is entered, and the hand piece is directed to the patient. The treatment is delivered through a hand piece that has a distance gauge which is placed on the patients' skin and is operated by a foot switch. The hand piece is moved to the appropriate lesion location and the process is repeated until all of the lesions have been dosed.

We believe that the principal benefits of Pharos are:

- **Wavelength.** Studies have shown that the action spectrum, or the rate of a physiological activity plotted against wavelength of light, for immunologically modulated skin disorders is centered at about 308 nanometers. Pharos is a 308 nanometer laser, making it ideally suited for use as a tool in the treatment of these disorders.
- **Energy.** The energy from excimer lasers has been shown, in both in vivo and in vitro studies, to have almost four times the T-cell apoptosis generation than non-laser sources. Pharos is a pulsed laser capable of producing very high peak powers, and we believe that this may produce an immunosuppressive effect.

- **Collimation.** Ultraviolet-B light has a very shallow penetration into the skin, typically less than 100 microns. Although the skin tends to scatter the light, collimation, or keeping the light rays parallel, helps prevent reflection and improves the dose delivery. Pharos has a moderately collimated beam and this collimation allows for treatment in intertriginous areas, such as the groin and armpits, and mucosal areas, such as the mouth and ears, without compromising dose.
- **Targeting.** Applying the laser energy only to the diseased tissue not only spares the healthy tissue from exposure, but also allows the operator to increase the dose to the affected areas. We believe that Pharos is the only system that has an integrated adjustable spot size offering continuous beam adjustment from a large square to a small circle.
- **Footprint.** Dermatological treatment rooms are small and often crowded with other equipment. Pharos has a small footprint and is among the lightest excimer lasers currently marketed, allowing physicians to conserve space and easily move the system.

There are essentially three main types of current treatments for dermatological skin disorders, which each have limitations, as listed below:

- **Topical therapies.** These can include corticosteroids, vitamin D3 derivatives, coal tar, anthralin and retinoids, among others, that are sold as a cream, gel, liquid, spray, or ointment. The efficacy of topical agents varies from person to person, and these products are commonly associated with poor compliance or side effects that include irritation, redness, and thinning of the skin.
- **Phototherapy.** There are several ultraviolet lamp systems that deliver ultraviolet-A and ultraviolet-B light for the treatment of skin conditions. Broadband ultraviolet therapy can be less desirable than targeted laser machines due to exposure of non-diseased skin and limited ability to deliver high intensity light, requiring more treatment sessions and increasing cancer risk.
- **Systemic medications including biologics.** There are a number of prescription medications available, which are delivered orally or by injection. Generally, these drugs are administered only after both topical treatments and phototherapy have failed, or for people who have severe disease. Some of the side effects include risks of infection or death.

Dermatological Disease

Dermatological disease refers to diseases of the skin caused by imbalance in the physiological condition of the skin. There are over 3,000 different skin conditions and diseases, including psoriasis, vitiligo, and atopic dermatitis. Psoriasis is a chronic autoimmune disorder that causes cells to rapidly accumulate and affects the surface of the skin. The extra skin cells form scales and red patches, or flares, which are itchy and sometimes painful. There is no known cure and multiple rounds of treatments are required to bring the disease under control. Vitiligo is an autoimmune condition causing the skin to turn white due to the loss of pigment from the melanocytes, cells that produce the pigment melanin, which gives skin color. There is no known cure. However, some medical treatments can reduce the severity of the condition. Atopic dermatitis, a chronic eczematous skin disease, can result in itchy, red, swollen, and cracked skin.

Additional proliferative skin disorders include alopecia areata, dyshidrotic eczema, and cutaneous T-cell lymphoma, or CTCL. Alopecia areata is a condition in which hair is lost from some or all areas of the body. Dyshidrotic eczema is a skin disease characterized by itchy blisters on the palms of the hands and bottoms of the feet. CTCL is a type of cancer of the immune system caused by a mutation of T-cells.

Market Overview

Psoriasis, atopic dermatitis and vitiligo are common skin disorders throughout the world. The National Psoriasis Foundation reports that psoriasis affects over 8 million people in the U.S. Globally, this skin condition is estimated to affect over 125 million people, 2-3% of the total population. A study on the economic costs of psoriasis, including direct costs (medical expenses), indirect costs (work productivity), quality of life costs, and comorbidity costs, showed an estimated \$135 billion annual expense for everyone with psoriasis in the United States. The study found that the majority of psoriasis patients miss an average of 26 days of work a year due to their disease. Currently, more than 18 million adults suffer from atopic dermatitis in the U.S., making it one of the most common inflammatory skin diseases. Vitiligo is a pigmentation disorder that affects approximately 1% of the population globally.

Customers

No single customer represented more than 10% of our total revenue for 2019 or 2018.

Sales and Marketing

We market and sell DABRA and Pharos primarily through our direct sales force in the U.S. Beginning in the third quarter of 2019, we implemented certain operational efficiency and cost-savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives include targeted workforce reductions of our sales and marketing teams. We reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to five clinical specialists as of December 31, 2019. Our initial focus for DABRA is OBLs. We partner with distributors for DABRA and Pharos in select geographies outside of the U.S.

Our marketing program focuses on:

- educating physicians regarding the proper use and application of DABRA and Pharos;
- supporting physicians' efforts to enhance referral opportunities;
- improving patient and caregiver awareness of our treatments; and
- facilitating national and international marketing programs.

We use a targeted marketing approach to introduce our products to the medical marketplace. We primarily target our marketing efforts to practitioners through marketing materials, medical conferences and journals. In addition, we host seminars and webinars where industry leaders discuss case studies and treatment techniques using DABRA and Pharos.

Manufacturing

We manufacture our excimer lasers and catheters in our approximately 32,000 square foot facility located in Carlsbad, California. Our vertically integrated facility is ISO 13485 certified and is licensed by the state of California to manufacture our sterile single-use catheters in our controlled environments. We specify and source our supplies primarily from U.S.-based manufacturers, contracting with local suppliers to manufacture custom components. We carefully choose our suppliers to ensure that all components meet our quality standards, adhere to all applicable regulations, and meet our supply needs. We inspect, test, and assemble our products under strict manufacturing processes supported by internal policies and procedures. We perform our own final quality control testing of all products before shipment. In addition to primary suppliers, secondary suppliers have been identified for contingency planning purposes for many key components. We audit our suppliers as required by our quality system and the FDA. We believe that our current manufacturing capacity is sufficient to produce enough lasers and catheters to meet our current expected demand for at least the next 12 months.

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. We face potential competition from major medical device companies worldwide, many of which have longer, more established operating histories, and significantly greater financial, technical, marketing, sales, distribution, and other resources. Our competitors also include pharmaceutical companies that manufacture drugs for the treatment of psoriasis, vitiligo, atopic dermatitis, leukoderma or other dermatological diseases. Our overall competitive position is dependent upon a number of factors, including product performance and reliability, manufacturing cost, and customer support.

Vascular blockages are currently treated with angioplasty balloons, stents, and atherectomy devices that include excimer laser ablation. Our major competitors for our vascular solutions include Medtronic plc, Cardiovascular Systems Inc., Boston Scientific Corp., Avinger, Inc., Koninklijke Philips N.V., including Volcano Corporation and Spectranetics Corporation, Becton Dickinson and Company, including products from the C.R. Bard acquisition, and Abbott Laboratories. We believe that DABRA competes favorably with our competitors' products in terms of safety, ease of use, utility and cost.

Dermatological diseases are currently treated with phototherapy, topical therapies, and systemic medications. Our major competitors for our dermatological solutions include The Daavlin Company, National Biological Corp., STRATA Skin Sciences and large pharmaceutical companies producing biologics. We believe Pharos competes favorably with our competitors' products.

Reimbursement

Our customers do not receive reimbursement for the purchase of our products. However, procedures performed using DABRA and Pharos are typically reimbursable using existing CPT codes. At this time we believe that the existing CPT codes are generally adequate to describe the procedures using our products. We believe that there is no current need to apply for separate product specific CPT codes and we recognize that the existence of codes does not guarantee coverage or reimbursement. The CPT process is dynamic and changes or interpretations of codes can occur yearly. Sales of DABRA and Pharos in the U.S. depend in part on the availability of coverage and adequate reimbursement to our customers for use of our products from third-party payors, such as private health insurers, managed care organizations and government health programs, like Medicare, Medicaid, TRICARE and the Department of Veterans Affairs. Medicare's coverage and reimbursement policies are significant to our operations, as a large percentage of DABRA and Pharos procedure patients are Medicare beneficiaries, and private third-party payors often rely upon Medicare coverage and reimbursement policies in setting their own payment policies. However, no uniform coverage or reimbursement policies for services using our products exist among third-party payors in the U.S. Changes in FDA regulatory status, clinical trials, and expanded indications can also have a bearing on coverage and reimbursement. The absence of uniform policies and limits on coverage can create barriers to sale. You should refer to the "Risk factors" section of this Annual Report on Form 10-K for risks related to reimbursement.

Market acceptance of the DABRA and Pharos devices is dependent on adequate payment levels from third-party payors to our customers. We receive payment from the provider, facility or other entity that purchases, leases, rents or uses the DABRA or Pharos devices and purchases related supplies. A physician who performs a procedure utilizing either device may be reimbursed separately from a hospital by third-party payors. Under Medicare, the physician would be reimbursed according to the physician fee schedule in effect at the time of the procedure. The physician fee schedule also applies when the procedure is performed in a free-standing OBL catheterization laboratory. When the procedure is performed in a hospital outpatient setting, the hospital would be reimbursed according to the outpatient hospital prospective payment system, based on ambulatory payment classification groups. Under Medicare, the physician fee schedule and outpatient hospital prospective payment amounts can change every year and may decline.

Reimbursement to facilities and physicians can vary substantially depending on the third-party payors' coverage and reimbursement policies and other factors. For example, the type and geographical location of the facility in which the procedure was performed may impact the level of reimbursement. In addition, the specific use of the product may impact reimbursement. For example, the laser treatment of psoriasis is reimbursable by Medicare and nearly all major insurance companies under three CPT codes that are available for Pharos procedures. These codes and the corresponding payment levels differ based on the size of the affected area to be treated. As a result, there is wide variability in reimbursement, and third-party payor's reimbursement policies are subject to change. Further, requests for reimbursement are subject to challenge, reduction or denial by third-party payors. In order to better manage the changing reimbursement environment, we have centralized our internal reimbursement resources.

Research and Development

The major focus of our research and development team is to leverage our existing technology platform for new applications and improvements to our existing applications. Future research and development efforts will involve continued enhancements to and cost reductions for DABRA and Pharos. We will also explore the development of other products that can be derived from our core technology platform and intellectual property. Our research and development team works together with our sales force to set development priorities based on communicated customer needs. The feedback received from our customers is reviewed and evaluated for incorporation into new products. We recognized \$4.5 million and \$2.8 million of research and development expenses in the years ended December 31, 2019 and 2018, respectively.

Patents and Proprietary Technology

Patents

In order to remain competitive, we must develop and maintain protection on the proprietary aspects of our technologies. We rely on a combination of patent, copyright, trademark and trade secret laws, and confidentiality and invention assignment agreements to protect our intellectual property rights. The protection of intellectual property has been and remains a priority for us. As of March 6, 2020, we own six U.S. issued patents and continue to pursue patent protection in five different patent families. In the patent family titled “Small Flexible Liquid Core Catheter for Laser Ablation in Body Lumens and Methods for Use,” we own one issued U.S. patent, one issued Chinese patent and one granted European patent which has been validated in Switzerland, Germany, Denmark, France, United Kingdom, Italy, Netherlands and Sweden. A U.S. divisional application and U.S. continuation application have also been filed in this patent family and remain pending. In the patent family titled “Methods and Devices for Treatment of Stenosis of Arteriovenous Fistula Shunts,” we own four issued U.S. patents and one continuation application remains pending in the U.S. In the patent family titled “Laser Ablation Catheters Having Expanded Distal Tip Windows for Efficient Tissue Ablation” we own one issued U.S. patent with one continuation application in this family still pending. An additional patent application titled “Catheter Grip Device and Method” remains pending. The patent family titled “Liquid Filled Ablation Catheter with Overjacket” includes pending applications in the U.S., China, Japan, and the European Regional Phase. Our issued U.S. patents expire between 2035 and 2037, subject to payment of required maintenance fees, annuities, and other charges.

Trademarks

We own or have rights to trademarks that we use in connection with the operation of our business. We own or have rights to trademarks for Ra Medical Systems and our logo as well as other marks such as DABRA and Pharos.

Trade Secrets

We also rely upon trade secrets, know-how and continuing technological innovation, and may in the future rely upon licensing opportunities, to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to proprietary information.

Government Regulation and Product Approval

United States

In the U.S., medical devices are subject to extensive regulation by the FDA, under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations, and certain other federal and state statutes and regulations. The laws and regulations govern, among other things, the design, manufacture, storage, recordkeeping, approval, labeling, promotion, post-approval monitoring and reporting, distribution and import and export of medical devices. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as FDA refusal to approve pending pre-market approval applications, or PMAs, issuance of warning letters or untitled letters, mandatory product recalls, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions, and criminal prosecution.

The FDCA classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Class II devices provide intermediate levels of risk. They are subject to general controls, and some Class II devices must also comply with special controls. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device’s safety and effectiveness. Class III devices must typically be approved by the FDA before they are marketed. Both DABRA and Pharos are Class II devices.

Generally, establishments that manufacture devices are required to register their establishments with the FDA and provide the FDA a list of the devices that they handle at their facilities.

The FDA enforces these requirements by market surveillance and periodic visits, both announced and unannounced, to inspect or re-inspect equipment, facilities, laboratories and processes to confirm regulatory compliance. These inspections may include the manufacturing facilities of subcontractors. Following an inspection, the FDA may issue a report, known as a Form 483, listing instances where the manufacturer has failed to comply with applicable regulations and/or procedures or, if observed violations are severe and urgent, a warning letter. If the manufacturer does not adequately respond to a Form 483 or warning letter, the FDA may take enforcement action against the manufacturer or impose other sanctions or consequences, which may include:

- cease and desist orders;
- injunctions, or consent decrees;
- civil monetary penalties;
- recall, detention or seizure of our products;
- operating restrictions, partial or total shutdown of production facilities;
- refusal of or delay in granting requests for 510(k) clearance, de novo classification, or premarket approval of new products or modified products;
- withdrawing 510(k) clearances, de novo classifications, or premarket approvals that are already granted;
- refusal to grant export approval or export certificates for devices; and
- criminal prosecution.

Pre-market Authorization and Notification

While most Class I and some Class II devices can be marketed without prior FDA authorization, most medical devices can be legally sold within the U.S. only if the FDA has: (i) approved a pre-market approval, or PMA, application prior to marketing, generally applicable to most Class III devices; (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class I and II devices; or (iii) authorized the device to be marketed through the de novo process, generally applicable for novel Class I or II devices. Some devices that have been classified as Class III are regulated pursuant to the 510(k) requirements because the FDA has not yet called for PMAs for these devices.

510(k) Notification

Product marketing in the U.S. for most Class II and limited Class I devices typically follows a 510(k) pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a legally marketed device, referred to as the predicate device. A predicate device may be a previously 510(k) cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for submission of PMA applications, or a product previously granted de novo authorization. The manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or it is shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device.

There are three types of 510(k)s: traditional; special, for certain device modifications; and abbreviated, for devices that conform to a recognized standard. The special and abbreviated 510(k)s are intended to streamline review. The FDA intends to process special 510(k)s within 30 days of receipt, and abbreviated 510(k)s within 90 days of receipt. Though the FDA has a user fee goal to clear a traditional 510(k) within 90 days of receipt, the clearance pathway for traditional 510(k)s can take substantially longer.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance for the modified device, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

We have received 510(k) premarket clearances from the FDA to market our excimer laser and catheter systems for treatment of psoriasis, vitiligo, atopic dermatitis, leukoderma, and for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease and with an intended use for ablating a channel in occlusive peripheral vascular disease. We expect to file additional 510(k) submissions for other diseases including, but not limited to, CAD, alopecia areata, and oral lichen planus in the future.

De Novo Classification

Devices of a new type that the FDA has not previously classified based on risk are automatically classified into Class III by operation of section 513(f)(1) of the FD&C Act, regardless of the level of risk they pose. To avoid requiring PMA review of low- to moderate-risk devices classified in Class III by operation of law, Congress enacted section 513(f)(2) of the FDCA. This provision allows the FDA to classify a low- to moderate-risk device not previously classified into Class I or II through the de novo classification pathway. The FDA evaluates the safety and effectiveness of devices submitted for review under the de novo classification pathway and devices determined to be Class II through this pathway can serve as predicate devices for future 510(k) applicants. The de novo classification pathway can require clinical data and is generally more burdensome than the 510(k) pathway and less burdensome than the PMA approval pathway.

PMA Approval

A product not eligible for 510(k) clearance or de novo classification must follow the PMA approval pathway, which requires proof of the safety and effectiveness of the device to the FDA's satisfaction.

Results from adequate and well-controlled clinical trials are required to establish the safety and effectiveness of a Class III PMA device for each indication for which FDA approval is sought. After completion of the required clinical testing, a PMA including the results of all preclinical, clinical, and other testing, and information relating to the product's marketing history, design, labeling, manufacture, and controls, is prepared and submitted to the FDA.

The PMA approval process is generally more expensive, rigorous, lengthy, and uncertain than the 510(k) premarket notification process and de novo classification process and requires proof of the safety and effectiveness of the device to the FDA's satisfaction. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with Quality System Regulation, or QSR, requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. The FDA's review of a PMA application typically takes one to three years, but may last longer. If the FDA's evaluation of the PMA application is favorable, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval and/or placement of restrictions on the sale of the device until the conditions are satisfied.

Even after approval of a PMA, a new PMA or PMA supplement may be required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

Clinical Trials

A clinical trial is almost always required to support a PMA application and de novo classification and is sometimes required for a premarket notification. For significant risk devices, the FDA regulations require that human clinical investigations conducted in the U.S. be approved under an Investigational Device Exemption, or IDE, which must become effective before clinical testing may commence. A nonsignificant risk device does not require FDA approval of an IDE. In some cases, one or more smaller IDE studies may precede a pivotal clinical trial intended to demonstrate the safety and efficacy of the investigational device. A 30-day waiting period after the submission of each IDE is required prior to the commencement of clinical testing in humans. If the FDA disapproves the IDE within this 30-day period, the clinical trial proposed in the IDE may not begin.

An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must also include a description of product manufacturing and controls, and a proposed clinical trial protocol. The FDA typically grants IDE approval for a specified number of patients to be treated at specified study centers. During the study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, and record keeping. The investigators must obtain patient informed consent, follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. Prior to granting PMA approval, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the PMA application for compliance with IDE requirements.

Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard intended to protect the rights and health of patients and to define the roles of clinical trial sponsors, investigators, and monitors; and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Clinical trials are typically conducted at geographically diverse clinical trial sites, and are designed to permit the FDA to evaluate the overall benefit-risk relationship of the device and to provide adequate information for the labeling of the device when considering whether a device satisfies the statutory standard for commercialized. Clinical trials, for significant and nonsignificant risk devices, must be approved by an institutional review board, or IRB – an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety, and welfare of the human research subject.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with the FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial it has approved to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions or sanctions.

Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that the FDA may impose with respect to manufacturing. Investigational devices may only be distributed for use in an investigation, and must bear a label with the statement: "CAUTION—Investigational device. Limited by Federal law to investigational use."

Postmarket Requirements

After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, the medical device reporting regulations (which require that manufacturers report to the FDA if their 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 it were to recur), and reports of corrections and removals regulations (which require manufacturers to report recalls or removals and field corrections to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA). After a May 2018 inspection, the FDA issued to us a Form 483 that included observations for failure to properly evaluate whether certain complaints related to Pharos and DABRA that we have received rose to a level required to be reported to the FDA. In response, we informed the FDA that we have modified our complaint review procedures and we completed a retrospective evaluation and have not found any complaints which require a submission to the FDA. In connection with our Audit Committee investigation, the Audit Committee also found failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to FDA's satisfaction. In addition, the FDA conducted an unannounced facility inspection in December 2019. The FDA issued to us a Form 483 that included observations that schedules for the adjustment, cleaning, and other maintenance of equipment have not been adequately established, a device master record index was not current, and document control procedures have not been fully established. We are working diligently to address the issues identified in the Form 483. Failure to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to FDA's satisfaction, can subject us to warning letters, recalls, or other sanctions and penalties.

Advertising, marketing and promotional activities for devices are also subject to FDA oversight and must comply with the statutory standards of the FDCA, and the FDA's implementing regulations. The FDA's oversight authority review of marketing and promotional activities encompasses, but is not limited to, direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving electronic media. The FDA also regulates industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context.

Manufacturers of medical devices are permitted to promote products solely for the uses and indications set forth in the approved or cleared product labeling. A number of enforcement actions have been taken against manufacturers that promote products for "off-label" uses (i.e., uses that are not described in the approved or cleared labeling), including actions alleging that claims submitted to government healthcare programs for reimbursement of products that were promoted for "off-label" uses are fraudulent in violation of the Federal False Claims Act or other federal and state statutes and that the submission of those claims was caused by off-label promotion. The failure to comply with prohibitions on "off-label" promotion can result in significant monetary penalties, revocation or suspension of a company's business license, suspension of sales of certain products, product recalls, civil or criminal sanctions, exclusion from participating in federal healthcare programs, or other enforcement actions. In the United States, allegations of such wrongful conduct could also result in a corporate integrity agreement with the U.S. government that imposes significant administrative obligations and costs.

Violations of the FDCA relating to the inappropriate promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

For a PMA or Class II 510(k) or de novo devices, the FDA also may require post-marketing testing, surveillance, or other measures to monitor the effects of an approved or cleared product. The FDA may place conditions on a PMA-approved device that could restrict the distribution or use of the product. In addition, quality-control, manufacture, packaging, and labeling procedures must continue to conform to QSRs after approval and clearance, and manufacturers are subject to periodic inspections by the FDA. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with QSRs. The FDA may withdraw product approvals or recommend or require product recalls if a company fails to comply with regulatory requirements.

Radiation Emitting Products

The FDA regulates radiation emitting electronic products even when they are not intended to be used for medical purposes. X-rays, microwaves, radio waves, laser, visible light, sound, ultrasound, and ultraviolet light are a few examples of the many types of radiation that may be produced by an electronic product. Diagnostic X-ray systems, laser products, laser light shows, and microwave ovens are a few examples out of the many different electronic products that emit radiation subject to FDA regulation. Many radiation emitting electronic products are also medical devices. In those cases, the products must comply with two independent sets of regulations—radiation safety regulations that apply to radiation emitting electronic products, as well as medical device regulations that apply to all medical devices.

Under the Electronic Product Radiation Control provisions of the FDCA, the FDA has established regulations specifying electronic product performance standards covering several varieties of radiation emitting electronic products. Companies that manufacture or import electronic products subject to an FDA performance standard are required to submit various electronic product reports to the FDA to demonstrate that their products comply with the standard. Unless exempted by the radiation safety regulations, a manufacturer or importer must also submit to the FDA follow-up reports for product updates or modifications, as well as an annual report for their radiation emitting electronic products. The radiation safety regulations provide specific certification and labeling requirements for electronic products. Labeling, which includes user manuals, must contain certain information, such as warnings, declarations and clear and concise instructions for use and service. The information must also be formatted in accordance with the regulations. The law and applicable federal regulations also require laser manufacturers to maintain manufacturing, testing and sales records, and report product defects. Various warning labels must be affixed and certain protective devices installed, depending on the class of the product.

Non U.S. Regulatory

International sales of medical devices are also subject to the regulatory requirements of each country in which the devices are commercialized. The international regulatory review process varies from country to country and authorization from one country to market a device does not guarantee that other countries will also grant marketing authorization. In China, the State Food and Drug Administration, or SFDA, is the agency primarily responsible for regulating medical devices. We have clearances from China, from both the SFDA and the China Food and Drug Administration, or CFDA. In Europe, the regulations of the European Union require that a medical device be granted a CE Mark indicating conformance with European Union laws and regulations before it can be sold in that market. We received a CE mark for the Pharos dermatological and DABRA vascular system in the third quarter of 2016, enabling our product launch in Europe.

Other Healthcare Laws

Our business operations and current and future arrangements with healthcare professionals, consultants, customers and patients, expose us to broadly applicable state, federal, and foreign fraud and abuse and other healthcare laws and regulations. These laws constrain the business and financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products. Such laws include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Persons and entities can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the health care fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- in addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other “transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members . Effective January 2022, we will also be required to collect and report information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives; and
- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by the patients themselves; state laws that require pharmaceutical and device companies to comply with the industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

In particular, activities and arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, waste and other abusive practices. These laws and regulations may restrict or prohibit a wide range of activities or other arrangements related to the development, marketing or promotion of products, including pricing and discounting of products, provision of customer incentives, provision of reimbursement support, other customer support services, provision of sales commissions or other incentives to employees and independent contractors and other interactions with healthcare practitioners, other healthcare providers and patients.

Because of the breadth of these laws and the narrow scope of the statutory or regulatory exceptions and safe harbors available, our business activities could be challenged under one or more of these laws. Relationships between medical product manufacturers and health care providers are an area of heightened scrutiny by the government. We engage in various activities, including the conduct of speaker programs to educate physicians, the provision of reimbursement advice and support to customers, and the provision of customer and patient support services, that have been the subject of government scrutiny and enforcement action within the medical device industry.

Government expectations and industry best practices for compliance continue to evolve and past activities may not always be consistent with current industry best practices. Further, there is a lack of government guidance as to whether various industry practices comply with these laws, and government interpretations of these laws continue to evolve, all of which creates compliance uncertainties. Any non-compliance could result in regulatory sanctions, criminal or civil liability and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in preventing such conduct, mitigating risks, or reducing the chance of governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

If a government entity opens an investigation into possible violations of any of these laws (which may include the issuance of subpoenas), we would have to expend significant resources to defend ourselves against the allegations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Allegations that we, our officers, or our employees violated any one of these laws can be made by individuals called “whistleblowers” who may be our employees, customers, competitors or other parties. Government policy is to encourage individuals to become whistleblowers and file a complaint in federal court alleging wrongful conduct. The government is required to investigate all of these complaints and decide whether to intervene. If the government intervenes and we are required to pay money back to the government as a result of a settlement or judgement, the whistleblower, as a reward, is awarded a percentage. If the government declines to intervene, the whistleblower may proceed on his or her own and, if successful, he or she will receive a percentage of any judgment or settlement amount the company is required to pay. The government may also initiate an investigation on its own. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines, and other sanctions that may materially impair our ability to run a profitable business. In particular, if our operations are found to be in violation of any of the laws described above or if we agree to settle with the government without admitting to any wrongful conduct or if we are found to be in violation of any other governmental regulations that apply to us, we, our officers and employees may be subject to sanctions, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, the curtailment or restructuring of our operations and the imposition of a corporate integrity agreement, any of which could adversely affect our business, results of operations and financial condition.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery laws in other jurisdictions, generally prohibit businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us to maintain books and records, which in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation, including international subsidiaries, if any, and to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements. The scope of the FCPA includes interactions with certain healthcare professionals in many countries.

We operate in parts of the world that have experienced governmental corruption to some degree and in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices. There is no assurance that our internal control policies and procedures will protect us from acts committed by our employees or agents. If we are found to be liable for FCPA or other violations (either due to our own acts or our inadvertence, or due to the acts or inadvertence of others), we could suffer from civil and criminal penalties or other sanctions, including contract cancellations or debarment, and loss of reputation, any of which could have a material adverse impact on our business, financial condition, and results of operations.

Privacy and Data Protection Laws

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the HITECH Act, and the regulations that have been issued under it, impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information. The requirements and restrictions apply to “covered entities” (which include health care providers and insurers) as well as to their business associates that receive protected health information from them in order to provide services to or perform certain activities on their behalf. The statute and regulations also impose notification obligations on covered entities and their business associates in the event of a breach of the privacy or security of protected health information. We occasionally receive protected health information from our customers in the course of our business. As such, we believe that we are business associates and therefore subject to HIPAA’s requirements and restrictions with respect to handling such protected health information, and have executed business associate agreements with certain customers.

In addition, California has enacted the California Consumer Privacy Act, or CCPA, which came into effect on January 1, 2020. Pursuant to the CCPA, certain businesses are required, among other things, to make certain enhanced disclosures related to California residents regarding the use or disclosure of their personal information, allow California residents to opt-out of certain uses and disclosures of their personal information without penalty, provide Californians with other choices related to personal data in our possession, and obtain opt-in consent before engaging in certain uses of personal information relating to Californians under the age of 16. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our non-compliance with the CCPA. The CCPA also allows for private lawsuits from Californians in the event of certain data breaches. Aspects of the CCPA remain uncertain, and we may be required to make modifications to our policies or practices in order to comply.

It is possible the data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country and state to state, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Further, compliance with data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. We can provide no assurance that we are or will remain in compliance with diverse privacy and security requirements in all of the jurisdictions in which we do business. If we fail to comply or are deemed to have failed to comply with applicable privacy protection laws and regulations such failure could result in government enforcement actions and create liability for us, which could include substantial civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

U.S. Healthcare Reform

In the U.S. and some non-U.S. jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, the Patient Protection and Affordable Care Act of 2010, or PPACA, and the Medicare Access and CHIP Reauthorization Act of 2015 substantially changed the way healthcare is delivered and financed by both governmental and private insurers. These changes included the creation of demonstration programs and other value-based purchasing initiatives that provide financial incentives for physicians and hospitals to reduce costs, including incentives for furnishing low cost therapies. Under the Trump Administration, there are ongoing efforts to modify or repeal all or part of PPACA or take executive action that affects its implementation. Tax reform legislation was passed that includes provisions that impact healthcare insurance coverage and payment such as the elimination of the tax penalty for individuals who do not maintain health insurance coverage (the so-called "individual mandate"). Such actions or similar actions could have a negative effect on the utilization of our products. We expect such efforts to continue and that there will be additional reform proposals at federal and state levels. On December 18, 2019, the United States Court of Appeals for the Fifth Circuit upheld a lower court's determination in *Texas v. Azar*, 4:18-cv-00167, that the individual mandate was unconstitutional and remanded the case to the lower court for further analysis as to whether PPACA as a whole is unconstitutional because the individual mandate is not severable from other provisions of the law. We cannot predict the ultimate results of the Texas case or whether additional legislative reform proposals will be adopted, when they will be adopted, or what impact they may have on us, but any such proposals could have a negative impact on our business and provide incentives for hospitals and physicians to not use our products.

General legislative action may also affect our business. For example, the Budget Control Act of 2011 included provisions to reduce the federal deficit. The Budget Control Act, as amended, resulted in the imposition of reductions of up to 2% in Medicare payments to providers which began in April 2013 and will remain in effect through 2025 unless additional congressional action is taken. These or other similar reductions in government healthcare spending could result in reduced demand for our products or additional pricing pressure.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Additionally, individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs.

Employees

As of December 31, 2019, we had 79 full-time employees. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Backlog

We have no material backlog of orders.

Financial Information about Segments

We manage our operations as two reportable segments for the purposes of assessing performance and making operating decisions. See “Note 15 – Segment Information” in the notes to the financial statements included elsewhere in this Annual Report on Form 10-K.

Geographic Information

During 2019 and 2018, substantially all of our long-lived assets were located within the United States. Approximately 9% of our revenue for 2019 and 7% of our 2018 revenue came from international markets. Please see Note 2 to our audited financial statements included in Item 8 of this Annual Report on Form 10-K for additional information related to our U.S. and non-U.S. revenue.

Seasonality

To date, we have not observed seasonal trends in our business.

Corporate and Other Information

We were incorporated in California on September 4, 2002 and reincorporated in Delaware in July 2018. Our principal executive offices are located at 2070 Las Palmas Drive, Carlsbad, California 92011 and our telephone number is (760) 804-1648 or (877) 635-1800 toll-free. Our corporate website address is www.ramed.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this document, and you should not consider information on our website to be part of this document.

You may find on our website at www.ramed.com electronic 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 of 1934. Such filings are placed on our website as soon as reasonably possible after they are filed with the SEC.

Investors and others should note that we announce material financial information to our investors using our investor relations website (<https://ir.ramed.com/>), SEC filings, press releases, public conference calls and webcasts. We use these channels as well as social media to communicate with our members and the public about our company, our services and other issues. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on the social media channels listed on our investor relations website.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, before making an investment decision. The risks and uncertainties described below may not be the only ones we face. If any of the risks actually occur, our business, financial condition, operating results, cash flows and prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.

Risks Related to Our Business and Products

We have determined that there is substantial doubt about our ability to continue as a going concern, and we will need additional financings to execute our business plan and to fund our operations.

We do not yet generate sufficient revenues from our operations to fund our activities and are therefore dependent upon external sources for financing our operations. As a result, our financial statements include disclosures expressing substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of the uncertainty regarding our ability to continue as a going concern. This disclosure with respect to our ability to continue as a going concern could materially limit our ability to raise additional funds through the issuance of equity or debt securities or otherwise. Future reports on our financial statements may continue to include such disclosures. If we cannot continue as a going concern, our stockholders may lose their entire investment in our common stock.

Historically, we have financed our operations through private and public placement of equity securities. Our ability to obtain financing is subject to multiple risks, many of which are beyond our control. We intend to raise additional capital in order to fund our operations and grow our business, however, no assurance can be provided that we will be able to do so on commercially reasonable terms, or at all. To the extent that we are unable to do so, we may need to curtail or cease our operations and implement a plan to extend payables or reduce overhead until sufficient additional capital is raised to support further operations.

We may be unable to successfully remedy the performance and calibration issues associated with our DABRA catheters, achieve market acceptance of DABRA, or achieve revenue growth.

Our ability to grow our revenue in future periods will depend on our ability to successfully remedy the inconsistencies in our DABRA catheter performance, penetrate our target markets and increase sales of our products and any new product indications that we introduce, which will, in turn, depend in part on our success in growing our installed unit base and driving continued use of our systems, including long-term adoption by physicians. In the third quarter of 2019, we reduced the number of sales and marketing personnel in order to conserve cash and focus our efforts on key territories and accounts. We also initiated a voluntary recall of our DABRA catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters. These actions will likely make it more difficult in the near term to achieve significant revenue growth. In addition, new product indications will also need to be approved or cleared by the FDA and comparable non-U.S. regulatory agencies to help drive revenue growth. If we cannot achieve revenue growth, it would have a material adverse effect on our business, financial condition, and results of operations.

Our success depends in large part on DABRA. If we are unable to successfully manufacture, market and sell DABRA, our business prospects will be significantly harmed.

Our future financial success will depend substantially on our ability to effectively and profitably manufacture, market and sell DABRA. The commercial success of DABRA will depend on a number of factors, including the following:

- our ability to timely remedy the current inconsistencies in our DABRA catheter performance and identify future issues;
- our ability to continue commercializing DABRA for its indications for use with a smaller sales force;
- our ability to receive FDA clearance for an atherectomy indication for use;
- our ability to successfully conduct the voluntary recall of our DABRA catheters and subsequently achieve market acceptance following the change in our labeling from a 12-month to two-month shelf life;

- any agreements or punitive actions that arise out the settlement of the ongoing investigations by the governmental agencies;
- our ability to receive regulatory clearance for, and timely introduce, enhancements to the DABRA catheter design;
- the effectiveness of our and our distributors' marketing and sales efforts in the U.S. and abroad, including our efforts to build out and properly train our sales team;
- our ability to attract, motivate, train and retain experienced and qualified sales personnel;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competing treatments, including the time and expertise needed for training to effectively use the DABRA system as compared to competing treatments;
- our ability to properly support DABRA usage with our own qualified personnel or our ability to properly train and support our customers to use the DABRA system effectively on their own;
- the availability of coverage and adequate levels of reimbursement under private and governmental health insurance plans for DABRA-based procedures;
- our ability to obtain, maintain, and enforce our intellectual property rights in and to DABRA;
- our ability to achieve and maintain compliance with regulatory requirements applicable to DABRA;
- our ability to continue to develop, validate and maintain a commercially viable manufacturing process that is compliant with current Good Manufacturing Practices, or cGMP; and
- whether we are required by the FDA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for future or current indications.

If we fail to successfully market, manufacture and sell DABRA, we may not be able to achieve or maintain profitability, which will have a material adverse effect on our business, financial condition, and results of operations.

We may face additional issues associated with the voluntary recall of our DABRA catheters if we are unable to show that we initiated a timely recall and improved calibration rates in the use of our DABRA catheters.

In the third quarter of 2019 we initiated a voluntary recall of our DABRA catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters, as we observed through field data and internal testing that catheters more than two months from sterilization have a significantly higher rate of non-calibration. The newly labeled DABRA catheters have shown a significant decrease in non-calibrations. However, if this trend does not continue, there could be an expanded or additional recall which would harm our reputation with our existing physician customers, adversely affect our ability to generate revenue, and have an adverse effect on our financial condition and results of operations. Any future recall could cause further harm to our reputation, cause a decrease in revenue, and require us to devote financial resources from other aspects of our business.

Physicians and staff may not commit enough time to sufficiently learn how to use our products.

In order for physicians and staff to learn to use our products, we encourage physicians to attend structured training sessions in order to familiarize themselves with our technology. There are many nuances to successfully using our products. For example, the DABRA catheter is fragile and may be prone to bending, a problem known as kinking. In addition, the DABRA laser needs to be calibrated correctly for each use. During the fourth quarter of 2018 and into 2019, we saw an increase in calibration issues experienced by physicians. In addition, in reviewing the performance inconsistencies, we found that our catheters occasionally overheated, which could cause a risk of injury to patients and physicians. Further, physicians and their staff must utilize the technology on a regular basis to ensure they maintain the skill set necessary to use our products. This will depend on their willingness to attend training sessions or sufficiently familiarize themselves with DABRA. An inability to train a sufficient number of physicians to generate adequate demand for our products could have a material adverse effect on our business, financial condition, and results of operations.

Our products may not gain or maintain market acceptance among physicians and patients and others in the medical community.

Our success will depend, in part, on the acceptance of our products as safe, useful and, with respect to physicians, cost effective and easy to use. We cannot predict how quickly, if at all, catheterization laboratories and physicians will accept our products or, if accepted, how frequently they will be used. Patients and their care providers must believe our products offer benefits over alternative treatment methods. Additional factors that will influence whether our products gain and maintain market acceptance, include:

- whether we are able to successfully and timely remedy the inconsistencies in our DABRA catheter performance;
- whether physicians, catheterization laboratory owners and operators, patients, and others in the medical community consider our products safe, effective, and cost-effective treatment methods;
- whether we are able to receive FDA clearance for an atherectomy indication for use;
- the potential and perceived advantages of our products over alternative treatment methods;
- the convenience, amount of training required, and ease of use of DABRA and Pharos relative to alternative treatment methods;
- matters arising out of our completed Audit Committee investigation, securities class actions, derivative lawsuits and government investigations;
- the prevalence and severity of any side effects associated with using our products;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling cleared or approved by the FDA or other authorities;
- the cost of treatment in relation to alternative treatments methods;
- pricing pressure, including from group purchasing organizations, or GPOs, seeking to obtain discounts on DABRA and Pharos based on the collective buying power of the GPO members;
- the availability of adequate coverage, reimbursement and pricing by third-party payors, including government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors, including government authorities;
- our ability to provide incremental clinical and economic data that shows the safety and clinical efficacy and cost effectiveness of, and patient benefits from, our products; and
- the effectiveness of our sales and marketing efforts for DABRA and Pharos.

If we do not adequately educate physicians about peripheral artery disease, or peripheral artery disease, or PAD, and the existence and proper use and reimbursement of our products, DABRA may not gain market acceptance, as many physicians do not routinely screen for PAD while screening for coronary artery disease, or CAD. Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products or technologies are introduced that are received more favorably or are more cost effective. Failure to achieve or maintain market acceptance and/or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition, and results of operations.

The continuing development of our products depends upon our developing and maintaining strong working relationships with physicians.

The research, development, marketing and sale of our current products and any potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. At the same time, companies in the medical device industry are under increasing scrutiny by

the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and the DOJ for improper relationships with physicians. In October 2019, the DOJ provided us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. In November 2019, we learned that the DOJ opened a criminal investigation relating to the Company. We have been, and intend to continue, cooperating with the DOJ investigations. Our failure to comply with requirements governing the industry's relationships with physicians, including the reporting of certain payments to physicians under the National Physician Payment Transparency Program (Open Payments) or an investigation into our compliance by the OIG or the DOJ, could impact physicians' willingness to conduct business with us, which would have a material adverse effect on our business, financial condition, and results of operations.

We are experiencing inconsistencies in our DABRA catheter performance. This and any other development or manufacturing problems or delays that could limit the potential growth of our revenue or increase our losses.

Beginning in the fourth quarter of 2018, we started experiencing inconsistencies in our DABRA catheter performance. We believed at the time, that these inconsistencies related to controlling the temperature of the oven used in the manufacturing process, which we had previously referred to as production limitations. These inconsistencies led to an increase in the number of catheters that failed to calibrate at customer sites, despite calibrating successfully during our quality assurance steps. During that same period, our sales team noted higher rates of non-calibration of catheters at customer physician offices. The higher than anticipated rates of non-calibration resulted in customer dissatisfaction with the product, resulting in what we believe to be fewer purchases by our customers and therefore lower revenue during the fourth quarter of 2018 and into 2019, however, such amount is not determinable. In response, we upgraded our temperature control regulator and made certain changes in our production flow and validated the changes that we believed corrected the production limitations. After manufacturing several well-performing lots with this upgraded process, the percentage of catheters that fail to calibrate began to increase after decreasing during April and May 2019. After collecting field data and performing internal testing, we observed that while catheters can perform satisfactorily up to one year, catheters that were more than two months from sterilization, had a significantly higher rate of non-calibration than catheters that were within two months from sterilization. As a result, in September 2019, we initiated a voluntary recall of our catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters, which we believe will significantly reduce the number of catheters that fail to calibrate. If our DABRA catheters are unable to consistently calibrate in the field, DABRA sales may continue to be adversely impacted and we will continue to incur additional costs.

There can be no assurance that we will be able to timely correct the performance issues related to the DABRA catheters or that a premarket FDA submission would not be required for such changes. In addition, the manufacture of our products is subject to strict regulatory requirements as described in the risk factor entitled "Our medical device operations are subject to pervasive and continuing FDA regulatory requirements." Problems can arise during the manufacturing process for a number of reasons, including equipment malfunction, failure to maintain or follow necessary protocols and procedures, raw material problems or human error. If we are unable to remedy our inconsistencies in our DABRA catheter performance or if we otherwise fail to meet our internal quality standards or the quality system regulations enforced by the FDA or other applicable regulatory bodies, which include detailed manufacturing and quality obligations, our reputation could be damaged, we could be required to issue a safety alert to our customer or initiate a recall, we could incur product liability and other costs, product approvals could be delayed, suspended or revoked, enforcement action could be initiated by regulatory authorities, we could be required to cease commercialization of DABRA and our business could otherwise be adversely affected.

In addition, our production processes and assembly methods may require additional changes to accommodate any significant expansion of our manufacturing capacity, which may increase our manufacturing costs, delay production of our products, reduce our product margin, be subject to FDA approval and adversely impact our business. Conversely, if demand for our products shifts such that a manufacturing facility is operated below its capacity for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.

Additionally, since our products are manufactured at our sole manufacturing facility in Carlsbad, any contamination of the controlled environment, equipment malfunction, or failure to strictly follow procedures can significantly reduce our yield. A drop in yield can increase our cost to manufacture our products or, in more severe cases, require us to halt the manufacture of our products until the problem is resolved. Identifying and resolving the cause of a drop in yield can require substantial time and resources.

If our manufacturing activities are adversely impacted, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors' products, which would have a material adverse effect on our business, financial condition, and results of operations.

We will require additional capital to finance our operations, which may not be available to us on acceptable terms or at all.

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development and commercialization efforts. As of December 31, 2019, we had cash and cash equivalents and short-term investments of \$30.6 million and an accumulated deficit of \$117.2 million. In 2019, we used \$33.2 million for operating activities. We have experienced recurring net losses from operations, negative cash flows from operating activities, and a significant accumulated deficit and expect to continue to incur net losses into the foreseeable future. As a result, our financial statements include explanatory disclosures expressing substantial doubt about our ability to continue as a going concern.

In the near term, we expect our recurring operational costs to decrease as a result of our cost savings initiatives. In the third quarter of 2019, we began implementing certain operational efficiency and cost savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives included targeted workforce reductions of our sales and marketing teams. We reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to five clinical specialists as of December 31, 2019. Further actions such as these may be required on an ongoing basis to optimize our organization. For example, we may need to decrease or defer capital expenditures and development activities or implement further operating expense reduction measures. Such measures may impair our ability to invest in developing, marketing and selling new and existing products. Until we are able to generate additional revenue to support our level of operating expenses, we will continue to incur operating and net losses and negative cash flow from operations. Additionally, we anticipate additional costs related to our Audit Committee investigation, securities class action and derivative lawsuits, and the Civil Investigative Demand issued by the DOJ and the DOJ's criminal investigation. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase our profitability.

The amount and timing of any expenditures needed to implement our commercial strategy will depend on numerous factors, including:

- whether we are able to successfully and timely remedy the inconsistencies in our DABRA catheter performance;
- our ability to achieve sufficient market acceptance, the ability for our customers to get coverage and adequate reimbursement from third-party payors and our ability to achieve acceptable market share for DABRA and Pharos;
- the cost to establish, maintain, expand, and defend the scope of our intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights;
- the emergence of competing technologies and other adverse market developments;
- the costs associated with manufacturing, selling, and marketing DABRA and Pharos for their cleared or approved indications or any other indications for which we receive regulatory clearance or approval, including the cost and timing of expanding our manufacturing capabilities, as well as establishing our sales and marketing capabilities;

- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the timing, receipt, and amount of license fees and sales of, or royalties on, our future products or future improvements on our existing products, if any; and
- the time and cost necessary to complete post-marketing studies that could be required by regulatory authorities or other studies required to obtain clearance for additional indications.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our products, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. If we are unable to obtain adequate financing on commercially reasonable terms when needed, we may have to delay, reduce the scope of or suspend our sales and marketing efforts, which would have a material adverse effect on our business, financial condition, and results of operations.

We have incurred losses in recent periods and may be unable to achieve profitability in the future.

We incurred net losses of \$57.0 million and \$30.8 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of \$117.2 million. We expect to continue to incur significant manufacturing, product development, regulatory and other expenses as we continue to remedy the inconsistencies in our DABRA catheter performance, to obtain regulatory clearances or approvals for our products in additional jurisdictions and for additional indications, and to develop new products or add new features to our existing products. In addition, our general and administrative expenses have increased following our initial public offering and we expect these costs to continue due to the additional costs associated with being a public company. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenue in order to achieve and sustain profitability and, even if we achieve profitability, we cannot be sure that we will remain profitable for an extended period of time. Our failure to achieve or maintain profitability would have a material adverse effect on our business, financial condition, and results of operations and could negatively impact the value of our common stock.

Matters relating to or arising from our Audit Committee investigation, including regulatory investigations and proceedings, litigation matters and potential additional expenses, may adversely affect our business and results of operations.

As previously disclosed in our public filings, the Audit Committee completed its internal investigation. In connection with the Audit Committee investigation, we voluntarily contacted the SEC Enforcement Division in August 2019 to advise them of the investigation of certain allegations made by a former employee. In October 2019, the Department of Justice, or DOJ, served the Company with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether the Company fraudulently obtained 510(k) marketing clearance for the Company's ablation devices marketed under the trade name DABRA, whether the Company marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether the Company paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. In November 2019, we learned that the DOJ opened a criminal investigation relating to the Company. On November 13, 2019 the Securities and Exchange Commission (the "SEC") notified us that it is conducting an investigation. We have been, and intend to continue, cooperating in these investigations.

If one or more government agencies commences legal action, we could be required to pay significant penalties and become subject to injunctions, a cease and desist order and other equitable remedies. If our operations are found to violate federal law or regulations, or if we settle these investigations, we may be subject to civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which would have a material adverse effect on our business, financial condition, and results of operations.

We have incurred, and may continue to incur, significant expenses related to legal, accounting, and other professional services in connection with the Audit Committee investigation and related legal matters. These expenses and the diversion of the attention of the management team that has occurred, and is expected to continue, has adversely affected, and could continue to adversely affect, our business, financial condition, and results of operations.

As a result of the matters reported above, we are exposed to greater risks associated with litigation, regulatory proceedings and government enforcement actions. In addition, securities class actions and other lawsuits have been filed against us, our directors and officers. Any future investigations or additional lawsuits could have a material adverse effect on our business, financial condition, and results of operations.

If our sole manufacturing facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to manufacture and sell our products and to pursue our research and development efforts may be jeopardized.

We currently manufacture and assemble our products in our sole manufacturing facility in Carlsbad, California. Our products consist of components sourced from a variety of suppliers, with final assembly completed at our facility. Our facility and equipment, or those of our suppliers, could be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, fires, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, extreme weather conditions, medical epidemics, and other natural or man-made disasters, pandemics, epidemics, or other business interruptions, for which we are predominantly self-insured. Any of these may render it difficult or impossible for us to manufacture products for an extended period of time. If our facility is inoperable for even a short period of time, the inability to manufacture our current products, and the interruption in research and development of any future products, may result in harm to our reputation, increased costs, lower revenue and the loss of customers, which would have a material adverse effect on our business, financial condition, and results of operations. Furthermore, it could be costly and time-consuming to repair or replace our facilities and the equipment we use to perform our research and development work and manufacture our products. We also rely on third-party component suppliers, and our ability to obtain commercial supplies of our products could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption, which would have a material adverse effect on our business, financial condition, and results of operations.

The emergence and effects related to a pandemic, epidemic or outbreak of an infectious disease could adversely affect our operations.

If a pandemic, epidemic, outbreak of an infectious disease or other public health crisis were to occur in an area in which we operate, our operations could be adversely affected. For example, in December 2019, a novel strain of Coronavirus was reported to have surfaced in Wuhan, China. The extent to which the novel Coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the novel Coronavirus and the actions to contain the novel Coronavirus or treat its impact, among others. If any disaster were to occur, our ability to operate our business could be seriously, or potentially completely, impaired. If any facilities that use our product were involved, or perceived as being involved, in treating patients from such an infectious disease, patients might cancel elective procedures or fail to seek needed care at those facilities, and our reputation may be negatively affected. Further, a pandemic, epidemic or outbreak might adversely affect our operations by disrupting or delaying production and delivery of materials and products in the supply chain or by causing staffing shortages. We have disaster plans in place and operate pursuant to infectious disease protocols, but the potential emergence of a pandemic, epidemic or outbreak is difficult to predict and could adversely affect our operations.

We are involved in securities litigation, and an adverse resolution of such litigation may adversely affect our business, financial condition, results of operations and cash flows.

In June 2019, we became the subject of a lawsuit alleging securities law violations based on alleged misstatements or omissions in the Registration Statement for our Initial Public Offering (our "IPO"). This type of litigation can be expensive and disruptive to normal business operations, and the outcome can be difficult to predict regardless of the facts involved. An unfavorable outcome with respect to this lawsuit could have a material adverse effect on our business, financial condition, results of operations or cash flows. For additional information regarding this lawsuit, see Note 14, "Commitments and Contingencies," in the notes to the financial statements.

The delayed filing of some of our periodic SEC reports has made us currently ineligible to use a registration statement on Form S-3 to register the offer and sale of securities, which could adversely affect our ability to raise future capital or complete acquisitions.

As a result of the delayed filing of some of our periodic reports with the SEC, we are not currently eligible to register the offer and sale of our securities using a registration statement on Form S-3. To regain eligibility to use Form S-3, we must be timely and current in our public reporting for a period of twelve months preceding our intended S-3 filing. Should we wish to register the offer and sale of our securities to the public prior to the time we are eligible to use Form S-3, both our transaction costs and the amount of time required to complete the transaction could increase, making it more difficult to execute any such transaction successfully and potentially harming our financial condition.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products and could result in recalls, delayed shipments and rejection of our products and damage to our reputation, and could expose us to regulatory or other legal action.

We face an inherent risk of product liability as a result of the marketing and sale of our products. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable during manufacturing, marketing or sale. For example, in connection with the review of our performance inconsistencies, our catheters were found to occasionally overheat. Any product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or breach of warranty. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on physicians in connection with the use of our products on patients. If these physicians are not properly trained, including on the intended use, or are negligent, the capabilities of our products may be diminished or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies.

There can be no assurance that we will be able to detect, remedy and report all defects in the products that we sell, including successfully remedying the issues with our catheters' performance. These issues with performance could result in the rejection of our products by physicians, damage to our reputation, lost sales, diverted development resources and increased customer service and support costs and warranty claims. Individuals could sustain injuries from our products, and we may be subject to claims or lawsuits resulting from such injuries. There is a risk that these claims or liabilities may exceed, or fall outside the scope of, our insurance coverage. Moreover, we may not be able to retain adequate liability insurance in the future.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit, delay or halt commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- harm to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- diversion of management's time and our resources;

- monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- inability to market and sell our products; and
- a resulting decline in the price of our common stock.

We believe our product liability insurance is customary for similarly situated companies, but it may not be adequate to cover all liabilities that we may incur. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition, and results of operations.

We face substantial competition, which may result in others discovering, developing or commercializing products more successfully than us.

The medical device industry is intensely competitive and subject to rapid and significant technological change. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may also develop products that are more effective, more convenient, more widely used, less costly, have higher reimbursement coverage or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, our programs. Competition for these people in the medical device industry is intense and we may face challenges in retaining and recruiting such individuals if, for example, other companies may provide more generous compensation and benefits, more diverse opportunities, and better chances for career advancement than we do. Some of these advantages may be more appealing to high-quality candidates and employees than those we have to offer. In addition, the decline in our stock price has created additional challenges by reducing the retention value of our equity awards. Because of the complex and technical nature of our systems and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our technology, which would have a material adverse effect on our business, financial condition, and results of operations.

We may be unable to compete successfully with companies in our highly competitive industry, many of whom have substantially greater resources than we do.

The healthcare industry is highly competitive. There are numerous approved products for treating vascular and dermatological diseases in the indications in which we have received clearance or approval and those that we may pursue in the future. Many of these cleared or approved products are well-established and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may encourage the use of competitors' products. In addition, many companies are developing products, and we cannot predict what the standard of care will be in the future.

Our primary competitors for DABRA include Medtronic plc, Cardiovascular Systems Inc., Boston Scientific Corp., Avinger, Inc., Koninklijke Philips N.V., including Volcano Corporation and Spectranetics Corporation, Becton Dickinson and Company, including products from the C.R. Bard acquisition, and Abbott Laboratories. These companies are manufacturers of products used in competing therapies within the peripheral arterial disease market such as:

- atherectomy, using mechanical and laser ablation methods to remove vascular blockages;
- balloon angioplasty and stents;
- specialty balloon angioplasty, such as scoring balloons, pillowing balloons, cutting balloons and drug-coated balloons; and
- amputation.

We also face competition from pharmaceutical companies that produce drugs which aim to destroy plaque or remove blockages in the bloodstream.

Our primary competitors for Pharos are The Daavlin Company, National Biological Corp., STRATA Skin Sciences and large pharmaceutical companies producing biologics used in the treatment of chronic skin conditions.

Many of our competitors have substantially greater financial, manufacturing, commercial, and technical resources than we do. There has been consolidation in the industry, and we expect that to continue. Larger competitors may have substantially larger sales and marketing operations than we do. This may allow those competitors to spend more time with current and potential customers and to focus on a larger number of current and potential customers, which gives them a significant advantage over our sales and marketing team and our international distributors in making sales. In addition, we are often selling to customers who already utilize our competitors' products and who have established relationships with our competitors' sales representatives and familiarity with our competitors' products.

We are also aware that some of our competitors have been giving false and misleading information to our customers regarding reimbursement for procedures using DABRA, alleging without any factual basis that procedures performed using DABRA are not reimbursable under atherectomy coding. While we believe that these allegations are without merit, they may be successful in dissuading physicians from using the DABRA system out of concerns regarding reimbursement.

Larger competitors may also have broader product lines, which enables them to offer customers bundled purchase contracts and quantity discounts. These competitors may have more experience than we have in research and development, marketing, manufacturing, preclinical testing, conducting clinical trials, obtaining FDA and non-U.S. regulatory clearances or approvals and marketing cleared or approved products. Our competitors may discover technologies and techniques, or enter into partnerships and collaborations, to develop competing products that are more effective or less costly than our products or the products we may develop. This may render our technology or products obsolete or noncompetitive. Our competitors may also be better equipped than we are to respond to competitive pressures. If we are unable to compete successfully in our industry, it would have a material adverse effect on our business, financial condition, and results of operations.

If DABRA and Pharos are not approved for new indications, our commercial opportunity will be limited.

We market and sell DABRA for use as a tool in the treatment of vascular blockages resulting from lower extremity vascular disease and Pharos for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma. Although physicians, in the practice of medicine, may prescribe or use marketed products for unapproved indications, manufacturers may promote their products only for the approved indications and in accordance with the provisions of the approved label. However, one of our strategies in the future is to pursue additional vascular indications for DABRA and additional dermatological indications for Pharos. Submitting the required applications for additional indications may require substantial additional funding beyond our cash and cash equivalents and short-term investments as of December 31, 2019. We cannot assure you that we will be able to successfully obtain approval for any of these additional product indications through the application process or that a premarket FDA submission may not be necessary.

Even if we obtain FDA clearance or approval to market our products for additional indications in the U.S., we cannot assure you that any such indications will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop our products for additional indications, our commercial opportunity will be limited, which would have a material adverse effect on our business, financial condition, and results of operations.

If we make acquisitions or divestitures, we could encounter difficulties that harm our business.

To date, the growth of our business has been organic, and we have no experience in acquiring other businesses, products or technologies. We may acquire companies, products or technologies that we believe to be complementary to the present or future direction of our business. If we engage in such acquisitions, we may have difficulty integrating the acquired personnel, financials, operations, products or technologies. Acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees, increase our expenses, subject us to liabilities, and increase our risk of litigation, all of which could harm our business. If we use cash to acquire companies, products or technologies, it may divert resources otherwise available for other purposes. If we use our common stock to acquire companies, products or technologies, our stockholders may experience substantial dilution.

Technological change may adversely affect sales of our products and may cause our products to become obsolete.

The medical device market is characterized by extensive research and development and rapid technological change. Technological progress or new developments in our industry could adversely affect sales of our products. Our products could be rendered obsolete because of future innovations by our competitors or others in the treatment of vascular diseases and dermatological diseases, which would have a material adverse effect on our business, financial condition, and results of operations.

Consolidation in the medical device industry could have an adverse effect on our revenue and results of operations.

Many medical device industry companies are consolidating to create new companies with greater market power. For example, the Spectranetics Corporation was acquired by Koninklijke Philips N.V in 2017. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for medical devices that incorporate components produced by us. If we reduce our prices because of consolidation in the healthcare industry, our revenue would decrease and our earnings, financial condition, or cash flows would suffer, which would have a material adverse effect on our business, financial condition, and results of operations.

We may be subject to enforcement actions, competitor lawsuits, or other claims if we engage or are found to have engaged in the off-label promotion of our products.

Our promotional materials and training methods must comply with FDA regulations and other applicable laws, including restraints and prohibitions on the promotion of off-label, or uncleared use, of our products. Physicians may use our products for off-label use without regard to these prohibitions, as FDA regulations do not restrict or regulate a physician's choice of treatment within the practice of medicine. Although our policy is to follow published FDA guidance in order to avoid promoting our products improperly, the FDA or other regulatory agencies or third parties could disagree and conclude that we have engaged in off-label promotion. For example, our DABRA Laser System has been cleared by the FDA for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease and has an intended use for ablating a channel in occlusive peripheral vascular disease. We have not received FDA clearance or approval to market DABRA for an atherectomy indication, and we may not promote DABRA for an atherectomy indication. While our pivotal clinical study of the DABRA Laser System would not be sufficient to expand our FDA-cleared indication for use to an atherectomy indication for use, which the FDA currently defines to include a prespecified improvement in luminal patency, or prespecified increase in the openness of the artery at a pre-defined time point, such as six months following a DABRA procedure, using a consistent assessment tool, we believe that we can promote the device using the truthful and not misleading information from this study that is not inconsistent with our cleared indication.

During our initial public offering process, we received correspondence from a competitor claiming our promotion for DABRA as an atherectomy tool used by surgeons to treat peripheral vascular disease is off-label promotion for the product. We are also aware of similar claims being made to physicians by our competitors. We disagree with our competitors' claims and believe FDA's regulations and judicial case law allow companies to engage in certain forms of truthful, non-misleading and non-promotional speech concerning the off-label use of products, and we believe that we comply with these restrictions. We cannot predict the extent to which our competitors may be successful in dissuading physicians from using the DABRA system out of concerns regarding

reimbursement. Furthermore, we may incur additional liability from claims initiated under the Lanham Act or other federal and state unfair competition laws with respect to how our products have been marketed and promoted.

In addition, we operate in an industry characterized by extensive litigation. However, the scope of potential liability with respect to any such claims, enforcement actions, or lawsuits is uncertain, and we cannot assure you that we will not receive claims from competitors or other third parties or be subject to enforcement actions in the future from regulatory agencies. For example, the FDA, FTC, the Office of the Inspector General of the Department of Health and Human Services (“HHS”), the DOJ and various state Attorneys General actively enforce laws and regulations that prohibit the promotion of off-label uses. In October 2019, the DOJ served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. In November 2019, we learned that the DOJ opened a criminal investigation relating to the Company. We have been, and intend to continue, cooperating with the DOJ in its investigations. The False Claims Act, prohibits, among other things, making a fraudulent claim for payment of federal funds, causing such a fraudulent claim to be made, or making a false statement to get a false claim paid. The government may assert that a claim resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim under the False Claims Act. Many companies have faced government investigations or lawsuits by whistleblowers who bring a *qui tam* action under the False Claims Act on behalf of themselves and the government for a variety of alleged improper marketing activities, including providing free product to customers expecting that the customers would bill federal programs for the product, providing consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company’s products, and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs. In addition, the government and private whistleblowers have pursued False Claims Act cases against medical device companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses. Medical device and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs. If we are found to have improperly promoted off-label uses, we may be subject to significant liability, including civil fines, criminal fines and penalties, civil damages, exclusion from federal funded healthcare programs and potential liability under the federal False Claims Act and any applicable state false claims act. Due to the Civil Investigative Demand seeking information with respect to the False Claims Act investigation, we could incur substantial legal costs, including settlement costs, and business disruption responding to such investigation or suit, regardless of the outcome. If we are found to have violated the False Claims Act, it may result in significant financial penalties, on a per claim or statement basis, treble damages and exclusion from participation in federal health care programs. In addition, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials, which could negatively impact our marketing and decrease demand for our products. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers, competitors, or other persons claiming to be harmed by such conduct. Notwithstanding the regulatory restrictions on off-label promotion, the FDA’s regulations, guidance and judicial case law allow companies to engage in certain forms of truthful, non-misleading and non-promotional speech concerning the off-label use of products, for example FDA’s June 2018 guidance document, “Medical Product Communications That Are Consistent With the FDA-Required Labeling - Questions and Answers.” Nonetheless, the FDA, HHS, DOJ, and/or state Attorneys General, competitors, and other third parties may take the position that we are not in compliance with such requirements, and if such non-compliance is proven, it could harm our reputation, financial condition or divert financial and management resources from our core business, and would have a material adverse effect on our business, financial condition and results of operations. Moreover, any threatened or actual government enforcement actions or lawsuits by third parties could also generate adverse publicity, which could decrease demand for our products and require that we devote substantial resources that could be used productively on other aspects of our business.

Litigation and other legal proceedings may adversely affect our business.

From time to time we are involved in and may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action, and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. For example, we are currently a party to securities litigation and other litigation as set forth in Part II, Item 1 “Legal Proceedings.” Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition, and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers’ confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

We must indemnify officers and directors, including, in certain circumstances, former employees and directors, against all losses, including expenses, incurred by them in legal proceedings and advance their reasonable legal defense expenses, unless certain conditions apply. A prolonged uninsured expense and indemnification obligation could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to numerous laws and regulations related to healthcare fraud and abuse, false claims, anti-bribery and anti-corruption laws, such as the U.S. Anti-Kickback Statute and Foreign Corrupt Practices Act of 1977, in which violations of these laws could result in substantial penalties, exclusion and prosecution.

In the United States, we are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our products. The federal Anti-Kickback Statute prohibits persons from knowingly and willingly 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. 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. Any allegation, investigation, or violation of domestic healthcare fraud and abuse laws could result in government or internal investigations, significant diversion of resources, exclusion from government healthcare programs and the curtailment or restructuring of our operations, significant fines, penalties, or other financial consequences, any of which may ultimately have a material adverse effect on our business, financial condition, and results of operations. For example, our Audit Committee identified potential healthcare compliance risk areas relating to the previous sales, marketing and education programs for our products such as lacking documentation of sufficient detail and specificity regarding payments that could be perceived as overpayments to obtain business from certain physicians, salespeople being instructed to provide potentially improper reimbursement information by characterizing treatment with DABRA as atherectomy and encouraging doctors to seek reimbursement under Medicare using atherectomy codes, and that determinations to direct potentially valuable benefits and opportunities to doctors were informed by sales prospects.

In October 2019, the DOJ served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. In November 2019, we learned that the DOJ opened a criminal investigation relating to the Company. We have been, and intend to continue, cooperating with the DOJ in its investigations.

For our sales and operations outside the United States, we are similarly subject to various heavily-enforced anti-bribery and anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, U.K. Bribery Act, and similar laws around the world. These laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third parties, fail to comply with the FCPA and other anti-corruption and anti-bribery laws.

We leverage various third parties to sell our products and conduct our business abroad, including to government owned universities and hospitals. We, our distributors and channel partners, and our other third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities (such as in the context of obtaining government approvals, registrations, or licenses or sales to government owned or controlled healthcare facilities, universities, institutes, clinics, etc.) and may be held liable for the corrupt or other illegal activities of these third-party business partners and intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize such activities. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, while we have adopted and implemented internal control policies and procedures and employee training and compliance programs to deter prohibited practices, such compliance measures ultimately may not be effective in prohibiting our employees, contractors, third parties, intermediaries or agents from violating or circumventing our policies and/or the law.

Responding to any enforcement action or related investigation, such as the current CID, may result in a materially significant diversion of managements attention and resources and significant defense costs and other professional fees. Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, healthcare laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, financial condition, and results of operations.

Governmental export or import controls could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our products may be subject to U.S. export controls. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, we may be fined or other penalties could be imposed, including a denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely materially and adversely affect our business, financial condition, and results of operations.

A variety of risks associated with marketing our products internationally could materially adversely affect our business.

In addition to selling our products in the U.S., we sell DABRA and Pharos outside of the U.S. We are subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- differing reimbursement regimes in foreign countries, including price controls and lower payment;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- product shortages resulting from any events affecting raw material or finished good supply or distribution or manufacturing capabilities abroad;
- the impact of the current situation relating to trade with China and tariffs and other trade barriers that may be implemented by governmental authorities;
- the impact of public health epidemics on the global economy, such as the Coronavirus currently impacting China and elsewhere; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations, which would have a material adverse effect on our business, financial condition, and results of operations.

We face additional credit and compliance risks related to our international sales using foreign distributors.

We partner with distributors for DABRA and Pharos in select geographies outside of the U.S. For the year ended December 31, 2019, approximately 9% of our sales were outside of the U.S. We may not be able to collect all of the funds owed to us by our foreign distributors. Some foreign distributors may experience financial difficulties, including bankruptcy, which may hinder our collection of accounts receivable. Where we extend credit terms to distributors, we periodically review the collectability and creditworthiness when determining the payment terms for such distributors. If our uncollectible accounts exceed our expectations, this could adversely impact our operating results. In addition, failure by our foreign distributors to comply with the Foreign Corrupt Practices Act or similar laws, insurance requirements, or other contract terms could have a negative impact on our business. Failure to manage the risks related to our foreign distributors would have a material adverse effect on our business, financial condition, and results of operations.

Changes in trade policies among the U.S. and other countries, in particular the imposition of new or higher tariffs, could place pressure on our average selling prices as our customers seek to offset the impact of increased tariffs on their own products. Increased tariffs or the imposition of other barriers to international trade could have a material adverse effect on our revenues and operating results.

The U.S. has imposed or proposed new or higher tariffs on certain products exported by a number of U.S. trading partners, including China, Europe, Canada, and Mexico. In response, many of those trading partners, including China, have imposed or proposed new or higher tariffs on American products. Continuing changes in government trade policies create a heightened risk of further increased tariffs that impose barriers to international trade. During the year ended December 31, 2019, approximately 9% of our revenue came from international markets.

Tariffs on our customers' products may adversely affect our gross profit margins in the future due to the potential for increased pressure on our selling prices by customers seeking to offset the impact of tariffs on their own products. We believe that increases in tariffs on imported goods or the failure to resolve current international trade disputes could have a material adverse effect on our business and operating results.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive medical devices industry depends upon our ability to attract and retain highly qualified managerial, scientific, sales and medical personnel. We are highly dependent on our senior management team. The loss of the services of any of our executive officers and other key employees, and our inability to find suitable replacements could result in delays in product development and harm our business.

For example, we terminated our Chief Executive Officer on August 11, 2019 and are searching for a permanent chief executive officer. We face intense competition for executive-level talent from a variety of sources, including from current and potential competitors in the medical device and healthcare industries, and it may be difficult to find a new chief executive officer on a timely basis. Our continued success is dependent, in part, upon our ability to attract and retain superior executive officers, including a permanent chief executive officer.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued stock options and restricted stock units that vest over time. The value to employees of stock options and restricted stock units that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. The decline in our stock price may create additional challenges by reducing the retention value of our equity awards to these employees. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition, and results of operations.

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of DABRA and Pharos, as well as for accounting, financial reporting, data storage, compliance, purchasing and inventory management. We do not have redundant information technology systems at this time. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures and user errors, among other malfunctions. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks. Technological interruptions would impact our business operations would disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers’ ability use our products for treatments. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition, and results of operations. Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount, subject to deductibles, and we cannot be certain that such potential losses will not exceed our policy limits. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition, and results of operations.

Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud.

We are required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with this annual report filed on Form 10-K for the year ended December 31, 2019. As an “emerging growth company,” we will avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an “emerging growth company.” When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the U.S. Securities and Exchange Commission, or SEC, or other regulatory authorities, which would require additional financial and management resources.

In reviewing the allegations and findings from an Audit Committee investigation related to an initially anonymous complaint, as well as additional matters discovered during the course of the investigation, as more fully described in Item 9A, “*Controls and Procedures*,” we identified material weaknesses in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to the aggregation of control deficiencies in the Company’s control environment, in particular an inappropriate “tone at the top” set by certain members of senior management, a failure to promote adherence to our Code of Ethics and Conduct, and the lack of sufficient competent resources in key roles at the organization.

The material weaknesses discussed above have been remediated as of December 31, 2019. We have incurred significant costs to remediate these weaknesses, primarily personnel costs, external consulting and legal fees, system implementation costs, and related indirect costs including the use of facilities and technology. However, completion of remediation does not provide assurance that our controls will operate properly or that our financial statements will be free from error, which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. There may be additional undetected material weaknesses in our internal control over financial reporting, as a result of which we may not detect financial statement errors on a timely basis. Further, to the extent we identify additional material weaknesses, we will not be able to fully assess whether corrective measures will remediate the material weakness in our internal control over financial reporting until we have completed our implementation efforts and sufficient time passes in order to evaluate their effectiveness. In addition, if we identify additional errors that result in material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. Moreover, in the future we may engage in business transactions, such as acquisitions, reorganizations or implementation of new information systems that could negatively affect our internal control over financial reporting and result in material weaknesses.

If we identify additional material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, we may be late with the filing of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our core business, and would have a material adverse effect on our business, financial condition and results of operations.

In order to increase our revenue over the longer term, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

At December 31, 2019, we had 79 full-time employees. In the third quarter of 2019, we began implementing certain operational efficiency and cost savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives include targeted workforce reductions of our sales and marketing teams. We reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to five clinical specialists as of December 31, 2019.

Over the longer term, we intend to hire and train additional skilled sales personnel. At such time, we would expect to need additional managerial, operational, sales, marketing, financial, and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees, including additional members of our sales force;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully market and sell our products will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our products and, accordingly, may not achieve our research, sales and marketing goals, which would have a material adverse effect on our business, financial condition, and results of operations.

We actively employ social media as part of our marketing strategy, which could give rise to regulatory violations, liability, fines, breaches of data security or reputational damage.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us, our employees or our customers to communicate about our products or business may cause us to be found in violation of applicable requirements, including requirements of regulatory bodies such as the FDA and Federal Trade Commission. For example, promotional communications and endorsements on social media that, among other things, promote our products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label uses"), do not contain a fair balance of information about risks associated with using our products, make comparative or other claims about our products that are not supported by sufficient evidence, and/or do not contain required disclosures could result in an enforcement actions against us. In addition, adverse events, product complaints, off-label usage by physicians, unapproved marketing or other unintended messages posted on social media could require an active response from us, which may not be completed in a timely manner and could result in regulatory action by a governing body. Further, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our corporate policies or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image and goodwill, which would have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Regulatory Approval and our Industry

Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

The FDA and similar agencies regulate our products as medical devices. Complying with these regulations is costly, time consuming, complex and uncertain. FDA regulations and regulations of similar agencies are wide-ranging and include, among other things, oversight of:

- product design, development, manufacture (including suppliers) and testing;
- pre-clinical and clinical studies;
- product safety and effectiveness;
- product labeling;
- product storage and shipping;
- record keeping;
- pre-market clearance or approval;
- marketing, advertising and promotion;
- product sales and distribution;
- product changes;
- product recalls; and
- post-market surveillance and reporting of deaths or serious injuries and certain malfunctions.

Our current products are subject to extensive regulation by the FDA and non-U.S. regulatory agencies. Further, all of our potential products and improvements of our current products will be subject to extensive regulation and will likely require permission from regulatory agencies and ethics boards to conduct clinical trials, and clearance or approval from the FDA and non-U.S. regulatory agencies prior to commercial sale and distribution. Failure to comply with applicable U.S. requirements regarding, for example, promoting, manufacturing or labeling our products, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. The FDA can also refuse to clear or approve pending applications. Any enforcement action by the FDA and other comparable non-U.S. regulatory agencies could have a material adverse effect on our business, financial condition, and results of operations.

Our medical device operations are subject to pervasive and continuing FDA regulatory requirements.

Medical devices regulated by the FDA are subject to “general controls” which include: registration with the FDA; listing commercially distributed products with the FDA; complying with cGMPs under the Quality System Regulations, or QSR; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting certain device field removals and corrections to the FDA; and obtaining premarket notification 510(k) clearance for devices prior to marketing. Some devices known as “510(k)-exempt” devices can be marketed without prior marketing clearance or approval from the FDA. In addition to the “general controls,” some Class II medical devices are also subject to “special controls,” including adherence to a particular guidance document and compliance with the performance standard. As Class II, 510(k)-cleared devices, our products are subject to both general and special controls. Instead of obtaining 510(k) clearance, most Class III devices are subject to premarket approval, or PMA. None of our current products are Class III devices, but future products could be, which would subject them to the PMA process.

Many medical devices, such as medical lasers, are also regulated by the FDA as “electronic products.” In general, manufacturers and marketers of “electronic products” are subject to certain FDA regulatory requirements intended to ensure the radiological safety of the products. These requirements include, but are not limited to, filing certain reports with the FDA about the products and defects/safety issues related to the products as well as complying with radiological performance standards.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting, or MDR, requirements, including the reporting of adverse events and malfunctions related to our products. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales. For example, the Audit Committee found that we failed to timely make at least two MDRs, to the FDA, which have since been reported. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearances or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which may have a material adverse effect on our business, financial condition, and results of operations.

The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices, and product quality management. Such reviews and investigations may result in the civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of our products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies, and result in our incurring substantial unanticipated costs and the diversion of key personnel and management's attention from their regular duties, any of which may have an adverse effect on our financial condition, results of operations and liquidity, and may result in greater and continuing governmental scrutiny of our business in the future.

Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, the U.S. Physician Payment Sunshine Act, now known as Open Payments, requires us to report to the Centers for Medicare & Medicaid Services, or CMS, payments and other transfers of value to all U.S. physicians and U.S. teaching hospitals, with the reported information made publicly available on a searchable website. Effective January 2022, we will also be required to collect and report information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which may also impact our business and which could have a material adverse effect on our business, financial condition, and results of operations.

Product clearances and approvals can often be denied or significantly delayed.

Under FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received 510(k) clearance, is authorized through the de novo classification process, or is the subject of an approved PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to another legally marketed product not subject to a PMA. Sometimes, a 510(k) clearance must be supported by preclinical and clinical data.

The PMA process typically is more costly, lengthy and stringent than the 510(k) process. Unlike a 510(k) review which determines "substantial equivalence," a PMA requires that the applicant demonstrate reasonable assurance that the device is safe and effective by producing valid scientific evidence, including data from preclinical studies and human clinical trials. Therefore, to obtain regulatory clearance or approvals, we typically must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to their satisfaction that our products satisfy the criteria for approval. Preclinical testing and clinical trials must comply with the regulations of the FDA and other government authorities in the U.S. and similar agencies in other countries.

We may be required to obtain PMAs, PMA supplements or additional 510(k) premarket clearances to market modifications to our existing products. The FDA requires device manufacturers to make and document a determination of whether a modification requires approval or clearance; however, the FDA can review a manufacturer's decision. The FDA may not agree with our decisions not to seek approvals or clearances for particular device modifications. If the FDA requires us to obtain PMAs, PMA supplements or pre-market clearances for any modification to a previously cleared or approved device, we may be required to cease manufacturing and marketing the modified device and perhaps also to recall such modified device until we obtain FDA clearance or approval. We may also be subject to significant regulatory fines or penalties.

The FDA may not approve our current or future PMA applications or supplements or clear our 510(k) applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business, financial condition, and results of operations.

The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations.

International regulatory approval processes may take more or less time than the FDA clearance or approval process. If we fail to comply with applicable FDA and comparable non-U.S. regulatory requirements, we may not receive regulatory clearances or approvals or may be subject to FDA or comparable non-U.S. enforcement actions. We may be unable to obtain future regulatory clearance or approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. A failure or delay in obtaining necessary regulatory clearances or approvals would materially adversely affect our business, financial condition, and results of operations.

Although we have obtained regulatory clearance for our products in the U.S. and certain non-U.S. jurisdictions, they will remain subject to extensive regulatory scrutiny.

Although our products have obtained regulatory clearance in the U.S. and certain non-U.S. jurisdictions, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, effectiveness, and other post-market information, including both federal and state requirements in the U.S. and requirements of comparable non-U.S. regulatory authorities.

Our manufacturing facility is required to comply with extensive requirements imposed by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to the QSR or similar regulations set by foreign regulatory authorities. Following our voluntary recall and given our Audit Committee findings, we have a heightened potential for an FDA inspection. As such, we will be subject to continual review and inspections to assess compliance with the QSR and adherence to commitments made in any 510(k) application. Accordingly, we continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory clearances or approvals that we have received for our products will be subject to limitations on the cleared or approved indicated uses for which the product may be marketed and promoted or to the conditions of approval, or contain requirements for potentially costly post-marketing testing. We are required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing product safety issues could result in increased costs to assure compliance. The FDA and other agencies, including the DOJ, closely regulate and monitor the post-clearance or approval marketing and promotion of products to ensure that they are marketed and distributed only for the cleared or approved indications and in accordance with the provisions of the cleared or approved labeling. We have to comply with requirements concerning advertising and promotion for our products.

Promotional communications with respect to devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's cleared or approved labeling. As such, we may not promote our products for indications or uses for which they do not have clearance or approval. However, physicians can use their independent and professional judgment and use our products for off-label purposes as FDA regulations do not restrict a physician's choice of treatment with the practice of medicine. For certain changes to a cleared product, including certain changes to product labeling, the holder of a cleared 510(k) application may be required to submit a new application and obtain clearance or approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with our facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- subject our manufacturing facility to an adverse inspectional finding or Form 483, or other compliance or enforcement notice, communication, or correspondence;
- issue warning or untitled letters that would result in adverse publicity or may require corrective advertising;
- impose civil or criminal penalties;
- suspend or withdraw regulatory clearances or approvals;
- refuse to clear or approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our sub-assembly suppliers' facilities;
- seize or detain products; or
- require a product recall.

In addition, violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition, and results of operations.

Our products may be subject to additional recalls, revocations or suspensions after receiving FDA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation, and adversely affect our business.

The FDA and similar foreign governmental authorities have the authority to order the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions, or other adverse events, such as serious injuries or deaths, or quality-related issues such as manufacturing errors or design or labeling defects. For example, the FDA conducted an unannounced facility inspection in December 2019. The FDA issued to us a Form 483 that included observations that schedules for the adjustment, cleaning, and other maintenance of equipment have not been adequately established, a device master record index was not current, and document control procedures have not been fully established. We are working diligently to address the issues identified in the Form 483. In addition, in the third quarter of 2019, we initiated a voluntary recall of DABRA catheters due to inconsistent performance caused by catheters that failed to calibrate. We recalled catheters with a 12-month shelf life and are replacing them with catheters with a two-month shelf life. Any government-mandated recall or additional voluntary recall by us could occur as a result of component failures, manufacturing errors, design or labeling defects or other issues. This voluntary recall and any future recalls of our products could divert managerial and financial resources, harm our reputation and adversely affect our business.

Depending on the corrective action we take to address a product's deficiencies or defects, the FDA may require, or we may voluntarily decide, that we will need to seek and obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including adverse inspection finding, FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

As part of our investigation into the DABRA device performance, we conducted an internal audit of the clinical study that was used to support the device's 510(k) application. The audit consisted of review of clinical study documentation that was retained by the study sponsor and found adequate evidence to support the safety and efficacy reported in the clinical study report submitted with the 510(k) application. The other observations identified by the audit were found to not have a major impact on the reported results of the study. If FDA were to disagree with the outcome of the audit and take the position that the issues with the clinical trial were reportable to the FDA, we could be required to issue a safety alert to our customers or initiate a recall, we could incur product liability and other costs, product approvals could be delayed, suspended or revoked, enforcement action could be initiated by regulatory authorities, we could be required to cease commercialization of DABRA and our business could otherwise be adversely affected.

In addition, we are subject to medical device reporting regulations that require us to report to the FDA or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would be likely to cause or contribute to a death or serious injury if the malfunction recurred. After a May 2018 inspection, the FDA issued to us a Form 483 that included observations for failure to properly evaluate whether certain complaints related to Pharos and DABRA that we have received rose to a level required to be reported to the FDA. At that time, in response, we informed the FDA that we have modified our complaint review procedures and we completed a retrospective evaluation and have not found any complaints which require a submission to the FDA. In connection with our Audit Committee investigation, the Audit Committee also found failures to properly identify reportable events or to file timely reports, as well as failure to address each of the May 2018 observations to FDA's satisfaction. These failures can subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

Material modifications to our devices may require new 510(k) clearances or premarket approvals or may require us to recall or cease marketing our devices until clearances or approvals are obtained.

Material modifications to the intended use or technological characteristics of our devices will require new 510(k) clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement, or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would constitute a material modification and would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new devices or for modifications to, additional indications for, our devices in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced devices in a timely manner, which in turn would harm our future growth. We have made modifications to our devices in the past and will make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop selling or marketing our devices as modified, which could harm our operating results and require us to redesign our platform devices. In these circumstances, we may also be subject to significant enforcement actions such as significant regulatory fines or penalties. Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to modify our previously cleared products, either by imposing stricter requirements on when a new 510(k) for a modification to a previously cleared product must be submitted, or applying more onerous review

criteria to such submissions. Specifically, on July 9, 2012, the FDA Safety and Innovation Act of 2012 was enacted which, among other requirements, obligates the FDA to prepare a report for Congress on the FDA's approach for determining when a new 510(k) will be required for modifications or changes to a previously cleared device. The FDA recently submitted this report and suggested that manufacturers continue to adhere to the FDA's 1997 Guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a device. However, the practical impact of the FDA's continuing scrutiny of these issues remains unclear.

If we fail to comply with the FDA's Quality System Regulation or any applicable state equivalent, our operations could be interrupted and our potential product sales and operating results could suffer.

We are required to comply with the FDA's QSR, which delineates, among other things, the design controls, document controls, purchasing controls, identification and traceability, production and process controls, acceptance activities, nonconforming product requirements, corrective and preventive action requirements, labeling and packaging controls, handling, storage, distribution and installation requirements, complaint handling, records requirements, servicing requirements, and statistical techniques potentially applicable to the production of our medical devices. We and our suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if we market products overseas. The FDA enforces the QSR through periodic and announced or unannounced inspections of manufacturing facilities. Our facilities have been inspected by the FDA and other regulatory authorities, and we anticipate that we and certain of our third-party component suppliers will be subject to additional future inspections. If our facilities and manufacturing processes are found to be in non-compliance or fail to take satisfactory corrective action in response to adverse QSR inspectional findings, FDA could take legal or regulatory enforcement actions against us and/or our products, including but not limited to the cessation of sales or the initiation of a recall of distributed products, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Current regulations depend heavily on administrative interpretation. If the FDA does not believe that we are in compliance with applicable FDA regulations, the agency could take legal or regulatory enforcement actions against us and/or our products. We are also subject to periodic inspections by the FDA, other governmental regulatory agencies, as well as certain third-party regulatory groups. Future interpretations made by the FDA or other regulatory bodies made during the course of these inspections may vary from current interpretations and may adversely affect our business and prospects. The FDA's and other comparable non-U.S. regulatory agencies' statutes, regulations, or policies may change, and additional government regulation or statutes may be enacted, which could increase post-approval regulatory requirements, or delay, suspend, prevent marketing of any cleared or approved products or necessitate the recall of distributed products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

The medical device industry has been under heightened FDA scrutiny as the subject of government investigations and enforcement actions. If our operations and activities are found to be in violation of any FDA laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and other legal and/or agency enforcement actions. Any penalties, damages, fines, or curtailment or restructuring of our operations or activities could adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of FDA laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend ourselves against that action and its underlying allegations, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Where there is a dispute with a federal or state governmental agency that cannot be resolved to the mutual satisfaction of all relevant parties, we may determine that the costs, both real and contingent, are not justified by the commercial returns to us from maintaining the dispute or the product.

Various claims, design features or performance characteristics of our medical devices, that we regarded as permitted by the FDA without marketing clearance or approval, may be challenged by the FDA or state or foreign regulators. The FDA or state or foreign regulatory authorities may find that certain claims, design features or performance characteristics, in order to be made or included in the products, may have to be supported by further studies and marketing clearances or approvals, which could be lengthy, costly and possibly unobtainable.

If any of our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, or MDR regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. For example, in 2015 we submitted to the FDA an MDR for an event that involved a patient who experienced significant erythema, or skin reddening, and transient blistering after treatment with Pharos. The patient was treated with topical antibiotics and subsequently continued treatment. For DABRA, the most frequent complication reported to us as a result of post-market surveillance is clinically non-significant vessel perforation. In connection with an internal audit of our regulatory reporting systems and our Audit Committee investigation, we are revising our internal operating procedures for complaint handling and adverse event classifications. We reviewed all adverse medical events that have been reported to us and retrospectively filed three MDRs with the FDA.

If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require our time and capital, distract management from operating our business, and may harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

Healthcare reform initiatives and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations and cash flows in our key markets.

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increasing costs of healthcare and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products on the market. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition, and results of operations.

For example, in the U.S., in March 2010, the Patient Protection and Affordable Care Act, or ACA, was passed. The ACA was intended to make significant changes to the way healthcare is financed by both federal and state governments and private insurers, with direct impacts to the medical device industry. Among other provisions, the ACA imposed, with limited exceptions, a deductible excise tax of 2.3% on sales of medical devices by entities, including us, that manufacture or import certain medical devices offered for sale in the U.S., including many of our products. The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law in December 2015, included a two-year moratorium on the medical device excise tax. A second two-year moratorium on the medical device excise tax was signed into law in January 2018 as part of the Extension of Continuing Appropriations Act, 2018 (Pub. L. 115-120), extending the moratorium through December 31, 2019. On December 20, 2019, President Trump signed into law a permanent repeal of the medical device tax under the ACA, but there is no guarantee that Congress or the President will not reverse course in the future. If such an excise tax on sales of certain of our products in the United States is enacted, it could have a material adverse effect on our business, financial condition, and results of operations.

In addition, the ACA and the Medicare Access and CHIP Reauthorization Act of 2015 substantially changed the way healthcare is delivered and financed by both governmental and private insurers. These changes included the creation of demonstration programs and other value-based purchasing initiatives that provide financial incentives for physicians and hospitals to reduce costs, including incentives for furnishing low cost therapies for chronic wounds even if those therapies are less effective than our products. Under the Trump Administration, there are ongoing efforts to modify or repeal all or part of ACA or take executive action that affects its implementation. Tax reform legislation was passed that includes provisions that impact healthcare insurance coverage and payment such as the elimination of the tax penalty for individuals who do not maintain health insurance coverage (the so-called "individual mandate"). Such actions or similar actions could have a negative effect on the utilization of our products. We expect such efforts to continue and that there will be additional reform proposals at federal and state levels. On December 18, 2019, the United States Court of Appeals for the Fifth Circuit upheld a lower court's determination in

Texas v. Azar, 4:18-cv-00167, that the individual mandate was unconstitutional and remanded the case to the lower court for further analysis as to whether ACA as a whole is unconstitutional because the individual mandate is not severable from other provisions of the law. We cannot predict the ultimate results of the *Texas* case or whether additional legislative reform proposals will be adopted, when they will be adopted, or what impact they may have on us, but any such proposals could have a negative impact on our business and provide incentives for hospitals and physicians to not use our products.

Other healthcare reform legislative changes have also been proposed and adopted in the U.S. since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control product costs. Additionally, individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, Medicare, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue, attain profitability.

Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could have a material adverse effect on our business, financial condition, and results of operations.

Healthcare cost containment pressures and legislative or administrative reforms resulting in restrictive coverage and reimbursement practices of third-party payors could decrease the demand for our products and the number of procedures performed using our devices, which could have an adverse effect on our business.

Our products are purchased principally by catheterization laboratories, which typically bill various third-party payors, including governmental programs, such as Medicare and Medicaid, private insurance plans and managed care plans, for the healthcare services provided to their patients. The ability of our customers to obtain reimbursement for procedures that are performed using our products from government and private third-party payors is critical to our success. The availability of coverage and reimbursement for procedures performed using our products affects which products customers purchase and the prices they are able to pay to us.

Reimbursement can vary based on geographical location, type of provider/customer, and third-party payor and can significantly influence the acceptance of new products and services. Third-party payors may view some procedures performed using our products as experimental and may not provide coverage. Third-party payors may not cover and reimburse our customers for certain procedures performed using our products in whole or in part in the future, or payment rates may decline and not be adequate, or both. Further, coverage and reimbursement by third-party payors to our customers is also related to billing codes to describe procedures performed using our products. Hospitals and physicians use several billing codes to bill for such procedures. Third-party payors may not continue to recognize the current CPT codes available for use by our customers. The CPT codes may change undermining our customer's ability to use those codes and reimbursement may be interrupted. Furthermore, some payors may not accept these new or revised codes for payment. If payors do not cover atherectomy, physicians may not perform as many DABRA treatments as they otherwise would perform. Consequently, we may not be able to sell as many catheters for DABRA treatments as projected.

Reimbursement rates are unpredictable, and we cannot project how our business may be affected by future legislative and regulatory developments. Future legislation or regulation, or changing payment methodologies, may have a material adverse effect on our business, financial condition, and results of operations, and reimbursement may not be adequate for all customers. From time to time, typically on an annual basis, payment amounts are updated and revised by third-party payors. Because the cost of our products generally is recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed, these updates, especially lower payments could directly impact the demand for our products. For example, in July 2013, the CMS proposed reimbursement changes that would have decreased reimbursement for procedures in an outpatient based facility, such as a catheterization lab. Although CMS chose not to implement those changes in 2013, we cannot assure you that CMS will not take similar actions in the future.

After we develop new products or seek to market our products for new approved or cleared indications, we may find limited demand for the product unless government and private third-party payors provide adequate coverage and reimbursement to our customers. Obtaining codes and reimbursement for new products may require an extended, multi-year effort. Even with reimbursement approval and coverage by government and private payors, providers submitting reimbursement claims for new products or existing products with new approved or cleared indications may face delay in payment if there is confusion by providers or payors regarding the appropriate codes to use in seeking reimbursement. Such delays may create an unfavorable impression within the marketplace regarding the level of reimbursement or coverage available for our products.

Demand for our products or new approved indications for our existing products may fluctuate over time if federal or state legislative or administrative policy changes affect coverage or reimbursement levels for our products or the services related to our products. In the U.S., there have been and we expect there will continue to be legislative and regulatory proposals to change the healthcare system, such as the potential repeal of the ACA, some of which could significantly affect our business. It is uncertain what impact the current U.S. presidential administration will have on healthcare spending including a campaign promise to repeal the ACA. If enacted and implemented, any measures to restrict healthcare spending could result in decreased revenue from the sale of our products and decreased potential returns from our research and development initiatives. Other legislative or administrative reforms to the U.S. or international reimbursement systems in a manner that significantly reduces reimbursement for procedures performed using our products or denies coverage for those procedures could have a material adverse effect on our business, financial condition, and results of operations.

Our sales into foreign markets expose us to risks associated with international sales and operations.

We are currently selling into foreign markets and plan to expand such sales. Conducting international operations subjects us to risks that could be different than those faced by us in the United States. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade, import and export and customs regulations and laws, including but not limited to, the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce. These regulations limit our ability to market, sell, distribute or otherwise transfer our products or technology to prohibited countries or persons.

Compliance with these regulations and laws is costly, and failure to comply with applicable legal and regulatory obligations could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

These risks may limit or disrupt our expansion, restrict the movement of funds or result in the deprivation of contractual rights or the taking of property by nationalization or expropriation without fair compensation. Operating in international markets also requires significant management attention and financial resources.

Our employees, independent contractors, consultants, commercial partners, distributors, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners, distributors, and vendors and other individuals or entities with whom we have arrangements may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing, and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, waste, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We have adopted a code of ethics and business conduct, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If such actions are instituted against us, in connection with the Audit Committee investigation or otherwise, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition, and results of operations.

Environmental and health safety laws may result in liabilities, expenses and restrictions on our operations.

Federal, state, local and foreign laws regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. Using hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling, or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our on our business, financial condition, and results of operations. Future changes to environmental and health and safety laws could cause us to incur additional expenses or restrict our operations, which could have a material adverse effect on our business, financial condition, and results of operations.

Our operations and relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation of our cleared devices and any future cleared or approved devices. Our current and future arrangements with providers, third-party payors and customers may be materially limited because of broadly applicable fraud and abuse and other healthcare laws and regulations. The business or financial arrangements and relationships through which we market, sell and distribute our cleared devices could also be constrained.

Restrictions under applicable U.S. federal and state healthcare laws and regulations may include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- federal false claims laws, including the federal False Claims Act, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Persons and entities can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, established new statutes imposing criminal healthcare fraud liability and increased civil monetary penalties for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the healthcare fraud statutes HIPAA established or specific intent to violate them in order to have a liability;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health, or HITECH, Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We believe we are not a covered entity for purposes of HIPAA, and we believe that we generally do not conduct our business in a manner that would cause us to be a business associate under HIPAA;
- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other “transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members. Effective January 2022, we will also be required to collect and report information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. In addition, we may be subject to state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Our Audit Committee identified certain conduct that may implicate healthcare laws and FDA regulatory requirements, and we have undertaken efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations. Such efforts may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of product candidates from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occurs, it could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which could have a material adverse effect on our business, financial condition, and results of operations.

If a breach of our measures protecting personal data covered by HIPAA, the HITECH Act, or the CCPA occurs, we may incur significant liabilities.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the HITECH Act, and the regulations that have been issued under it, impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information. The requirements and restrictions apply to "covered entities" (which include health care providers and insurers) as well as to their business associates that receive protected health information from them in order to provide services to or perform certain activities on their behalf. The statute and regulations also impose notification obligations on covered entities and their business associates in the event of a breach of the privacy or security of protected health information. We occasionally receive protected health information from our customers in the course of our business. As such, we believe that we are business associates and therefore subject to HIPAA's requirements and restrictions with respect to handling such protected health information, and have executed business associate agreements with certain customers.

In addition, California has enacted the California Consumer Privacy Act ("CCPA"), which came into effect on January 1, 2020. Pursuant to the CCPA, certain businesses are required, among other things, to make certain enhanced disclosures related to California residents regarding the use or disclosure of their personal information, allow California residents to opt-out of certain uses and disclosures of their personal information without penalty, provide Californians with other choices related to personal data in our possession, and obtain opt-in consent before engaging in certain uses of personal information relating to Californians under the age of 16. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our non-compliance with the CCPA. The CCPA also allows for private lawsuits from Californians in the event of certain data breaches. Aspects of the CCPA remain uncertain, and we may be required to make modifications to our policies or practices in order to comply.

It is possible the data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country and state to state, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Further, compliance with data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. We can provide no assurance that we are or will remain in compliance with diverse privacy and security requirements in all of the jurisdictions in which we do business. If we fail to comply or are deemed to have failed to comply with applicable privacy protection laws and regulations such failure could result in government enforcement actions and create liability for us, which could include substantial civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain patent protection for our products, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our existing products and any products we may develop, and our technology may be adversely affected.

As with other medical device companies, our ability to maintain and solidify a proprietary position for our products will depend upon our success in obtaining effective patent claims that cover such products, their manufacturing processes and their intended methods of use, and enforcing those claims once granted. Furthermore, in some cases, we may not be able to obtain issued claims covering DABRA and Pharos, as well as other technologies that are important to our business, which are sufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to DABRA and Pharos could have a material adverse effect on our business, financial condition, and results of operations.

Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our issued patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, and the like, although we are unaware of any such defects that we believe are of material importance. If we or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are

material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition, if any patents are issued in the future, they may not provide us with any competitive advantages, or may be successfully challenged by third parties. Agreement terms that address non-competition are difficult to enforce in many jurisdictions and may not be enforceable in any particular case. To the extent that our intellectual property and other proprietary rights are not adequately protected, third parties might gain access to our proprietary information, develop and market products or services similar to ours, or use trademarks similar to ours, each of which could materially harm our business. Existing United States federal and state intellectual property laws offer only limited protection. Moreover, the laws of other countries in which we now, or may in the future, conduct operations or contract for services may afford little or no effective protection of our intellectual property. The failure to adequately protect our intellectual property and other proprietary rights could materially harm our business.

The strength of patent rights involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. The patent applications that we own may fail to result in issued patents in the United States or foreign countries with claims that cover our products or services. Even if patents do successfully issue from the patent applications that we own, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products and services. Furthermore, even if they are unchallenged, our patents may not adequately protect our products and services, provide exclusivity for our products and services, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our products and services is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our products and services.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products and services, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our products and services under patent protection would be reduced.

In addition to the protection afforded by patents, we also rely on trade secret protection to protect proprietary know-how that may not be patentable or that we elect not to patent, processes for which patents may be difficult to obtain or enforce, and any other elements of our products and services that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and products would be adversely affected.

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our products or which effectively prevent others from commercializing competitive technologies and products.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether DABRA and Pharos will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. We may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of DABRA and Pharos. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us, which would have a material adverse effect on our business, financial condition, and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the U.S. over the lifetime of our patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, and results of operations.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Third parties may attempt to commercialize competitive products or services in foreign countries where we do not have any patents or patent applications where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting, and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the U.S. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the U.S. could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the U.S. transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our products or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, and results of operations.

Issued patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. or abroad.

If we initiated legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our patents before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes review*, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products. Such a loss of patent protection would have a material adverse effect on our business, financial condition, and results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our products, we rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position. We seek to protect our proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors, advisors, consultants, and other third parties, and invention assignment agreements with our employees. We also have agreements with some of our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of technologies that are developed through a relationship with a third party.

Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know-how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could have a material adverse effect on our business, financial condition, and results of operations.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products. Litigation may be necessary to defend against these and other claims challenging inventorship or our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations.

We may become involved in intellectual property litigation either due to claims by others that we are infringing their intellectual property rights or due to our own assertions that others are infringing upon our intellectual property rights.

The medical device industry in general has been characterized by extensive litigation and administrative proceedings regarding patent infringement and intellectual property rights. Our competitors hold a significant number of patents relating to medical laser technology. From time to time, we may commence litigation to enforce our intellectual property rights. An adverse decision in these actions or in any other legal action could limit our ability to assert our intellectual property rights, limit the value of our technology or otherwise negatively impact our business, financial condition and results of operations.

Monitoring unauthorized use of our intellectual property is difficult and costly. Unauthorized use of our intellectual property may have occurred or may occur in the future. Although we have taken steps to minimize the risk of this occurring, any such failure to identify unauthorized use and otherwise adequately protect our intellectual property would adversely affect our business. Moreover, if we are required to commence litigation, whether as a plaintiff or defendant, not only will this be time-consuming, but we will also be forced to incur significant costs and divert our attention and efforts of our employees, which could, in turn, result in lower revenue and higher expenses.

We cannot provide assurance that our products or methods do not infringe the patents or other intellectual property rights of third parties. Additionally, if our business is successful, the possibility may increase that others will assert infringement claims against us.

Determining whether a product infringes a patent involves complex legal and factual issues, and the outcome of a patent litigation action is often uncertain. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. Because of the number of patents issued and patent applications filed in our technical areas, our competitors or other parties may assert that our products and the methods we employ in the use of our products are covered by U.S. or foreign patents held by them. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. There could also be existing patents that one or more of our products or parts may infringe and of which we are unaware. As the number of competitors in the market for medical lasers and as the number of patents issued in this area grows, the possibility of patent infringement claims against us increases. In certain situations, we may determine that it is in our best interests or their best interests to voluntarily challenge a party's products or patents in litigation or other proceedings, including patent interferences or re-examinations. As a result, we may become involved in unwanted litigation that could be costly, result in diversion of management's attention, require us to pay damages and force us to discontinue selling our products.

Infringement and other intellectual property claims and proceedings brought against us, whether successful or not, could result in substantial costs and harm to our reputation. Such claims and proceedings can also distract and divert management and key personnel from other tasks important to the success of the business. We cannot be certain that we will successfully defend against allegations of infringement of patents and intellectual property rights of others. In the event that we become subject to a patent infringement or other intellectual property lawsuit and if the other party's patents or other intellectual property were upheld as valid and enforceable and we were found to infringe the other party's patents or violate the terms of a license to which we are a party, we could be required to do one or more of the following:

- cease selling or using any of our products that incorporate the asserted intellectual property, which would adversely affect our revenue;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all, and which could reduce profitability; and
- redesign or rename, in the case of trademark claims, our products to avoid violating or infringing the intellectual property rights of third parties, which may not be possible and could be costly and time-consuming if it is possible to do so.

Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the sale and marketing of our products.

The medical devices industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and any potential future collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. It is uncertain whether the issuance of any third-party patent would require us or any licensee to alter our development or commercial strategies, obtain licenses, or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Third parties may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes upon these patents. In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our products. In this case, the holders of such patents may be able to block our ability to commercialize the applicable products or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our products, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

For example, in December of 2017, we were contacted by a third party suggesting that we should consider licensing three U.S. patents directed to the treatment of vitiligo, U.S. Pat. No. 6,979,327 (“’327 patent”), U.S. Pat. No. 7,261,729 (“’729 patent”), and U.S. Pat. No. 8,387,621 (“’621 patent”). In addition, we were also previously contacted in 2006 by the same third party suggesting that we should consider licensing the ‘327 patent as well as the then pending application that became the ‘729 patent. We believe that we will be meritorious if a claim of infringement of the ‘327 patent, the ‘729 patent, or the ‘621 patent is asserted against us in a legal proceeding by this or any other third party. However, although we believe that we do not infringe the claims of the ‘327 patent, the ‘729 patent, or the ‘621 patent, nor do we believe that we need a license to the ‘327 patent, the ‘729 patent, or the ‘621 patent in order to freely commercialize our products, there is a possibility that a suit claiming infringement of the ‘327 patent, the ‘729 patent, or the ‘621 patent will be brought against us, and we cannot assure that a court or an administrative agency will agree with our assessment with regard to non-infringement of the ‘327 patent, the ‘729 patent, or the ‘621 patent. If it was necessary to obtain a license to the ‘327 patent, the ‘729 patent, or the ‘621 patent and a license was not available on commercially reasonable terms or available at all, that could affect our ability to commercialize our products and materially and adversely affect our business.

If a third party commences a patent infringement action against us it could consume significant financial and management resources, regardless of the merit of the claims or the outcome of the litigation. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing products. In addition, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our products, which could harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because they may have greater financial resources. Patent litigation and other proceedings may also consume significant management time. Uncertainties resulting from the initiation or continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents, or we may be required to defend against claims of infringement. In addition, our patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants and scientific advisors are currently or were previously employed at universities or healthcare companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we have been and may in the future become subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. If we fail in defending any such claims, it could have a material adverse effect on our business, financial condition, and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs to us and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, and results of operations.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, and results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of the patents that we may own or that incorporate certain technology in our products that is in the public domain;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own now or in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;

- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Reliance on Third Parties

We depend on third-party suppliers for key components and sub-assemblies used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate components and sub-assemblies could harm our business.

We are currently experiencing inconsistencies in our DABRA catheter performance as more fully described in the risk factor entitled “*We are experiencing inconsistencies in our DABRA catheter performance. This and any other development or manufacturing problems or delays that could limit the potential growth of our revenue or increase our losses.*” In addition to the inconsistencies and risks described in the foregoing risk factor, we may encounter unforeseen situations that would result in delays or shortfalls in manufacturing. Key components and sub-assemblies of DABRA and Pharos are currently provided by a limited number of suppliers, and we do not maintain large inventory levels of these components and sub-assemblies. For example, we rely on a limited number of suppliers for the Thyatron used to manufacture our lasers. If we experience a shortage in any of these components or sub-assemblies, we would need to identify and qualify new supply sources, which could increase our costs, result in manufacturing delays, and cause delays in the delivery of our products. We may also experience a delay in completing validation and verification testing or sterility audits for controlled-environment rooms at our manufacturing facility.

We also depend on limited source suppliers for some of our product components and sub-assemblies, and if any of those suppliers are unable or unwilling to produce these components or sub-assemblies or supply them in the quantities that we need, and at acceptable prices, we would experience manufacturing delays and may not be able to deliver our products on a timely or cost-effective basis to our customers, or at all, which could reduce our product sales, increase our costs, and harm our business. While we believe that we could obtain replacement components from alternative suppliers, we may be unable to do so. Losing any of these suppliers could cause a disruption in our production. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors. Establishing additional or replacement suppliers for these materials may take significant time, as certain of these suppliers must be approved by regulatory authorities, which could disrupt our production. As a result, we could experience significant delays in manufacturing and delivering our products to customers. We cannot assure you we can continue obtaining required materials, components, and sub-assemblies that are in short supply within the time frames we require at an affordable cost, if at all. If we cannot secure on a timely basis sufficient quantities of the materials we depend on to manufacture our products, if we encounter delays or contractual or other difficulties in our relationships with these suppliers, or if we cannot find replacement suppliers at an acceptable cost, then manufacturing our products may be disrupted, which could increase our costs, prevent or impair our development or commercialization efforts, and have a material adverse effect on our business, financial condition, and results of operations.

We and our component suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have an adverse effect on our business, financial condition, and results of operations.

As a medical device manufacturer, we must register with the FDA and non-U.S. regulatory agencies, and we are subject to periodic inspection by the FDA and foreign regulatory agencies, for compliance with certain good manufacturing practices, including design controls, product validation and verification, in process testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA and foreign regulatory agencies. Our component suppliers are also required to meet certain standards applicable to their manufacturing processes.

We cannot assure you that we or our component suppliers comply or can continue to comply with all regulatory requirements. A failure by us or one of our component suppliers to achieve or maintain compliance with these requirements or quality standards may disrupt our ability to supply products sufficient to meet demand until compliance is achieved or, with a component supplier, until a new supplier has been identified and evaluated. Our or any of our component supplier's failure to comply with applicable regulations could cause sanctions to be imposed on us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals or clearances, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, which could harm our business. We cannot assure you that if we need to engage new suppliers to satisfy our business requirements, we will be able to locate new suppliers in compliance with regulatory requirements at a reasonable cost and in an acceptable timeframe. Our failure to do so could have a material adverse effect on our business, financial condition, and results of operations.

In the European Union, we must maintain certain International Organization for Standardization, or ISO, certifications to sell our products and must undergo periodic inspections by notified bodies, including the British Standards Institution, to obtain and maintain these certifications. If we fail these inspections or fail to meet these regulatory standards, it could have a material adverse effect on our business, financial condition, and results of operations.

We may form or seek strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits or costs of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our sales and marketing efforts with respect to our products and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our products. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our products could delay the commercialization of our products in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Risks Related to Ownership of Our Common Stock

We must comply with the New York Stock Exchange's requirements for the continued listing of our common stock on the NYSE.

Our common stock is listed on the New York Stock Exchange ("NYSE"). We received a deficiency notice from the NYSE on December 4, 2019 that we are not in compliance with a NYSE continued listing requirement for maintaining an average market capitalization over a consecutive 30 trading-day period of not less than \$50 million at the same time shareholders' equity is less than \$50 million. We submitted a compliance plan on January 20, 2020, and the NYSE accepted our plan on February 28, 2020. We have 18 months to cure this deficiency. In addition, however, if our average market capitalization over a consecutive 30 trading-day period is less than \$15 million, we will be delisted from the NYSE immediately. As of March 6, 2020, our market capitalization was \$20.8 million. There can be no assurance that we will be able to successfully implement the necessary actions to maintain or regain compliance with NYSE listing requirements or that any appeal of a decision to delist the Company's common stock would be successful.

Failure to maintain our NYSE listing could negatively impact us and our stockholders by reducing the willingness of investors to hold our common stock because of the resulting decreased price, liquidity and trading of our common stock, limited availability of price quotations, and reduced news and analyst coverage. These developments may also require brokers trading in our common stock to adhere to more stringent rules and may limit our ability to raise capital by issuing additional shares in the future. Delisting may adversely impact the perception of our financial condition, and cause reputational harm with investors and parties conducting business with us.

The price of our stock may be volatile, which could result in substantial losses for investors. Further, an active, liquid and orderly trading market for our common stock may not be sustained and we do not know what the market price of our common stock will be, and as a result it may be difficult for you to sell your shares of our common stock.

Prior to our listing on the NYSE in September 2018, there was no public market for shares of our common stock. Although our common stock is listed on the NYSE, the market for our shares has demonstrated varying levels of trading activity. Furthermore, an active trading market for our shares may not be sustained in the future. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our common stock as consideration, which could have a material adverse effect on our business, financial condition, and results of operations. In addition, the trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk factors" section and elsewhere in this Annual Report on Form 10-K, these factors include:

- increased expenses from remedying the performance issues of our catheters;
- our failure to increase the sales of our products, specifically DABRA and remedy the performance issues associated with our DABRA catheters;
- the failure by our customers to obtain adequate reimbursements or reimbursement levels that would be sufficient to support product sales to our customers and pricing of our products to support revenue projections;
- unanticipated serious safety concerns related to the use of our products;
- changes in our organization and our search for a permanent chief executive officer;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our future growth;
- the size and growth of our target markets;
- actual or anticipated variations in quarterly operating results;

- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including stockholder litigation, government actions or litigation related to intellectual property;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- any delay in any regulatory filings for our future products and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such products;
- adverse regulatory decisions, including failure to receive regulatory approval of our future products, failure to maintain regulatory approval for our existing products or failure to obtain regulatory approval for additional indications for our existing products;
- changes in laws or regulations applicable to our products;
- adverse developments concerning our suppliers or distributors;
- our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices;
- our inability to establish and maintain collaborations if needed;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of large blocks of our common stock including sales by our executive officers and directors;
- trading volume of our common stock;
- limited "public float" in the hands of a small number of persons whose sales or lack of sales of our common stock could result in positive or negative pricing pressure on the market price for our common stock;
- additions or departures of key scientific or management personnel;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of managements attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. Our operating results may fluctuate due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- increased expenses from remedying the performance of our catheters;
- the timing and cost of, and level of investment in, research and development activities relating to our current and any future products, which will change from time to time;
- the cost of manufacturing our current and any future products, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with suppliers;
- the degree and rate of market acceptance for DABRA and Pharos, including the ability of our customers to receive adequate reimbursement for procedures performed using our products;
- expenditures that we will or may incur to acquire or develop additional products and technologies;
- competition from existing and potential future products that compete with our products, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the level of demand for our current and future products, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products, and existing and potential future products that compete with our products;
- our ability to commercialize additional products, if approved, inside and outside of the U.S., either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing, or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- changes in FDA regulations and comparable foreign regulations;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

From time to time, we may also enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend in part on any potential future license and collaboration agreements and sales of our products. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

We do not intend to pay dividends on our common stock so any returns will be limited to increases, if any, in our stock's value.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Any return to stockholders will therefore be limited to the appreciation in the value of their stock, if any.

Our ability to use our net operating loss carryforwards may be limited.

As of December 31, 2019, we had net operating loss carryforwards, or NOLs, of approximately \$63.7 million for federal income tax purposes, and \$66.0 million for state income tax purposes. These federal and state NOLs begin expiring in 2029. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. These NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership by 5% stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. We have determined that we have not experienced Section 382 ownership changes in the past and therefore our NOLs are not subject to an annual limitation under Section 382. In addition, we may experience ownership changes in the future as a result of subsequent changes in our stock ownership, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical NOLs is materially limited, it could harm our future operating results by effectively increasing our future tax obligations. In addition, under the Tax Cuts and Jobs Act of 2017, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely and the deductibility of such federal NOLs is limited.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, on December 22, 2017, President Trump signed tax legislation into law, commonly referred to as the Tax Cuts and Jobs Act of 2017, that contains many significant changes to the U.S. tax laws, the consequences of which have not yet been fully determined. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings, and the deductibility of expenses contained in the Tax Cuts and Jobs Act of 2017 or other tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense. The foregoing items could have a material adverse effect on our business, cash flow, financial condition or results of operations. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax legislation. The impact of this tax legislation on holders of our common stock is also uncertain and could be adverse. We urge our stockholders and investors to consult with our legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2019, our executive officers, directors, and 10% stockholders owned approximately 38% of the outstanding shares of our common stock. In addition, as of December 31, 2019, our officers, directors, 10% stockholders, and their affiliates held (i) options to purchase an aggregate of 1,412,432 shares of our common stock at a weighted average exercise prices of \$20.75 per share; and (ii) 560,186 restricted stock units, which would give our officers, directors, and 10% stockholders ownership of approximately 39% of our outstanding common stock if such awards are fully vested and are exercised in full. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, certain financing transactions or other major corporate transactions. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders, which could have a material adverse effect on our business, financial condition, and results of operations.

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which may allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We have incurred and will continue to incur significant costs as a result of operating as a public company, and our management has devoted and will continue to devote substantial time to new compliance initiatives, including maintaining an effective system of internal controls over financing reporting.

As a public company, we have incurred and will continue to incur significant legal, accounting, insurance, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the New York Stock Exchange to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Emerging growth companies are permitted to implement many of these requirements over a longer period and up to five years from the completion of our initial public offering. We intend to take advantage of this legislation but cannot guarantee that we will not be required to implement these requirements sooner than anticipated or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

These rules and regulations applicable to public companies have increased and will continue to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Future sales and issuances of a substantial number of shares of our common stock or rights to purchase common stock by our stockholders in the public market could result in additional dilution of the percentage ownership of our stockholders and cause our stock price to fall.

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of December 31, 2019, we had outstanding 13,770,349 shares of our common stock.

In addition, pursuant to our 2018 Equity Incentive Plan, or 2018 Plan, equity incentive awards representing up to an aggregate of 953,275 shares of our common stock were available for issuance to our employees, directors and consultants as of December 31, 2019. The 2018 Plan includes an annual increase in the number of shares available for future grant each year pursuant to the “evergreen” provision of our 2018 Plan. Additionally, pursuant to our 2018 Employee Stock Purchase Plan, or ESPP a total of 446,160 shares were available for sale under our ESPP as of December 31, 2019. The ESPP also includes an annual increase in the number of shares available for sale under our ESPP each year pursuant to the “evergreen” provision of our ESPP. If these additional shares of common stock are issued and sold, or if it is perceived that they will be sold, in the public market, this could result in additional dilution and the trading price of our common stock could decline.

Further, additional capital may be needed in the future to continue our planned operations, including commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business.

If one or more of the analysts covering us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. In addition, if one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors or our current management and may adversely affect the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- our board of directors is divided into three classes serving staggered three-year terms, such that not all members of the board is elected at one time, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at an annual or special meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairperson of the board of directors, the chief executive officer or president (in the absence of a chief executive officer) or a majority vote of our board of directors, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the issuance of preferred stock and management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt;
- the ability of our board of directors, by majority vote, to amend our amended and restated bylaws, which may allow our board of directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend our amended and restated bylaws to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, because we are now incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; and any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition, and results of operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters occupy approximately 32,000 square feet in Carlsbad, California under a lease that expires in December 2027. We are currently operational in this facility which also incorporates our manufacturing operations.

We have invested in our manufacturing facility, including making upgrades to our controlled environments by increasing the total square footage from approximately 500 square feet to approximately 2,000 square feet. This provides an adequate work area for fabricating sterile, high quality catheters for the DABRA laser systems and high-reliability laser pump chambers to support both the dermatology and the vascular markets. We have further invested in capital equipment and staff, and believe that our current manufacturing capacity will be sufficient to meet the current expected demand for our products for at least the next 12 months. We believe our existing facility is capable of producing 400 lasers per year and 140,000 catheters per year, and this capability will be sufficient for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

Securities Litigation

On June 7, 2019, a putative securities class action complaint captioned *Derr v. Ra Medical Systems, Inc., et. al.*, (Civil Action no. 19CV1079 LAB NLS) was filed in the United States District Court for the Southern District of California against us, certain current and former officers and directors, and certain underwriters of our IPO. The complaint alleged that the defendants made material misstatements or omissions in our registration statement in violation of Sections 11 and 15 of the Securities Act of 1933. On September 5, 2019, the court appointed Lead Plaintiffs. On January 13, 2020, the Lead Plaintiffs filed an amended complaint. In addition to the Securities Act violations alleged in the original complaint, the amended complaint alleges that the defendants made material misstatements or omissions between September 27, 2018 and November 27, 2019, inclusive, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. The defendants have until March 13, 2020 to file their responsive pleadings or motions. Management intends to vigorously defend against this lawsuit. At this time, we cannot predict how a court or jury will rule on the merits of the claims and/or the scope of the potential loss in the event of an adverse outcome. Should we ultimately be found liable, the liability could have a material adverse effect on our financial condition and our results of operations for the period or periods in which it is incurred.

On October 1, 2019, a shareholder derivative complaint captioned *Noel Borg v. Dean Irwin, et. al* (Civil Action no. 1:99-cm-09999) was filed in the United States District Court for the District of Delaware against certain current and former officers and directors, purportedly on behalf of the Company, which is named as a nominal defendant in the action. The complaint alleges breaches of fiduciary duty, unjust enrichment, waste, and violations of Section 14(a) of the Securities Exchange Act of 1934. On October 21, 2019, pursuant to the parties' stipulation, the court stayed the derivative lawsuit until the related class action is resolved.

Governmental Investigations

As previously announced in the Form 8-K filed on August 12, 2019, the Audit Committee of Ra Medical's Board of Directors (the "Audit Committee") conducted an investigation of certain allegations raised by a former employee. We announced the Audit Committee's findings in the Form 8-K filed on October 31, 2019. The primary investigative findings were: (i) the DABRA catheter frequently failed to calibrate and occasionally overheated, posing a risk of injury to physicians and patients; (ii) our explanations regarding our fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because they did not explicitly reference inconsistent DABRA catheter performance and catheter failures; (iii) we failed to timely make at least two Medical Device Reports, or MDRs, to the FDA; (iv) we, out of a concern for the DABRA catheters' performance, engaged in systematic efforts to replace product held by customers, which constituted product recalls, but were not documented as such, (v) we lack documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, and as to three physicians did not accurately reflect the purpose and nature of approximately \$300,000 of payments, which could be perceived as an improper attempt to obtain business or to gain special advantage, (vi) while the indication for use in the 510(k) clearance we obtained for the DABRA system is not for

atherectomy, our salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes, (vii) our determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects, and (viii) we received complaints regarding regulatory or compliance concerns that, because they implicated executive officers, should have been brought to the attention of the Board or the Audit Committee, but were not. The Audit Committee, in reviewing the allegations, identified certain behavior inconsistent with our Code of Ethics and Conduct and related policies.

As also previously announced, we voluntarily contacted the Securities and Exchange Commission's (the "SEC") Enforcement Division regarding the Audit Committee's investigation. On November 13, 2019, the SEC notified us that it is conducting an investigation. We have been, and intend to continue, cooperating with the SEC in its investigation.

In October 2019, the Department of Justice, or DOJ, served us with a Civil Investigative Demand ("CID") seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. We have been, and intend to continue, cooperating with the DOJ in its investigation.

On November 21, 2019, we became aware that the Criminal Division, Fraud Section of the U.S. Department of Justice has an open investigation related to us. At this time, it is unclear if we are a target in this investigation. We have been, and intend to continue, cooperating with the DOJ in its investigation.

We are unable to predict the ultimate outcome of these governmental investigations, and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

Other Litigation

On August 30, 2018, Strata Skin Sciences, Inc. ("Strata") and Uri Geiger, a member of the board of directors of Strata Skin Sciences, Inc. filed an action against us in Court of Common Pleas of Montgomery County, Pennsylvania (Civil Action No. 18-21421) (the "Pennsylvania Case"), requesting declaratory relief that: (1) Strata and Mr. Geiger are not liable for tortious interference, defamation, libel, or unfair competition based on an e-mail by Mr. Geiger to an investment bank (the "Geiger Email"); (2) Strata and Mr. Geiger made no actionable statements about us to such investment bank; (3) we cannot enforce the 2011 settlement and release agreement between us and PhotoMedex, Inc. ("Settlement Agreement") against Strata; and (4) that any dispute regarding the Geiger Email does not relate to the Settlement Agreement. The action filed by Strata and Mr. Geiger does not request any monetary damages. We believe that the action by Strata and Mr. Geiger was filed as a response to a letter that we sent to Strata on August 22, 2018 demanding that Strata and Mr. Geiger cease and desist from making statements about alleged patent infringement and affirmatively retract the statements made in the Geiger Email. We were served with the action on August 31, 2018, and responded with preliminary objections to the action on September 19, 2018. The court overruled our preliminary arguments on April 29, 2019. We filed a motion for partial summary judgment on December 9, 2019 for the court to rule that Strata is bound by the Settlement Agreement. Strata filed a motion on February 4, 2020 asking the court to enforce a settlement to which Strata believes we agreed, despite such agreement never having been signed. A hearing on the motion for partial summary judgment and the motion to enforce a settlement is scheduled for March 20, 2020. We believe that Strata's action in the Pennsylvania Case lacks merit, and plans to vigorously oppose the action on procedural and substantive grounds within the prescribed time limits.

On May 16, 2019, we filed an action against Strata, Mr. Geiger and Accelmed Growth Partners, L.P. (collectively, the "Strata Parties") in the United States District Court for the Southern District of California (Civil Action No. 19-cv-0920-AJB-MSB (the "California Case")) alleging (1) breach of the Settlement Agreement, (2) intentional interference in contractual relations, (3) intentional interference in prospective economic relations and (4) trade libel. In the California Case, we allege, among other things, that the statements in the Geiger Email regarding alleged patent infringement constitute a breach of the Settlement Agreement, that the Strata Parties employed deceptive practices designed to delay our initial public offering and reduce the amount of capital raised by us, and that statements in the Geiger Email regarding patent infringement, off label promotion and reimbursement constitute trade libel. We seek an injunction barring the Strata Parties from continuing the alleged conduct, monetary damages, and other available legal and equitable relief. We amended our complaint on July 25, 2019 to allege violations of the

Lanham Act's prohibition on false advertising. The Strata Parties filed motions to dismiss on August 25, 2019, and we responded with its oppositions to the motions to dismiss on September 27, 2019. On February 28, 2020, we filed a supplemental complaint to include additional allegations of violations of the Lanham Act. We and the Strata Parties filed a joint motion to treat the pending motions to dismiss as if they were directed at this supplemental complaint. On March 6, 2020, the court denied the motion but indicated that we may file a new amended complaint with these additional allegations, rather than a supplemental complaint.

On February 12, 2020, Dean Irwin, our former Chief Executive Officer, filed a Demand for Arbitration, alleging that we attempted to coerce him into signing a non-standard separation agreement and release of claims, contrary to the terms of his Severance Agreement. Mr. Irwin claims that he was willing to sign our standard separation agreement and release of claims. Based on this allegation, Mr. Irwin is claiming nonpayment of wages, penalties for nonpayment of wages, failure to provide wage statements, breach of contract, and breach of implied covenant of good faith and fair dealing. We believe that Mr. Irwin's allegations lack merit, and plan to vigorously defend the action.

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II — FINANCIAL INFORMATION

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

On March 6, 2020, the last reported sales price of our common stock was \$1.5 land, according to our transfer agent, as of March 6, 2020, there were 77 record holders of our common stock. The actual number of stockholders is greater than the number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust or by other entities.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions, the terms of any future credit agreements and other factors that our board of directors may deem relevant.

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On September 26, 2018, our Registration Statement on Form S-1 (File No. 333-226191) relating to our initial public offering was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 4,485,000 shares of our common stock, including 585,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a price of \$17.00 per share. The aggregate offering price for shares sold in the offering was approximately \$76.2 million. Piper Sandler Companies and Cantor Fitzgerald & Co. acted as lead joint book-running managers for the offering. SunTrust Robinson Humphrey, Inc. acted as lead manager and Nomura Securities International, Inc. and Maxim Group LLC acted as co-managers for the offering. On October 1, 2018, we closed the sale of such shares, resulting in aggregate cash proceeds to us of approximately \$67.3 million, net of \$5.3 million of underwriting discounts and commissions and \$3.6 million of offering expenses paid or payable by us. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

We stated, in our Registration Statement for our initial public offering, that we intend to use the net proceeds as follows:

- approximately \$21 million for the expansion of our direct sales force and marketing of our products;
- approximately \$14 million to support clinical studies for new products and product enhancements including for expanded indications; and
- the balance of the proceeds may be used to support other research and development activities, working capital, and general corporate purposes.

As discussed elsewhere in this Form 10-K, we are currently focusing on servicing core accounts while we prioritize remedying the inconsistencies in our DABRA catheter performance. Accordingly, we intend to use the remainder of the net proceeds for these and other general corporate purposes, including our clinical studies.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, before making an investment decision. The risks and uncertainties described below may not be the only ones we face. If any of the risks actually occur, our business, financial condition, operating results, cash flows and prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.

Overview

We are a commercial-stage medical device company leveraging our advanced excimer laser-based platform for use in the treatment of vascular and dermatological immune-mediated inflammatory diseases. We believe our products enhance patients' quality of life by restoring blood-flow in arteries and clearing chronic skin conditions. The DABRA laser system and single-use catheter, together referred to as DABRA, is cleared by the U.S. Food and Drug Administration, or FDA, as a device for crossing chronic total occlusions, or CTOs, in patients with symptomatic infrainguinal lower extremity vascular disease and with an intended use for ablating a channel in occlusive peripheral vascular disease. DABRA is used as a tool in the treatment of peripheral artery disease, or PAD, a form of peripheral vascular disease, which commonly occurs in the legs. We currently are pursuing an atherectomy indication for use, which the FDA currently defines to include a prespecified improvement in luminal patency, or a prespecified increase in the openness of the artery at a pre-defined time point. To satisfy the FDA's data requirements to support an atherectomy indication, we are performing a pivotal study designed to allow the FDA to evaluate the DABRA atherectomy procedure. We received final IDE approval in January 2020 and enrolled the first patient in the study in February 2020.

In the fourth quarter of 2018 and into 2019, we experienced inconsistencies in our DABRA catheter performance. After collecting field data and performing internal testing, we observed that while catheters can perform satisfactorily up to one year, catheters that were more than two months from sterilization, had a significantly higher rate of non-calibration than catheters that were within two months from sterilization. As a result, in September 2019, we initiated a voluntary recall of our catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters.

In addition, in the third quarter of 2019 we implemented certain operational efficiency and cost-savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives included targeted workforce reductions of our sales and marketing teams. We reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to five clinical specialists as of December 31, 2019. In the near term, we are focusing on servicing core accounts while we prioritize remedying the inconsistencies in our DABRA catheter performance. We are encouraged by the results, as we have seen significant decreases in the rates of non-calibrations following the voluntary recall.

Our business strategy is focused on continuing to service our core accounts while we complete initiatives that are key to relaunching DABRA to the broader market. Key components of our DABRA relaunch strategy include:

- A longer shelf life;
- A braided overjacket designed to reduce kinking, and that will also allow the physician to apply more pressure when advancing the DABRA catheter;
- A rapid exchange designed to allow physicians to use more standard techniques, including a guidewire, to navigate the vasculature more easily; and
- An atherectomy indication for use.

As these initiatives are at or near completion, we intend to begin expanding our sales force to prepare for a commercial relaunch.

In the future, we may pursue additional uses for DABRA, including seeking regulatory clearance or approval for the use of DABRA as a tool for the treatment of vascular blockages associated with coronary artery disease, or CAD, in-stent restenosis, and other vascular-related indications. However, there can be no assurance that DABRA will receive the necessary clearances for these additional indications. The DABRA laser system is based on the same core technology and utilizes a similar excimer laser as Pharos, a medical device that we have marketed as a tool for the treatment of proliferative skin conditions since October 2004. Pharos is designed for use in the treatment of inflammatory skin conditions and is FDA cleared as a tool used in the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. Because DABRA and Pharos are both based on our core excimer laser technology platform and deploy similar mechanisms of action, we benefit from economies of scale in product development, manufacturing, quality assurance and distribution.

DABRA is our minimally-invasive excimer laser and single-use catheter system that is used by physicians as a tool in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease, a form of PAD, both above- and below-the-knee, by breaking down plaque to its fundamental chemistry, such as proteins, lipids and other chemical compounds, eliminating blockages by essentially dissolving them without generating potentially harmful particulates. The accumulation of plaque in arteries, which is a result of lower extremity vascular disease, most commonly occurs in the pelvis and legs. Plaque accumulation, known as atherosclerosis, causes the narrowing of arteries, thereby reducing the flow of oxygenated blood to tissue and organs. If vascular blockages are left untreated, they can increase the risk of heart attack, stroke, amputation or death. Major risk factors for PAD include age, smoking, diabetes and obesity. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including CAD, in part because up to half of the PAD population is asymptomatic, or shows no symptoms, and many dismiss symptoms as normal signs of aging. Recent analysis suggests that approximately 17.6 million people in the U.S. suffer from PAD. However, only 20-30% of PAD patients are actively being treated. We anticipate revenue from this recently commercialized business segment to grow over time. Our sales strategy includes either selling the DABRA laser with a transfer in title or placing it in high-volume practices for a nominal periodic fee while we retain title. We sell extended warranties for our lasers that have been purchased. Each vascular procedure requires the one-time use of our proprietary catheters which we expect to be the primary source of revenue for the vascular segment. Therefore, under both the sale and periodic fee options, we anticipate recurring revenue in catheter sales for each laser in operation. We currently use our internal sales force to target the U.S. market and we utilize distributors outside the U.S.

Pharos is our excimer laser device that emits highly concentrated ultraviolet light and is used as a tool in the treatment of dermatological skin disorders. Physicians use Pharos by applying 308 nanometer ultraviolet light to the skin. The FDA has granted 510(k) clearance to market Pharos in the U.S. for psoriasis, vitiligo, atopic dermatitis, and leukoderma. Pharos was granted CE mark approval in Europe in September of 2016 for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma by the application of UVB ultraviolet light. We have also received clearance to market Pharos from the China Food and Drug Administration, or CFDA. While we have entered into periodic fee arrangements, our primary strategy is to sell Pharos. We recognize additional recurring revenue from the sale of extended warranties for Pharos. We do not anticipate significant organic revenue growth in the near term from this mature product line.

We incurred net losses of \$57.0 million and \$30.8 million for the years ended December 31, 2019 and December 31, 2018, respectively, and had an accumulated deficit of \$117.2 million as of December 31, 2019. As of December 31, 2019, we had available cash and cash equivalents and short-term investments of approximately \$30.6 million and had current liabilities of approximately \$6.8 million and long-term liabilities of approximately \$4.1 million, which includes operating lease liabilities relating to our building leases of \$2.6 million and equipment financings of \$0.3 million. Since inception, we have financed our operations primarily through sales of our products and services, the net proceeds from our initial public offering, and, to a lesser extent, private placements of our common stock and debt financing arrangements. We expect to continue to incur net losses for the near term as we commercialize our products in the U.S., including building our sales and marketing organization and expanding our manufacturing facilities, continuing research and development efforts, and seeking regulatory clearance for new products and product enhancements, including new indications, both in the U.S. and in select non-U.S. markets. We may need additional funding to pay expenses relating to our operating activities, including selling, general and administrative expenses and research and development expenses. If needed, adequate funding may not be available to us on commercially acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, financial condition, and results of operations.

Initial Public Offering

On October 1, 2018, we closed on our initial public offering, or IPO, of 4,485,000 shares of common stock at an offering price of \$17.00 per share, which included the full exercise of the underwriters' option to purchase 585,000 additional shares of our common stock. We raised a total of \$76.2 million in gross proceeds from the IPO, or approximately \$67.3 million in net proceeds after deducting underwriting discount and commissions of \$5.3 million and offering costs of \$3.6 million. Our registration statement on Form S-1 relating to our IPO was declared effective by the Securities and Exchange Commission on September 26, 2018.

Components of our Results of Operations

Net revenue

Product sales consist of the sale of DABRA and Pharos lasers, the sale of catheters for use with the DABRA laser and the sale of consumables and replacement parts.

Service and other revenue consists primarily of sales of extended warranties, which we recognize over the contract period and billable services, including repair activity, which is recognized when the service is provided. It also includes income from the rental of our lasers.

We currently use our commercial team to service the U.S. market, and we utilize distributors outside the U.S. in markets where we have received regulatory approval. We expect to continue to seek regulatory approvals for our products in additional strategic markets.

Cost of revenue and gross profit (loss)

Cost of revenue for product sales consists primarily of costs of components for use in our products, the labor that are used to produce our products, and the manufacturing overhead that support production.

Cost of revenue for service and other includes the cost of maintaining and servicing the warranties on our products, including the depreciation on lasers we own.

We expect cost of revenue to increase to the extent our total revenue grows.

We calculate gross profit (loss) as revenue less cost of revenue. Our gross profit (loss) has been and will continue to be affected by a variety of factors, primarily production volumes, the cost of direct materials, discounting practices, manufacturing costs, product yields, headcount and cost-reduction strategies. We expect our gross loss to reduce and become gross profit over the long term as our production volume increases and certain costs remain fixed or increase at a slower rate. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs. While we expect gross profit (loss) to improve over the long term as our production volume increases, it will likely fluctuate from quarter to quarter as we continue to introduce new products and adopt new manufacturing processes and technologies.

Research and development expenses

Research and development, or R&D, expenses consist of applicable personnel, clinical trial expenses, materials and consulting. R&D expenses include:

- certain employee-related expenses, including salaries, benefits, travel expense and stock-based compensation expense;
- cost of clinical studies to support new products and product enhancements, including expanded indications;
- supplies used for internal research and development and clinical activities; and
- cost of outside consultants who assist with technology development and clinical affairs.

We expense R&D costs as incurred. In the future, we expect R&D expenses to increase as we continue to develop new products, enhance existing products and technologies and perform activities related to obtaining additional regulatory approval. However, we expect R&D expenses as a percentage of total revenue to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trials and studies and other related activities.

Selling, general and administrative expenses

Selling, general and administrative, or SG&A, expenses consist of employee-related expenses, including salaries, benefits, travel expense, sales commissions and stock-based compensation expense. Other SG&A expenses include promotional activities, marketing, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses, facilities-related expenses and shipping and handling costs. We expect continued increased costs due to the additional legal, accounting, insurance and other expenses associated with being a public company compared to when we were privately held. We also expect continued legal costs associated with ongoing litigation.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

The following table shows our results of operations (in thousands):

| | Years Ended December 31, | | |
|---------------------------------------|--------------------------|--------------------|--------------------|
| | 2019 | 2018 | Change \$ |
| Statements of operations data: | | | |
| Net revenue | | | |
| Product sales | \$ 3,859 | \$ 3,159 | \$ 700 |
| Service and other | 3,340 | 3,098 | 242 |
| Total net revenue | <u>7,199</u> | <u>6,257</u> | <u>942</u> |
| Cost of revenue | | | |
| Product sales | 5,856 | 2,652 | 3,204 |
| Service and other | 2,994 | 1,554 | 1,440 |
| Total cost of revenue | <u>8,850</u> | <u>4,206</u> | <u>4,644</u> |
| Gross (loss) profit | <u>(1,651)</u> | <u>2,051</u> | <u>(3,702)</u> |
| Operating expenses: | | | |
| Selling, general and administrative | 51,549 | 30,435 | 21,114 |
| Research and development | 4,530 | 2,776 | 1,754 |
| Total operating expenses | <u>56,079</u> | <u>33,211</u> | <u>22,868</u> |
| Operating loss | <u>(57,730)</u> | <u>(31,160)</u> | <u>(26,570)</u> |
| Other income, net | 788 | 338 | 450 |
| Loss before income taxes | <u>(56,942)</u> | <u>(30,822)</u> | <u>(26,120)</u> |
| Income tax expense | 15 | 10 | 5 |
| Net loss | <u>\$ (56,957)</u> | <u>\$ (30,832)</u> | <u>\$ (26,125)</u> |

Comparison of years ended December 31, 2019, and 2018—By reportable segments

We organize our business into two operating segments based on the product specialties: the vascular segment and the dermatology segment. In deciding how to allocate resources and assess performance, we regularly evaluate the net revenue and gross profit (loss) of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to us and not specific to a particular segment; therefore, these amounts are not evaluated by us on a segmented basis. Additional information on our reportable segments is contained in Note 15 to the financial statements appearing elsewhere in this Annual Report on Form 10-K.

Net revenue

The following table shows our net revenue from our two segments (in thousands):

| | Years Ended December 31, | | |
|-------------------|--------------------------|-----------------|---------------|
| | 2019 | 2018 | Change \$ |
| Vascular | \$ 1,275 | \$ 1,552 | \$ (277) |
| Dermatology | 5,924 | 4,705 | 1,219 |
| Total net revenue | <u>\$ 7,199</u> | <u>\$ 6,257</u> | <u>\$ 942</u> |

Vascular

Net revenue was \$1.3 million and \$1.6 million for the years ended December 31, 2019 and 2018, respectively. The decrease of approximately \$0.3 million was due to decreased catheter unit sales. We do not expect our net revenue to increase in the near term with our reduced sales force and as we focus on remedying the inconsistencies in our DABRA catheter performance. Over the longer term, if we are able to improve the consistency of our catheter performance and introduce design changes to the catheter, we believe we will be able to increase our vascular revenue.

Dermatology

Net revenue was \$5.9 million and \$4.7 million for the years ended December 31, 2019 and 2018, respectively. The increase of approximately \$1.2 million was due primarily to an increase of \$1.0 million in direct unit product sales and \$0.2 million in service revenue.

Cost of revenue

The following table shows our cost of revenue from our two segments (in thousands):

| | Years Ended December 31, | | |
|-----------------------|--------------------------|-----------------|-----------------|
| | 2019 | 2018 | Change \$ |
| Vascular | \$ 4,036 | \$ 1,521 | \$ 2,515 |
| Dermatology | 4,814 | 2,685 | 2,129 |
| Total cost of revenue | <u>\$ 8,850</u> | <u>\$ 4,206</u> | <u>\$ 4,644</u> |

Vascular

Cost of revenue was \$4.0 million and \$1.5 million for the years ended December 31, 2019 and 2018. The \$2.5 million increase was due to (i) increased labor, material and overhead costs to support the continued efforts to remedy the inconsistencies in our DABRA catheter performance and warranty costs of replacement units, including \$0.2 million relating to the voluntary recall of catheters, (ii) stock-based compensation expense due to continued expenses related to the modification accounting treatment of replacement awards that took place in the second quarter of 2018 and (iii) maintenance costs and depreciation expense related to our lasers at our customer site.

Dermatology

Cost of revenue was \$4.8 million and \$2.7 million for the years ended December 31, 2019 and 2018, respectively. The increase of \$2.1 million was due to an increase in direct unit product sales and increased service costs due to increases in stock-based compensation expense as a result of continued expenses related to the modification accounting treatment of replacement awards that took place in the second quarter of 2018, depreciation expense and maintenance costs.

Gross (loss) profit

The following table shows our gross (loss) profit from our two segments (in thousands):

| | Years Ended December 31, | | |
|---------------------------|--------------------------|-----------------|-------------------|
| | 2019 | 2018 | Change \$ |
| Vascular | \$ (2,761) | \$ 31 | \$ (2,792) |
| Dermatology | 1,110 | 2,020 | (910) |
| Total gross (loss) profit | <u>\$ (1,651)</u> | <u>\$ 2,051</u> | <u>\$ (3,702)</u> |

Vascular

Gross loss was \$2.8 million for the year ended December 31, 2019 and gross profit was \$31.0 thousand for the year ended December 31, 2018. The decrease of \$2.8 million is due to (i) increased labor, material and overhead costs to support the continued efforts to remedy the inconsistencies in our DABRA catheter performance and warranty costs of replacement units, including \$0.2 million relating to the voluntary recall of catheters, (ii) stock-based compensation expense due to continued expenses related to the modification accounting treatment of replacement awards that took place in the second quarter of 2018 and (iii) maintenance costs and depreciation expense related to our lasers at our customer sites.

We expect our gross profit (loss) to be negatively impacted in the short term with our reduced sales force and as we continue efforts to remedy the inconsistencies in our DABRA catheter performance.

Dermatology

Gross profit was \$1.1 million and \$2.0 million for the years ended December 31, 2019 and 2018, respectively. The decrease of \$0.9 million was primarily due increased costs of service including non-cash charges relating to depreciation and stock-based compensation.

Comparison of years ended December 31, 2019, and 2018—General

Selling, general and administrative expenses. SG&A expenses were \$51.5 million and \$30.4 million for the years ended December 31, 2019 and 2018, respectively. The \$21.1 million increase primarily related to increases of (i) \$8.5 million in stock-based compensation expense primarily due to continued expenses related to the modification accounting treatment of replacement awards that took place in the second quarter of 2018 and new grants, (ii) \$4.8 million increase in legal expense primarily due to the Audit Committee investigation and securities litigation, (iii) \$4.4 million in salary, benefits, recruiting expenses and other personnel-related costs due to expanding our sales force in the first half of the year (later reduced in the second half of the year) and hiring administrative staff to operate as a public company, (iv) \$1.4 million in insurance due to being publicly traded, (v) \$1.2 million in outside services to operate as a public company, including audit, consulting, board of directors and investor relations fees including \$0.4 million related to the investigation conducted by the Audit Committee, (vi) \$0.4 million in sales training related costs, (vii) \$0.3 million in other costs including depreciation, and (viii) \$0.1 million in travel and trade shows. Note 12 to the financial statements appearing elsewhere in this Annual Report on Form 10-K more fully describes the accounting treatment for stock-based compensation awards.

Research and development expenses. R&D expenses were \$4.5 million and \$2.8 million for the years ended December 31, 2019 and 2018, respectively. The \$1.7 million increase was primarily due to increases of \$1.6 million in personnel costs, supplies and consulting expenses to understand the inconsistencies in our DABRA catheter performance and efforts on the next generation of products, \$0.6 million in clinical study expenses offset by a decrease of \$0.4 million in stock-based compensation expense.

Other income (expense), net. Other income (expense), net was net other income of \$0.8 million and \$0.3 million for the years ended December 31, 2019 and 2018, respectively. Other income was primarily comprised of interest income on one year of the net proceeds from the IPO that were received in October 2018. Other income is offset by interest expense primarily related to the significant financing component for multi-year warranty service contracts.

Non-GAAP Measures

EBITDA and Adjusted EBITDA are performance measures that provide supplemental information we believe is useful to analysts and investors to evaluate our ongoing results of operations, when considered alongside other GAAP measures. These Non-GAAP Measures exclude the financial impact of items management does not consider in assessing our ongoing operating performance, and thereby facilitate review of our operating performance on a period-to-period basis. Comparability to our results of operations to other companies may be impacted by our stock-based compensation which was classified as a liability and revalued at each reporting period with the change in fair value recorded to compensation expense in the statement of operations in 2018.

We believe that non-GAAP financial information, when taken collectively, may be helpful to investors because it provides consistency and comparability with past financial performance. However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with U.S. GAAP. Some of these limitations are that:

- EBITDA excludes certain recurring, non-cash charges such as depreciation and amortization of long-lived assets, although these are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future; and
- Adjusted EBITDA further excludes stock-based compensation expense, which has been, and will continue to be for the foreseeable future, a significant recurring expense in our business and an important part of our compensation strategy.

In addition, other companies, including companies in our industry, may calculate similarly-titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison.

A reconciliation for each non-GAAP financial measure to the most directly comparable financial measure stated in accordance with U.S. GAAP is included below. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures, and not to rely on any single financial measure to evaluate our business. We define Adjusted EBITDA as our GAAP net loss as adjusted to exclude depreciation and amortization, interest income, interest expense, income tax expense and stock-based compensation.

The following is a reconciliation of Net loss to Adjusted EBITDA:

| | Year Ended December 31, | |
|---------------------------------------|-------------------------|---------------------|
| | 2019 | 2018 |
| | (in thousands) | |
| Statements of Operations Data: | | |
| Net loss | \$ (56,957) | \$ (30,832) |
| Depreciation and amortization | 1,750 | 624 |
| Interest income | (1,038) | (352) |
| Interest expense | 250 | 14 |
| Income tax expense | 15 | 10 |
| EBITDA | (55,980) | (30,536) |
| Stock-based compensation | 23,543 | 14,728 |
| Adjusted EBITDA | <u>\$ (32,437)</u> | <u>\$ (15,808)</u> |

Adjusted EBITDA was negative \$32.4 million compared to negative \$15.8 million for the years ended December 31, 2019 and 2018, respectively. The decrease in Adjusted EBITDA primarily reflects higher selling, general and administrative costs, including salary, benefits, recruiting expenses, legal fees and consulting costs due to increased personnel, costs associated with increasing the sales force, costs associated with efforts to remedy the inconsistencies in our DABRA catheter performance, and the costs of operating as a public company, including the investigation conducted by the Audit Committee.

Liquidity and Capital Resources

As of December 31, 2019, we had cash and cash equivalents and short-term investments of \$30.6 million and an accumulated deficit of \$117.2 million. Our primary sources of capital have been from the sale of our products and services, the net proceeds of \$67.3 million from our initial public offering, and, to a lesser extent, private placements of common stock and equipment financing arrangements.

Management expects operating losses and negative cash flows to continue for the foreseeable future with the our reduced commercial footprint, and as we continue to incur costs related to our atherectomy clinical trial, engineering efforts to improve the shelf-life of its catheters and develop next generation products and legal costs associated with ongoing litigation. In the third quarter of 2019, we began implementing certain operational efficiency and cost savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives included targeted workforce reductions of our sales and marketing teams. We reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to five clinical specialists employees as of December 31, 2019. In addition, we may need to decrease or defer capital expenditures and development activities to further optimize our operations. Such measures may impair our ability to invest in developing, marketing and selling new and existing products.

We are incurring additional costs as a result of operating as a public company, including increases in legal, accounting, insurance and other expenses. Additionally, we expect legal and related expenses to remain high in the near term in connection with the legal proceedings discussed in Note 14, "Commitments and Contingencies," in the notes to the financial statements.

Our future capital requirements will depend on many factors, including:

- the revenue generated by sales of our DABRA and Pharos products, related consumables, and other products that get approved in the U.S. and select non-U.S. markets, as well as the amount of sales personnel required to generate the revenue;
- our ability to remedy the inconsistencies in our DABRA catheter performance;
- following our voluntary product recall, our ability to achieve market acceptance of DABRA;
- matters arising out of our completed Audit Committee investigation;
- the cost, timing and outcomes of any litigation involving our company, products, and business activities, including securities class actions and derivative lawsuits, and government investigations in which we are involved;
- the extent to which our products are adopted by the physician community;
- the ability of our customers to obtain adequate reimbursement from third-party payors for procedures performed using DABRA;
- the degree of success we experience in commercializing our excimer lasers and related consumables;
- the costs, timing and outcomes of any future clinical studies and regulatory reviews, including to seek and obtain approvals for new indications for our products;
- the costs and timing of developing variations of our excimer lasers, and, if necessary, obtaining FDA clearance to market such variations;
- the emergence of competing or complementary technologies;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the level of our selling, general and administrative expenses.

Management estimates that based on our liquidity resources, there is substantial doubt about our ability to continue as a going concern within 12 months from the date of issuance of the financial statements.

Our ability to continue as a going concern is dependent upon our ability to raise additional funding. We plan to raise additional capital through public or private equity or debt financings to fulfill our operating and capital requirements for at least 12 months from the date of the issuance of the financial statements. However, we may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if we issue equity securities to raise additional funds, its existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of our existing stockholders.

Our financial statements include explanatory disclosures regarding substantial doubt about our ability to continue as a going concern. Future reports on our financial statements may also include explanatory disclosures with respect to our ability to continue as a going concern. Our financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue our operations.

Cash Flows

| | Years Ended December 31, | |
|---|--------------------------|------------------|
| | 2019 | 2018 |
| | (in thousands) | |
| Net cash (used in) provided by: | | |
| Operating activities | \$ (33,173) | \$ (18,508) |
| Investing activities | (16,032) | (582) |
| Financing activities | (526) | 75,168 |
| Net change in cash and cash equivalents | <u>\$ (49,731)</u> | <u>\$ 56,078</u> |

Net cash used in operating activities

During the year ended December 31, 2019, net cash used in operating activities was \$33.2 million, consisting primarily of a net loss of \$57.0 million and an increase in net operating assets of \$1.9 million, partially offset by non-cash charges of \$25.7 million consisting of primarily stock-based compensation expense, depreciation and amortization and allowance for doubtful accounts.

During the year ended December 31, 2018, net cash used in operating activities was \$18.5 million, consisting primarily of a net loss of \$30.8 million and an increase in net operating assets of \$3.3 million primarily related to decreases in accounts receivables, accrued expenses and inventories partially offset by increases in accounts payable. These items were partially offset by non-cash charges of \$15.6 million consisting of depreciation, stock-based compensation expense and provision for doubtful accounts.

Net cash used in investing activities

During the year ended December 31, 2019, net cash used in investing activities was \$16.0 million, consisting of \$36.5 million to purchase short-term investments and \$0.3 million to purchase manufacturing equipment and vehicles for our sales force to transport our laser equipment, partially offset by \$21.0 million from proceeds of sales of investments.

During the year ended December 31, 2018, net cash used in investing activities was \$0.6 million consisting primarily of purchases of manufacturing equipment and computer hardware and software.

Net cash (used in) provided by financing activities

During the year ended December 31, 2019, net cash used in financing activities was \$0.5 million due to payments on our financed equipment of \$0.3 million and payments for taxes on the settlement of restricted stock units of \$0.2 million, partially offset by proceeds from issuance of common stock related to the employee stock purchase plan of \$37,000.

During the year ended December 31, 2018, net cash provided by financing activities was \$75.2 million, consisting primarily of net proceeds of \$67.3 million from the issuance of common stock related to our IPO and \$7.9 million received from the issuance of common stock related to a private placement financing, partially offset by payments of \$0.1 million in equipment financing payments.

Off-Balance Sheet Arrangements

We do not engage in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, as a part of our ongoing business. Accordingly, we did not have any off-balance sheet arrangements during any of the periods presented.

Contractual Obligations

Our principal obligations consist of the operating leases for our facilities. The following table sets out, as of December 31, 2019, our contractual obligations due by period (in thousands):

| | Payments due by period | | | | |
|--|------------------------|---------------------|-----------------|---------------|----------------------|
| | Total | Less than 1 Year | 1-3 Years | 3-5 Years | More than 5 Years |
| Operating lease obligations ⁽¹⁾ | \$ 3,837 | \$ 514 | \$ 960 | \$ 904 | \$ 1,459 |
| Equipment Financing ⁽²⁾ | 558 | 293 | 265 | — | — |
| Total | <u>\$ 4,395</u> | <u>\$ 807</u> | <u>\$ 1,225</u> | <u>\$ 904</u> | <u>\$ 1,459</u> |

(1) Consists of obligations under multi-year, non-cancelable building leases for our facilities in Carlsbad, California.

(2) Consists primarily of obligations under the equipment financing for automobiles.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in the notes to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

We have previously identified material weaknesses in our internal control over financial reporting, which are now remediated. For additional information, see Item 9A, "Controls and Procedures."

Revenue recognition

We adopted ASC Topic 606 (Topic 606), *Revenue from Contracts with Customers*, on January 1, 2019 using the modified retrospective method to all contract agreements not completed as of January 1, 2019. Results for reporting periods beginning after January 1, 2019 are presented under Topic 606 while, as permitted by Topic 606, prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. We recorded a cumulative catch up adjustment to beginning accumulated deficit to reflect the impact of adopting Topic 606. The adoption of Topic 606 did not have a material effect on our results of operations for the year ended December 31, 2019.

We generate revenue from the sale of products and services. Product sales consist of the sale of DABRA and Pharos laser systems, the sale of catheters for use with the DABRA laser, and the sale of consumables and replacement parts. Our sales agreements generally do not include right-of-return provisions for any form of consideration including partial refund or credit against amounts owed to us. Services and other revenue primarily consist of sales of extended warranty and billable services, including repair activity and income from rental of lasers.

We determine revenue recognition incorporating the following steps:

- Identification of each contract with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when, or as, performance obligations are satisfied.

We account for a contract with a customer when we have a legally enforceable contract with the customer, the arrangement identifies the rights of the parties, the contract has commercial substance, and we determine it is probable that it will collect the contract consideration. We recognize revenue when control of the promised goods or services transfers to customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. Taxes collected from customers relating to goods or services and remitted to governmental authorities are excluded from revenue.

Catheter Revenue

We enter into a DABRA laser commercial usage agreement or DABRA laser placement acknowledgement with each customer that is supplied a DABRA laser, collectively the “usage agreement”. The usage agreement provides for specific terms of continued use of DABRA laser, including a nominal periodic fee. The terms of a usage agreement typically allow us to place a DABRA laser at a customer’s specified location without a specified contract term. Under the usage agreement terms, we retain all ownership rights to the DABRA laser and are permitted to request the return of the equipment within 10 business days of notification. While the laser periodic fees are nominal, the laser usage agreements provide us the exclusive rights to supply related single-use catheters to the customer which aggregate the majority of the vascular segment revenue. There are no specified minimum purchase commitments for the catheters.

We recognize revenue associated with the usage agreement and catheter supply arrangements in accordance with Topic 606 as the contract primarily includes variable payments, the catheters are priced at their standalone selling price and the laser equipment is insignificant in the context of the contract. Revenue is recognized when the performance obligation is satisfied, which is generally upon shipment of the catheter.

Laser Sales

Laser sales consist of sales of DABRA and Pharos laser systems and are included in product sales in the statements of operations. We recognize revenue on laser sales at the point in time that control transfers to the customer. Control of the product typically transfers upon shipment.

Warranty Service Revenue

We typically provide a 12-month warranty with the purchase of our laser systems. Customers can extend the warranty period through the purchase of extended warranty service contracts. Extended warranty service contracts are sold with contract terms ranging from 12 to 60 months and cover periods after the end of the initial 12-month warranty period. The warranty provides the customer with maintenance services in addition to the assurance that the laser product complies with agreed-upon specifications. Therefore, the warranty service is treated as a separate performance obligation from the laser system. Warranty services are a stand-ready obligation, and we recognize revenue on a straight-line basis over the service contract term. Warranty service revenue is included in service and other revenue in the statements of operations.

Distributor Transactions

In certain markets outside the U.S., we sell products and provide services to customers through distributors that specialize in medical device products. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers. We account for these transactions in accordance with our revenue recognition policy described herein.

Contracts with multiple performance obligations

Certain of our contracts with customers contain multiple performance obligations. For these contracts, we account for individual products and services as separate performance obligations if they are distinct, which is if (i) a product or service is separately identifiable from other items in the arrangement and (ii) the customer can benefit from the product or service on its own or with other readily available resources. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. We determine standalone selling prices based on observable prices of products or services sold separately in comparable circumstances to similar customers.

Significant Financing Component

For multi-year warranty service contracts in which there is a difference between the cash selling price and the consideration in the contract and a significant amount of time between the payment, which is due up-front, and delivery of the services (greater than one year), we record an adjustment for significant financing to reflect the time value of money. We recognize revenue associated with the cash selling price and interest expense using the effective interest method as we satisfy our performance obligation(s). The amount of interest expense we recognize over the contract term is based on the contract liability balance, which increases for the accrual of interest and decreases as services are provided.

For services contracts that have an original duration of one year or less, we use the practical expedient applicable to such contracts and does not adjust the transaction price for the time value of money.

Practical expedients elected

As part of our adoption of Topic 606, we elected to use the following practical expedients:

- not to adjust the promised amount of consideration for the effects of a significant financing component when we expect, at contract inception, that the period between our transfer of a promised product or service to a customer and when the customer pays for that product or service will be one year or less;
- to expense costs as incurred for costs to obtain a contract when the amortization period would have been one year or less;
- to exclude government assessed taxes from the transaction price; and
- not to recast revenue for contracts that begin and end in the same fiscal year.

Contract Costs

We capitalize costs to obtain contracts that are considered incremental and recoverable, such as sales commissions. The capitalized costs are amortized to selling, general and administrative expense over the estimated period of benefit of the asset, which is the contract term. We elected to use the practical expedient to expense the costs to obtain a contract when the amortization period is less than one year.

Rental Income

We also adopted ASC Topic 842, *Leases*, on January 1, 2019 using the optional transitional method. There was no adjustment to accumulated deficit at January 1, 2019.

We derive income pursuant to product lease agreements for our Pharos laser systems, as operating leases. Consequently, we retain title to the equipment and the equipment remains on our balance sheet within property and equipment. Depreciation expense on these leased lasers is recorded to cost of revenues on a straight-line basis. The costs to maintain these leased lasers are charged to cost of revenues as incurred.

These lease arrangements contain one lease component (the laser) and one nonlease component (warranty service) for which we elected the practical expedient to not separate the nonlease component from the lease component. We account for the combined lease component as an operating lease and recognizes lease income on a straight-line basis over the lease term.

Stock-based compensation

We evaluate whether an award should be classified and accounted for as a liability award or equity award for all stock-based compensation awards granted.

Stock-based compensation for liability awards issued to employees, directors, consultants, and other service providers were measured based on fair value of the award using the Black Scholes option pricing model. Changes in the fair value of a liability incurred under a share-based payment arrangement that occur during the requisite service period are recognized as compensation cost over that period. The percentage of the fair value that is accrued as compensation cost at the end of each period is equal to the percentage of the requisite service that has been rendered at that date. Any difference between the amount for which a liability award is settled and its fair value at the settlement date is recorded as an adjustment to compensation cost in the period of settlement. There were no liability awards outstanding at December 31, 2019 or 2018.

Stock-based compensation expense for equity instruments issued to employees and directors is measured based on estimating the fair value of each stock option on the date of grant using the Black Scholes option pricing model. Equity instruments issued to nonemployee consultants and service providers are valued using the Black Scholes option pricing model and are subject to revaluation as the underlying equity instruments vest.

We recognize stock-based compensation expense as follows:

| | <u>Employees</u> | <u>Nonemployees</u> |
|--|---|---|
| Service condition only | Straight-line | In the same period and in the same manner as if we paid cash for services. |
| Performance criterion is probable of being met: | | |
| Service criterion is complete | Recognize the grant date fair value of the award once the performance criterion is considered probable of occurrence | Recognize the grant date fair value of the award once the performance criterion is considered probable of occurrence |
| Service criterion is not complete | Straight-line | Straight-line unless a performance condition is not probable |
| Performance criterion is not probable of being met | No expense is recognized until the performance criterion is considered probable, at which point expense is recognized per above | No expense is recognized until the performance criterion is considered probable, at which point expense is recognized per above |

As described in Note 12 of the financial statements, on June 4, 2018, our board of directors authorized replacement equity awards of stock options and, effective June 8, 2018, restricted stock units, or collectively, the "Replacement Awards." The issuance of the Replacement Awards and cancellation of the stock-based compensation awards classified as liabilities was treated as a modification. As of the date of the modification, which resulted in the settlement of the stock-based compensation liability, the fair value of the stock-based compensation liability was estimated using the Black Scholes option pricing model and the assumptions used in the model are noted below:

- *Fair value of our common stock*—The common stock price was estimated utilizing a hybrid method, a combination of the Probability Weighted Expected Return Method, or PWERM, and Option Pricing Model, or OPM. The estimate incorporated a near-term IPO scenario using PWERM weighted at 80%. Other near-term exit events, a long-term stay private case, and dissolution were all considered as non-IPO scenarios using OPM, and were weighted at 20%. The estimate also reflected a 10% and 15% discount for lack of marketability under PWERM and OPM, respectively.
- *Risk-free interest rate*—The risk-free interest rate approximated the implied yield available on United States Treasury securities with an equivalent remaining term.
- *Volatility*—Expected volatility was based on the historical volatilities of certain "guideline" companies.

- *Expected dividend yield*—Expected dividend yield was based on dividends historically paid by us.
- *Expected life*—The expected life was based on the “simplified” method using the average of the term and vesting period.

For stock awards following our initial public offering, the fair value of each share of underlying common stock is based on the closing price of our common stock as reported on the date of grant.

If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. To the extent that our assumptions are incorrect, the amount of stock-based compensation recorded will change.

Income taxes

We account for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences reverse. Any resulting net deferred tax assets are evaluated for recoverability and, accordingly, a valuation allowance is provided when it is more likely than not that all or some portion of the deferred tax asset will not be realized.

We account for uncertainty in income taxes using a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining whether it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. An uncertain tax position is considered effectively settled on completion of an examination by a taxing authority if certain other conditions are satisfied. Should we incur interest and penalties relating to tax uncertainties, such amounts would be classified as a component of interest expense and other expense, respectively.

Jobs Act Accounting Election

An emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption. See Note 2 to the financial statements included elsewhere in this Annual Report on Form 10-K for a description of relevant new accounting pronouncements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business, including the effects of interest rate changes and foreign currency fluctuations. Information relating to quantitative and qualitative disclosures about these market risks is described below. We do not hold or issue financial instruments for trading purposes.

Interest Rate Sensitivity

We had cash, cash equivalents and short-term investments of \$30.6 million as of December 31, 2019, which came from sales of our products and services, the net proceeds from our initial public offering and, to a lesser extent, private placements of common stock and equipment financing arrangements. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short term nature of our cash and cash equivalents. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

Foreign Currency Exchange Risk

As we expand internationally our results of operations and cash flows may become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Most of our revenue is denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States. As of December 31, 2019, the effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables would not have been material for the periods presented. As our operations in countries outside of the United States grow, our results of operations and cash flows may be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any material foreign currency hedging contracts although we may do so in the future.

Inflation risk

We do not believe that inflation has had a material effect on our business, results of operations, or financial condition. Nonetheless, if our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs. Our inability or failure to do so could harm our business, results of operations, or financial condition.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements and supplementary data required by this item are set forth at the pages indicated in Item 15(a)(1) and 15(a)(2), respectively.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Financial Officer, who is also our Interim Chief Executive Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of December 31, 2019. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives of ensuring that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures, and is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

In reviewing the allegations and findings from an Audit Committee investigation related to an initially anonymous complaint, as well as additional matters discovered during the course of the investigation, we identified, in 2019, certain deficiencies in our internal controls, which existed in 2018 as well, which were considered material weaknesses. Although no material misstatements or omissions in our financial statements or disclosures were identified, the material weaknesses in internal controls could have resulted in material misstatements or omissions to our financial statements or disclosures.

As discussed below, we took actions to remediate these material weaknesses in internal control over financial reporting. Based upon our evaluation and the remediation efforts described below, our Interim Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2019, our disclosure controls and procedures were effective at the reasonable assurance level.

Control environment

We identified certain deficiencies in our internal controls, which aggregated to a material weakness in the control environment component of the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control - Integrated Framework (the "COSO Framework")*. The material weakness results from the aggregation of control deficiencies in the Company's control environment, in particular an inappropriate "tone at the top" set by certain members of senior management, including a failure to promote adherence to our Code of Ethics and Conduct, and the lack of sufficient competent resources in key roles at the organization. The ineffective control environment resulted in the following:

- behavior that was inconsistent with our Code of Ethics and Conduct and related policies involving certain former executive officers and employees of the Company;
- explanations regarding the issues that had an impact on our fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because the explanations did not explicitly reference the effect of inconsistent catheter performance and catheter failures;
- failure to timely make at least two Medical Device Reports, or MDRs, to the FDA;
- engagement in systematic efforts to replace product held by customers, which constituted product recalls, were not documented as such;
- lack of documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, to three physicians did not accurately reflect the purpose and nature of approximately \$300,000 of payments, which could be perceived as an improper attempt to obtain business or to gain special advantage;
- while the indication for use in the 510(k) clearance we obtained for the DABRA system is not for atherectomy, our salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes;
- determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects.

The ineffective control environment contributed significantly to the material weakness described below.

Information and communication

We identified a deficiency in the information and communication component of the COSO Framework that resulted in a material weakness. This deficiency related to the ineffective design of internal communication of information, including objectives and responsibilities for internal control, necessary to support the functioning of internal control. The deficiency resulted in the receipt of complaints regarding regulatory or compliance concerns that, because the complaints implicated executive officers, should have been brought to the attention of the board of directors or the Audit Committee, but were not.

Changes in Internal Control over Financial Reporting

We previously disclosed material weaknesses in our internal control over financial reporting related to the matters discussed above.

We took actions to remediate the material weaknesses relating to our internal controls over financial reporting, as described below. The remedial activities we took included separation of certain former executives and employees, hiring qualified personnel including a VP Quality, Regulatory and Clinical, implementing additional and enhanced policies and training, including with respect to our Code of Business Ethics and Conduct, strengthening our quality and regulatory systems, bolstering documentation requirements for certain third-party consulting, advisory and training agreements, and adopting certain enhanced controls related to the matters investigated by the Audit Committee.

As a result of the remediation activities and controls in place as of December 31, 2019 described above, we have remediated the previously disclosed material weaknesses. However, completion of remediation does not provide assurance that our remediated controls will continue to operate properly or that our financial statements will be free from error. There may be undetected material weaknesses in our internal control over financial reporting, as a result of which we may not detect financial statement errors on a timely basis. Moreover, in the future we may implement new offerings and engage in business transactions, such as acquisitions, reorganizations or implementation of new information systems, that could require us to develop and implement new controls and could negatively affect our internal control over financial reporting and result in material weaknesses.

We continue to develop our internal controls, processes and reporting systems in an effort to maintain the effectiveness of our internal control over financial reporting, and we expect to incur ongoing costs in this effort. However, we may not be successful in developing and maintaining adequate internal controls, which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results.

There were no additional changes in our internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting and Attestation Report of the Registered Public Accounting Firm

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on the assessment, management has concluded that its internal control over financial reporting was effective as of December 31, 2019 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. Our independent registered public accounting firm, Deloitte & Touche LLP, is not required to and has not issued an attestation report as of December 31, 2019 due to a transition period established by the rules of the SEC for newly public companies that have not lost their "emerging growth company" status as defined in the JOBS Act.

Inherent Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

On February 3, 2020, the compensation committee of our board approved cash bonus payments for the 2019 fiscal year for our named executive officers. Bonus payments were based on the compensation committee's evaluation of each executive's performance and our accomplishments during 2019 with reference to the bonus targets in each executive's employment agreement. Andrew Jackson received \$150,000, Jeffrey Kraws received \$65,000 and Daniel Horwood received \$78,000.

On March 9, 2020, the compensation committee of our board of directors approved increases in the annual base salaries for our named executive officers. Effective as of March 1, 2020, the annual base salary for Andrew Jackson increased to \$370,269 from \$358,440, for Jeffrey Kraws increased to \$358,565 from \$347,110, and for Daniel Horwood increased to \$333,659 from \$299,730.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Composition of the Board

Our business and affairs are managed under the direction of our Board, which currently consists of five members, all of which are “independent” under New York Stock Exchange, or NYSE, listing standards. Our bylaws provide that the number of directors will be fixed from time to time by resolution of the Board. All directors hold office until their successors have been elected and qualified or until their earlier death, resignation, disqualification or removal. We have divided the terms of office of the directors into three classes with staggered three year terms: Class I, whose term expires at the 2022 Annual Meeting of Stockholders; Class II, whose term expires at the 2020 Annual Meeting of Stockholders; and Class III, whose term expires at the 2021 Annual Meeting of Stockholders.

Information about the Board of Directors

The following table sets forth the names, ages as of March 6, 2020, and certain other information regarding each member of the Board are set forth below. The following information has been furnished to us by the directors.

| Name | Class | Age | Position | Director Since | Current Term Expires |
|--------------------------------|-------|-----|----------|----------------|----------------------|
| Martin Colombatto (2)(3) | II | 61 | Chairman | 2017 | 2020 |
| Maurice Buchbinder, M.D. (1) | II | 66 | Director | 2017 | 2020 |
| William R. Enquist, Jr. (1)(3) | III | 63 | Director | 2018 | 2021 |
| Richard Mejia, Jr. (2)(3) | III | 72 | Director | 2018 | 2021 |
| Mark E. Saad(1)(2) | I | 50 | Director | 2018 | 2022 |

- (1) Member of our nominating and corporate governance committee.
- (2) Member of our audit committee.
- (3) Member of our compensation committee.

Martin Colombatto has served as a director of Ra Medical since January 2017. Mr. Colombatto has served as a Venture and Industry Partner of Seven Peaks Ventures LLP, a venture capital fund based in Bend, OR, since January 2016. From December 2013 to August 2014, Mr. Colombatto served as a director of PLX Technology, Inc., a technology company. Mr. Colombatto has also served as the Chief Executive Officer and President of Staccato Communications, Inc., an Ultra Wideband semiconductor company, from January 2006 to March 2009 and as Executive Chairman of Staccato Communications, Inc., from January 2006 to September 2010. Prior to joining Staccato, Mr. Colombatto served as Vice President and General Manager of the Networking Business unit of Broadcom Corp., a broadband communication semiconductor company, from July 1996 to July 2002. Mr. Colombatto was also previously employed by LSI Logic, an application specific semiconductor company, from August 1987 to July 1996. Mr. Colombatto also previously held engineering positions at Reliance Electric, a production automation and control company, from August 1985 to June 1987 and Texas Instruments, an electronics company, from June 1982 to April 1985. Mr. Colombatto holds a Bachelor’s of Science Degree in Electronic Engineering Technology from California State Polytechnic University, Pomona. We believe that Mr. Colombatto is qualified to serve as a member of our board of directors due to his extensive management experience and familiarity with our business and strategy.

Maurice Buchbinder has served as a director of Ra Medical since January 2017. Dr. Buchbinder has served as Interventional Cardiologist for Maurice Buchbinder M.D., C.M., A Professional Corporation, from October 1994 to present. Dr. Buchbinder holds a Bachelor’s of Science degree from McGill University in Montreal, Canada, and a Doctor of Medicine, Master of Surgery, from McGill University. He completed his post-graduate education at Stanford University where he specialized in Cardiovascular Medicine. We believe that Dr. Buchbinder is qualified to serve as a member of our board of directors due to his extensive experience in the medical and medical device industries.

William R. Enquist, Jr. has served as a director of Ra Medical since July 2018. Mr. Enquist held various roles at Stryker Corporation, a medical device company, from 1986 to 2014, including Advisor from 2013 to 2014 and President, Global Endoscopy from 1998 to 2013. From 2015 to 2016, Mr. Enquist served as the chairman of the board of directors of EndoChoice Holdings, Inc., a publicly traded medical device company, until its acquisition by Boston Scientific in 2016. Mr. Enquist currently is chairman of the board of directors of Clinical Innovations and board director for SpineEx and Firefly Medical, all medical device companies. Mr. Enquist earned a BBA from the University of San Diego and completed Harvard University's Program for Management Development. We believe that Mr. Enquist is qualified to serve as a member of our board of directors because of his extensive experience as a senior executive officer of other healthcare companies.

Richard Mejia, Jr. has served as a director of Ra Medical since July 2018. Mr. Mejia previously served as a partner in the San Diego office of Ernst & Young LLP, a public accounting firm, from 1988 up until his retirement in 2008, including that from 2001 through 2008 he led the Life Sciences practice. From 2014 to 2018 he served on the Board of Stemedica Cell Technologies, Inc., a life science company and from 2008 to 2015, Mr. Mejia served on the board of directors of Dot Hill Systems Corp., a public company which manufactures software and hardware storage systems. From 2010 to 2012 he served on the board of directors of Sharp Health, a healthcare delivery system. Mr. Mejia holds a B.S. in Accounting from the University of Southern California. We believe that Mr. Mejia is qualified to serve as a director because of his extensive experience in public accounting, financial matters, industry knowledge and serving on boards of directors.

Mark E. Saad has served as a director of Ra Medical since July 2018. Mr. Saad currently serves as Partner and Chief Operating Officer of Alethea Capital Management, LLC, an asset management firm based in San Diego. From August 2014 to February 2017, Mr. Saad served as the Chief Financial Officer of Bird Rock Bio, Inc., a clinical stage biopharmaceutical company focused on developing innovative immuno-inflammatory regulators. Previously, Mr. Saad served as Chief Financial Officer of Cytori Therapeutics, a medical device developer and manufacturer, from 2004 to 2014, where he was responsible for finance and accounting, business development, and other operating functions. Prior to Cytori, he served as Executive Director of UBS Investment Bank, a multinational investment bank and financial services company, where he was the Chief Operating Officer of the Global Healthcare Group. Prior to UBS, Mr. Saad was part of the Health Care Investment Banking Group at Salomon Smith Barney, an investment bank. Mr. Saad has been a member of the board of directors of Axsome Therapeutics, Inc., a clinical-stage biopharmaceutical company, since December 2014. Mr. Saad holds a Bachelor of Arts from Villanova University. We believe that Mr. Saad is qualified to serve as a member of our board of directors due to his financial expertise and leadership experience.

Executive Officers

The names of our executive officers and key employees, their ages, their positions with the Company and other biographical information as of March 6, 2020 are set forth below. There are currently no family relationships among any of our directors or executive officers. For a description of the prior family relationships among our directors or executive officers, see the section entitled "*Certain Relationships and Related Party Transactions: Certain Family Relationships.*"

| Name | Age | Position |
|----------------|-----|---|
| Andrew Jackson | 51 | Chief Financial Officer and Interim Chief Executive Officer |
| Jeffrey Kraws | 55 | Co-President |
| Daniel Horwood | 46 | General Counsel, Chief Compliance Officer and Secretary |

Andrew Jackson has served as our Chief Financial Officer since April 2018, and as our Interim Chief Executive Officer since August 2019. From October 2016 to April 2018 he was Chief Financial Officer for AltheaDx, Inc, a molecular diagnostics company specializing in precision medicine. From March 2014 to March 2016, Mr. Jackson held senior financial positions, including Chief Financial Officer, at Celladon Corporation, a publicly-traded, clinical stage biotechnology company. From April 2013 to March 2014 he held senior financial positions at Sapphire Energy, an industrial biotechnology company. Mr. Jackson received a MSBA in Finance in December 2006 from San Diego State University and a BSB in Accounting in June 1992 from the University of Minnesota. Mr. Jackson is also a certified public accountant (inactive).

Jeffrey J. Kraws has served as our Co-President since May 2018 and served as the President of Ra Medical from August 2016 until May 2018. Since 2003, Mr. Kraws has served as Chief Executive Officer and co-founder of Crystal Research Associates and CRA Advisors. Mr. Kraws is a partner at Grannus Securities Pty Ltd. (an Australian based private equity fund) since November 2015. Mr. Kraws is an Industry Advisor to the Healthcare Investment Banking Group at Piper Sandler Companies since March 2019. Prior to founding Crystal Research Associates, Mr. Kraws served as co-president of The Investor Relations Group (IRG), a firm representing primarily under-followed, small-capitalization companies. Previously, Mr. Kraws served as a managing director of healthcare research for Ryan Beck & Co. and as director of research/senior pharmaceutical analyst and managing director at Gruntal & Co., LLC (prior to its merger with Ryan Beck & Company). Mr. Kraws served as managing director of the healthcare research group and senior pharmaceutical analyst at First Union Securities (formerly EVEREN Securities); as senior U.S. pharmaceutical analyst for the Swedish-Swiss conglomerate Asea Brown Boveri; and as managing director and president of the Brokerage/Investment Banking operation of ABB Aros Securities, Inc. He also served as senior pharmaceutical analyst at Nations Banc Montgomery Securities, BT Alex Brown & Sons, and Buckingham Research. Mr. Kraws also served in the treasury group at Bristol-Myers-Squibb Company. Mr. Kraws serves on the board of directors of Avivagen (TSX:VIV), Saleen Automotive, Inc. (OTC: SLNN), and is Chairman of the Board of Synthetic Biologics (NYSE:SYN). Mr. Kraws holds an MBA from Cornell University and a BS degree from State University of New York, Buffalo.

Daniel Horwood has served as our General Counsel since October 2018, as our Secretary since December 2018 and as our Chief Compliance Officer since October 2019. From April 2018 until October 2018, Mr. Horwood served as Corporate Counsel to Teradata Corporation, a data and analytics, cloud analytics and consulting company. Mr. Horwood was Counsel at Wilson Sonsini Goodrich & Rosati, P.C. from November 2014 through April 2018, advising life sciences and technology companies on public offerings, private financing, mergers and acquisitions, securities compliance, public company reporting and corporate governance. From January 2012 until October 2014, Mr. Horwood served as Associate General Counsel and Assistant Corporate Secretary to Groupon, Inc., a worldwide e-commerce company. Mr. Horwood began his legal career at the United States Securities and Exchange Commission, where he served as Special Counsel in the Division of Corporation Finance. Mr. Horwood received a B.A. from Connecticut College and a J.D. from the University of Pennsylvania.

Code of Conduct

We have adopted a code of ethics and conduct that applies to our directors, officers and employees, including our principal executive officer and principal financial officer.

Our Code of Ethics and Conduct is available at our website by visiting ir.ramed.com and clicking through "Governance," "Governance Documents" and "Code of Ethics and Conduct." We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendments to, or waiver from, a provision of our Code of Conduct by posting such information on the website address and location specified above.

Director Independence

Our common stock is listed on the NYSE. Under the rules of the NYSE, independent directors must comprise a majority of a listed company's board of directors within a specified period of the completion of such company's initial public offering. In addition, the rules of the NYSE require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and corporate governance committees be independent. Under the rules of the NYSE, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered independent for purposes of Rule 10A-3 of the Exchange Act and under the rules of NYSE, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries.

Our board of directors undertook a review of the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that each of Martin Colombatto, Maurice Buchbinder, Richard Mejia, Jr., Mark E. Saad, and William R. Enquist, Jr., representing all of our directors, is “independent” as that term is defined under the rules of NYSE.

Our board of directors also determined that Richard Mejia, Jr. (Chairperson of our audit committee), Martin Colombatto, and Mark E. Saad, who currently comprise our audit committee, and Martin Colombatto (Chairperson of our compensation committee), Richard Mejia, Jr., and William R. Enquist, who currently comprise our compensation committee, and Mark E. Saad (Chairperson of our nominating and governance committee), Maurice Buchbinder, M.D., and William R. Enquist, Jr., who currently comprise our nominating and corporate governance committee, satisfy the independence standards for those committees established by applicable Securities and Exchange Commission, or SEC, rules and the listing standards of the NYSE.

In making these determinations, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining their independence, including consulting relationships, family relationships and the beneficial ownership of our capital stock by each non-employee director.

There are currently no family relationships among any of our directors or executive officers. For a description of the family relationships among our prior directors or executive officers, see the section entitled “*Certain Relationships and Related Party Transactions: Certain Family Relationships.*”

Board Leadership Structure

Martin Colombatto is the chairman of our board of directors. Our current Interim Chief Executive Officer does not serve on the Board of Directors. Our corporate governance principles require that we designate one independent, non-employee director to serve as Lead Director at any time when our Chief Executive Officer serves as the Chairman of our board of directors or if the Chairman is not otherwise independent.

Mr. Colombatto previously served as our Lead Director from September 2018 to August 2019. The board chose Mr. Colombatto as our Lead Director because of his substantial executive experience in the technology industry. Mr. Colombatto became chairman of the board of directors on August 11, 2019.

Role of Board in Risk Oversight Process

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through its standing committees that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure. Our audit committee is responsible for reviewing and discussing our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies with respect to risk assessment and risk management. Our audit committee also monitors compliance with legal and regulatory requirements and reviews related party transactions, in addition to oversight of the performance of our external audit function. Our nominating and corporate governance committee assists our board of directors in fulfilling its oversight responsibilities with respect to the management of risk associated with board organization, membership and structure, and corporate governance. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. The board believes its leadership structure is consistent with and supports the administration of its risk oversight function.

Board Meetings and Committees

During our fiscal year ended December 31, 2019, our board of directors held eleven (11) meetings (including regularly scheduled and special meetings), and each current director attended at least 75% of the aggregate of (i) the total number of meetings of our board of directors held during the period for which he has been a director and (ii) the total number of meetings held by all committees of our board of directors on which he served during the periods that he served.

It is the policy of our Board to regularly have separate meeting times for independent directors without management. Although we do not have a formal policy regarding attendance by members of our board of directors at annual meetings of stockholders, we encourage, but do not require, our directors to attend.

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and the responsibilities described below. We believe that the composition of these committees meets the criteria for independence under, and the functioning of these committees comply with the requirements of, the Sarbanes-Oxley Act of 2002, the rules of the NYSE, and SEC rules and regulations.

Audit Committee

The members of our audit committee are Richard Mejia, Jr., Martin Colombatto and Mark E. Saad. Mr. Mejia serves as the chairperson of our audit committee. Our board of directors has determined that each of the members of our audit committee is an independent director under the NYSE listing rules, satisfies the additional independence criteria for audit committee members and satisfies the requirements for financial literacy under the NYSE listing rules and Rule 10A-3 of the Exchange Act, as applicable. Our board has also determined that Mr. Mejia qualifies as an audit committee financial expert within the meaning of the applicable rules and regulations of the SEC and satisfies the financial sophistication requirements of the NYSE listing rules.

Our audit committee oversees our corporate accounting and financial reporting process and assists our board of directors in monitoring our financial systems and our legal and regulatory compliance. Our audit committee responsibilities also include, among other things:

- selecting and hiring the independent registered public accounting firm to audit our financial statements;
- overseeing the performance of the independent registered public accounting firm and taking those actions as it deems necessary to satisfy itself that the accountants are independent of management;
- reviewing financial statements and discussing with management and the independent registered public accounting firm our annual audited and quarterly financial statements, the results of the independent audit and the quarterly reviews, and the reports and certifications regarding internal control over financial reporting and disclosure controls;
- preparing the audit committee report that the SEC requires to be included in our annual proxy statement;
- reviewing the adequacy and effectiveness of our internal controls and disclosure controls and procedures;
- overseeing our policies on risk assessment and risk management;
- reviewing related party transactions; and
- approving or, as required, pre-approving, all audit and all permissible non-audit services and fees to be performed by the independent registered public accounting firm.

Our audit committee operates under a written charter approved by our board of directors and that satisfies the applicable rules and regulations of the SEC and the listing requirements of NYSE. The charter is available on our website, www.ramed.com, under the Investor Relations tab under Governance. Our audit committee held seventeen (17) meetings during 2019.

Compensation Committee

The members of our compensation committee are Martin Colombatto, William R. Enquist, Jr. and Richard Mejia, Jr. Mr. Colombatto serves as the chairperson of our compensation committee. Our board of directors has determined that each member of our compensation committee is an independent director under the current rules of NYSE, satisfies the additional independence criteria for compensation committee members under Rule 10C-1 and the NYSE listing rules and is a “non-employee director” within the meaning of Rule 16b-3 under the Exchange Act.

Our compensation committee oversees our corporate compensation programs. The compensation committee responsibilities also include, among other things:

- reviewing and approving or recommending to the board for approval compensation of our executive officers;
- reviewing and recommending to the board for approval compensation of directors;
- overseeing our overall compensation philosophy and compensation policies, plans and benefit programs for service providers, including our executive officers;
- reviewing, approving and making recommendations to our board of directors regarding incentive compensation and equity plans; and
- administering our equity compensation plans.

Our compensation committee operates under a written charter approved by our board of directors and that satisfies the applicable rules and regulations of the SEC and the listing requirements of NYSE. The charter is available on our website, www.ramed.com, under the Investor Relations tab under Governance. Our compensation committee held six (6) meetings during 2019.

Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are Mark E. Saad, Maurice Buchbinder and William R. Enquist, Jr. Mr. Saad serves as the chairperson of our nominating and corporate governance committee. All members of our nominating and corporate governance committee meet the requirements for independence under current NYSE listing standards and SEC rules and regulations. The nominating and corporate governance committee oversees our nominations for directors and corporate governance matters. The nominating and corporate governance committee responsibilities also include, among other things:

- identifying, evaluating and selecting, or making recommendations to our board of directors regarding, nominees for election to our board of directors and its committees;
- evaluating the performance of our board of directors and of individual directors;
- considering and making recommendations to our board of directors regarding the composition of our board of directors and its committees; and
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters.

Our nominating and corporate governance committee operates under a written charter approved by our board of directors and that satisfies the listing requirements of NYSE. The charter is available on our website, www.ramed.com, under the Investor Relations tab under Governance. Our nominating and corporate governance committee held two (2) meetings during 2019.

Compensation Committee Interlocks and Insider Participation

None of our executive officers currently serves, or in the past year has served, as a member of the compensation committee, or other board committee performing equivalent functions (or in the absence of any such committee, the entire board of directors) or director of any entity that has one or more executive officers serving on our compensation committee or our board of directors. None of the members of our compensation committee during the last fiscal year, which included Martin Colombatto, William R. Enquist, Jr. and Richard Mejia, Jr. is or has been an officer or employee of the Company.

Compensation Committee Report

The compensation committee has reviewed and discussed the foregoing “Executive Compensation” section of this Annual Report on Form 10-K with management. Based on this review and discussion, the compensation committee recommended to our board of directors that such information be included in this Annual Report on Form 10-K.

The Compensation Committee

Martin Colomatto
William R. Enquist, Jr.
Richard Mejia, Jr.

The information contained in the Compensation Committee Report shall not be deemed to be soliciting material or to be filed with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference in such filing.

Considerations in Evaluating Director Nominees

The nominating and corporate governance committee uses the following procedures to identify and evaluate any individual recommended or offered for nomination to the Board:

- The nominating and corporate governance committee will consider candidates recommended by stockholders in the same manner as candidates recommended to the nominating and corporate governance committee from other sources.
- In its evaluation of director candidates, including the members of the Board eligible for re-election, the nominating and corporate governance committee will consider the following:
 - o The current size and composition of the Board and the needs of the Board and the respective committees of the Board.
 - o Such factors as character, integrity, judgment, diversity of background (including gender diversity) and experience, independence, area of expertise, corporate experience, length of service, potential conflicts of interest, other commitments and the like. The nominating and corporate governance committee evaluates these factors, among others, and does not assign any particular weighting or priority to any of these factors.
 - o Other factors that the nominating and corporate governance committee may consider appropriate.

The nominating and corporate governance committee evaluates all incumbent, replacement or additional nominees for election as directors, taking into account (i) all factors the committee considers appropriate, which may include career specialization, relevant technical skills or financial acumen, diversity of viewpoint and industry knowledge, and (ii) the following minimum qualifications:

- the highest personal and professional ethics and integrity;
- proven achievement and competence in the nominee’s field and the ability to exercise sound business judgment;
- skills that are complementary to those of the existing board;
- the ability to assist and support management and make significant contributions to the Company’s success; and
- an understanding of the fiduciary responsibilities required of a member of the board and the commitment of time and energy necessary to diligently carry out those responsibilities.

The nominating and corporate governance committee also focuses on issues of diversity, such as diversity of gender, race, and national origin, education, professional experience and differences in viewpoints and skills. The nominating and corporate governance committee believes that it is essential that members of our board of directors represent diverse viewpoints.

If our nominating and corporate governance committee determines that an additional or replacement director is required, the nominating and corporate governance committee may take such measures as it considers appropriate in connection with its evaluation of a director candidate, including candidate interviews, inquiry of the person or persons making the recommendation or nomination, engagement of an outside search firm to gather additional information, or reliance on the knowledge of the members of the nominating and corporate governance committee, board, or management.

The nominating and corporate governance committee may propose to the Board a candidate recommended or offered for nomination by a stockholder as a nominee for election to the Board. Our nominating and corporate governance committee has discretion to decide which individuals to recommend for nomination as directors and our board of directors has the final authority in determining the selection of director candidates for nomination to our board.

Stockholder Recommendations for Nominations to Our Board of Directors

It is the policy of our nominating and corporate governance committee to consider recommendations for candidates to our board of directors from our stockholders holding no less than one percent (1%) of the outstanding shares of the Company's common stock continuously for at least twelve (12) months prior to the date of the submission of the recommendation or nomination. A stockholder that wishes to recommend a candidate for consideration by the committee as a potential candidate for director must direct the recommendation in writing to Ra Medical Systems, Inc., 2070 Las Palmas Drive, Carlsbad, California 92011, Attention: Corporate Secretary, and must include the candidate's name, home and business contact information, detailed biographical data, relevant qualifications, a signed letter from the candidate confirming willingness to serve, information regarding any relationships between us and the candidate and evidence of the recommending stockholder's ownership of our stock. Such recommendation must also include a statement from the recommending stockholder in support of the candidate, particularly within the context of the criteria for board membership, including issues of character, integrity, judgment, and diversity of experience, independence, area of expertise, corporate experience, length of service, potential conflicts of interest, other commitments and the like and personal references. Our Board will consider the recommendation but will not be obligated to take any further action with respect to the recommendation.

A stockholder that instead desires to nominate a person directly for election to the Board at an annual meeting of the stockholders must meet the deadlines and other requirements set forth in Section 2.4 of the Company's Bylaws. Section 2.4 of the Company's Bylaws requires that a stockholder who seeks to nominate a candidate for director must provide a written notice to the Secretary of the Company not later than the 45th day nor earlier than the 75th day before the one-year anniversary of the date on which the corporation first mailed its proxy materials or a notice of availability of proxy materials (whichever is earlier) for the preceding year's annual meeting; provided, however, that in the event that no annual meeting was held in the previous year or if the date of the annual meeting is advanced by more than 30 days prior to or delayed by more than 60 days after the one-year anniversary of the date of the previous year's annual meeting, then notice by the stockholder to be timely must be so received by the Secretary of the Company not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of (i) the 90th day prior to such annual meeting and (ii) the 10th day following the day on which Public Announcement (as defined below) of the date of such annual meeting is first made. That notice must state the information required by Section 2.4 of the Company's Bylaws, and otherwise must comply with applicable federal and state law. The Secretary of the Company will provide a copy of the Bylaws upon request in writing from a stockholder. "Public Announcement" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Securities Exchange Act of 1934, as amended, or any successor thereto.

Communications with the Board of Directors

The Board believes that management speaks for the Company. Individual Board members may, from time to time, communicate with various constituencies that are involved with the Company, but it is expected that Board members would do this with knowledge of management and, in most instances, only at the request of management.

In cases where stockholders or other interested parties wish to communicate directly with our non-management directors, messages can be sent to Ra Medical Systems, Inc., 2070 Las Palmas Drive, Carlsbad, California 92011, Attention: Corporate Secretary. Our corporate secretary monitors these communications and will provide a summary of all received messages to the board at each regularly scheduled meeting. Our board typically meets on a quarterly basis. Where the nature of a communication warrants, our Secretary may determine, in his or her judgment, to obtain the more immediate attention of the appropriate committee of the board or non-management director, of independent advisors or of our management, as our Secretary considers appropriate.

Our Secretary may decide in the exercise of his or her judgment whether a response to any stockholder or interested party communication is necessary.

This procedure for stockholder and other interested party communications with the non-management directors is administered by our nominating and corporate governance committee. This procedure does not apply to (a) communications to non-management directors from our officers or directors who are stockholders, (b) stockholder proposals submitted pursuant to Rule 14a-8 under the Exchange Act, or (c) communications to the audit committee pursuant to our procedures for complaints regarding accounting and auditing matters.

ITEM 11. EXECUTIVE COMPENSATION

Processes and Procedures for Executive Compensation

Our compensation committee assists the board in discharging the board's responsibilities relating to oversight of the compensation of our chief executive officer and our other executive officers, including reviewing and making recommendations to the board with respect to the compensation, plans, policies and programs for our chief executive officer and our other executive officers and administering our equity compensation plans for our executive officers and employees.

Our compensation committee annually reviews the compensation, plans, policies and programs for our chief executive officer and our other executive officers. In connection therewith, our compensation committee considers, among other things, each executive officer's performance in light of established individual and corporate goals and objectives and the recommendations of our chief executive officer. In particular, our compensation committee considers the recommendations of our chief executive officer when reviewing base salary and incentive performance compensation levels of our executive officers and when setting specific individual and corporate performance targets under our annual incentive bonus plan for our executive officers. While our chief executive officer provides input on his compensation, he does not participate in compensation committee or board deliberations regarding his own compensation. Our compensation committee may delegate its authority to a subcommittee, but it may not delegate any power or authority required by agreement, law, regulation or listing standard to be exercised by the compensation committee as a whole.

In April 2018, prior to the establishment of our compensation committee, our board of directors engaged Compensia, Inc., or Compensia, an independent compensation consultant, to provide information, recommendations and other advice relating to director and executive compensation on an ongoing basis. Following the establishment of our compensation committee, Compensia served and continues to serve at the discretion of our compensation committee. Compensia was engaged to assist in developing an appropriate group of peer companies to help us determine the appropriate level of overall compensation for our directors and executive officers, as well as assess each separate element of compensation, with a goal of ensuring that the compensation we offer to our directors and executive officers is competitive and fair. Our compensation committee assessed the independence of Compensia taking into account, among other things, the enhanced independence standards and factors set forth in Exchange Act Rule 10C-1 and the applicable NYSE listing standards, and concluded that there were no conflicts of interest with respect to the work that Compensia performed for the compensation committee.

Our named executive officers for 2019, which consist of our principal executive officer and our next two most highly compensated executive officers who were officers as of December 31, 2019, were as follows:

- Andrew Jackson, Chief Financial Officer and Interim Chief Executive Officer;
- Jeffrey Kraws, Co-President; and
- Daniel Horwood, General Counsel, Chief Compliance Officer and Secretary.

In addition, Dean Irwin, former Chief Executive Officer, Co-President, Chief Technology Officer, and Chairman of the Board of Directors, served as the Company's principal executive officer until August 11, 2019, and his compensation is also listed below.

Summary Compensation Table

The following table provides information regarding the compensation of our chief executive officer, and each of the next two most highly compensated executive officers during 2019, together referred to as our "named executive officers," for 2019 and 2018, as applicable.

| Name and Principal Position | Year | Salary (\$) | Bonus (\$) | Stock Awards \$(1) | Option Awards \$(2) | All Other Compensation(3) | Total (\$) |
|--|------|-------------|-------------|--------------------|---------------------|---------------------------|------------|
| Andrew Jackson(4) Chief Financial Officer and Interim Chief Executive Officer | 2019 | 348,808 | 194,805 (6) | — | 91,385 | 16,575 | 651,573 |
| Jeffrey R. Kraws Co-President | 2019 | 345,425 | 65,000 (7) | — | 93,832 | 13,265 | 517,522 |
| | 2018 | 348,104 | 114,000 | 5,280,219 | 3,292,050 | — | 9,034,373 |
| Daniel Horwood(5) General Counsel | 2019 | 298,275 | 104,226 (8) | — | 91,385 | 13,753 | 507,639 |
| Dean S. Irwin, Former Chief Executive Officer | 2019 | 311,983 | — | — | — | — | 311,983 |
| | 2018 | 292,109 | 175,200 | 7,180,014 | 3,227,500 | — | 10,874,823 |

- (1) This column reflects the aggregate grant date fair value of restricted stock units granted to the named individuals during the corresponding year, computed in accordance with the provisions of ASC Topic 718. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of restricted stock units. The actual value that may be realized is also subject to time-based vesting restrictions that require the named executive officer to continue to provide services to us. As described in Note 12 to our audited financial statements in this Annual Report on Form 10-K, in June 2018 the Company's board of directors authorized 1,901,900 replacement equity awards of stock options and 1,340,832 restricted stock units to certain service providers, including certain named executive officers, to replace option awards communicated to optionees that were not validly authorized.
- (2) This column reflects the aggregate grant date fair value of stock options granted to the named individuals during the corresponding year computed in accordance with the provisions of ASC Topic 718. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options. The actual value that may be realized is also subject to time-based vesting restrictions that require the named executive officer to continue to provide services to us. As described in Note 12 to our audited financial statements in this Annual Report on Form 10-K, in June 2018 the Company's board of directors authorized 1,901,900 replacement equity awards of stock options and 1,340,832 restricted stock units to certain service providers, including certain named executive officers, to replace option awards communicated to optionees that were not validly authorized.
- (3) This column reflects Company matching contributions to the Named Executive Officers' 401(k) plans.
- (4) Mr. Jackson was not a Named Executive Officer in 2018.
- (5) Mr. Horwood was not a Named Executive Officer in 2018.
- (6) Includes a retention bonus payment of \$44,805 paid in December 2019. Mr. Jackson will receive additional retention bonus payments of \$44,805 on each of March 31, 2020, June 30, 2020 and September 30, 2020, subject to Mr. Jackson's continued service as of each date. Also includes a discretionary bonus payment of \$150,000 based on the compensation committee's evaluation of Mr. Jackson's performance and our accomplishments during 2019, with reference to Mr. Jackson's bonus targets.

- (7) Includes a discretionary bonus payment of \$65,000 based on the compensation committee's evaluation of Mr. Kraw's performance and our accomplishments during 2019, with reference to Mr. Kraw's bonus targets.
- (8) Includes a retention bonus of \$26,226 paid in December 2019. Mr. Horwood will receive additional retention bonus payments of \$26,226 on each of March 31, 2020, June 30, 2020 and September 30, 2020, subject to Mr. Horwood's continued service as of each date. Also includes a discretionary bonus payment of \$78,000 based on the compensation committee's evaluation of Mr. Horwood's performance and our accomplishments during 2019, with reference to Mr. Horwood's bonus targets.

Executive Employment Agreements and Arrangements

Andrew Jackson

We entered into a confirmatory employment letter with Mr. Jackson dated September 12, 2018, and effective as of the closing of our initial public offering. The confirmatory employment letter has no specific term and provides for at-will employment. The confirmatory employment letter provided for an initial base salary, effective on the closing of our initial public offering, of \$348,000 and eligibility annually for a target cash bonus of 50% of his annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. In connection with his appointment as Interim Chief Executive Officer, on August 11, 2019, the compensation committee also approved an Interim Chief Executive Officer offer letter that includes an additional \$6,000 per month stipend amount, less applicable tax withholdings, to Mr. Jackson during the period in which Mr. Jackson serves as Ra Medical's Interim Chief Executive Officer. This stipend will be discontinued once Mr. Jackson no longer serves as Interim Chief Executive Officer. Mr. Jackson is also eligible for severance benefits, as more fully described in "*Executive Change in Control and Severance Agreements*."

Jeffrey Kraws

We entered into a confirmatory employment letter with Mr. Kraws dated September 12, 2018, and effective as of the closing of our initial public offering. The confirmatory employment letter has no specific term and provides for at-will employment. The confirmatory employment letter provided for an initial base salary, effective on the closing of our initial public offering, of \$337,000 and eligibility annually for a target cash bonus of 50% of his annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. Mr. Kraws is also eligible for severance benefits, as more fully described in "*Executive Change in Control and Severance Agreements*."

Daniel Horwood

We entered into an offer letter with Mr. Horwood dated October 24, 2018. The offer letter has no specific term and provides for at-will employment. The confirmatory employment letter provided for an initial base salary of \$291,000 and eligibility annually for a target cash bonus of 35% of his annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. Mr. Horwood is also eligible for severance benefits, as more fully described in "*Executive Change in Control and Severance Agreements*."

Dean S. Irwin

We entered into a confirmatory employment letter with Mr. Irwin dated July 13, 2018, and effective as of the closing of our initial public offering. The confirmatory employment letter has no specific term and provides for at-will employment. The confirmatory employment letter provided for an initial base salary, effective on the closing of our initial public offering, of \$418,000 and eligibility annually for a target cash bonus of 100% of his annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. Upon his termination, effective August 12, 2019, Mr. Irwin was eligible for severance benefits, as more fully described in "*Management— Executive Change in Control and Severance Agreements*." However, Mr. Irwin did not receive any severance benefits upon his termination.

Executive Change in Control and Severance Agreements

Our board of directors has approved a change in control and severance agreement for certain of our current and former executive officers, including Messrs. Jackson, Kraws, Horwood and Irwin, which agreements provide for certain severance and change in control benefits as described below. Each change in control and severance agreement supersedes any prior agreement or arrangement the executive officer may have had with us that provides for severance and/or change in control payments or benefits. Mr. Irwin was terminated by the Company without cause, effective August 12, 2019, but did not receive any severance payment or benefits. As discussed in “Item 3. *Legal Proceedings*,” Mr. Irwin filed a Demand for Arbitration alleging, among other things, that he is owed severance benefits.

Each change in control and severance agreement has an initial term of three years, starting on the effective date of the agreement, which was the closing date of our initial public offering. On the third anniversary of the effective date of the agreement, the agreement will renew automatically for additional one year terms unless either party provides the other party with written notice of nonrenewal at least one year prior to the date of automatic renewal. However, if a change in control (as defined in the applicable agreement) occurs when there are fewer than 12 months remaining during the initial term or during an additional term, the term of the change in control and severance agreement will extend automatically through the date that is 12 months following the date of the change in control.

If an executive officer’s employment is terminated outside the period beginning 3 months before a change in control and ending 12 months following a change in control, or the Change in Control Period either (1) by the Company (or any of its subsidiaries) without “cause” (excluding by reason of death or disability) or (2) by the executive officer for “good reason” (as such terms are defined in the executive officer’s change in control and severance agreement), the executive officer will receive the following benefits if he or she timely signs and does not revoke a release of claims in our favor:

- a lump-sum payment equal to 12 months (6 months for Mr. Horwood) of the executive officer’s annual base salary as in effect immediately prior to such termination (or if such termination is due to a resignation for good reason based on a material reduction in base salary, then as in effect immediately prior to the reduction); and
- payment of premiums for coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or COBRA, for the executive officer and the executive officer’s eligible dependents, if any, for up to 12 months (6 months for Mr. Horwood), or taxable monthly payments for the equivalent period in the event payment of the COBRA premiums would violate or be subject to an excise tax under applicable law.

If, within the Change in Control Period, the executive officer’s employment is terminated either (1) by the Company (or any of its subsidiaries) without cause (excluding by reason of death or disability) or (2) by the executive officer for good reason, the executive officer will receive the following benefits if he or she timely signs and does not revoke a release of claims in our favor:

- a lump-sum payment equal to 12 months of the executive officer’s annual base salary as in effect immediately prior to such termination (or if such termination is due to a resignation for good reason based on a material reduction in base salary, then as in effect immediately prior to the reduction) or if greater, at the level in effect immediately prior to the change in control);
- a lump-sum payment equal to 100% of the executive officer’s target annual bonus as in effect for the fiscal year in which such termination occurs;
- payment of premiums for coverage under COBRA for the executive officer and the named executive officer’s eligible dependents, if any, for up to 12 months, or taxable monthly payments for the equivalent period in the event payment of the COBRA premiums would violate or be subject to an excise tax under applicable law; and
- 100% accelerated vesting and exercisability of all outstanding equity awards and, in the case of an equity award with performance-based vesting, all performance goals and other vesting criteria generally will be deemed achieved at target.

If any of the amounts provided for under these change in control and severance agreements or otherwise payable to our named executive officers would constitute “parachute payments” within the meaning of Section 280G of the Internal Revenue Code and could be subject to the related excise tax, the executive officer would be entitled to receive either full payment of benefits under his or her change in control or severance agreement or such lesser amount which would result in no portion of the benefits being subject to the excise tax, whichever results in the greater amount of after-tax benefits to the executive officer. The change in control and severance agreements do not require us to provide any tax gross-up payments.

Outstanding Equity Awards at 2019 Fiscal Year-End

The following table sets forth certain information concerning outstanding equity awards for our named executive officers at December 31, 2019:

| Name and Position | Option Awards | | | | Stock Awards | |
|--|---|---|----------------------------|------------------------|---|--|
| | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price (\$) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested (#) | Market Value of Shares or Units of Stock That Have Not Vested(\$)(1) |
| Andrew Jackson <i>Interim Chief Executive Officer and Chief Financial Officer</i> | 144,999 (2) | 145,001 | \$ 28.94 | 6/4/2028 | — | — |
| Jeffrey R. Kraws <i>Co- President</i> | 127,498 (2) | 127,502 (3) | \$ 1.22 | 12/3/2029 | — | — |
| Daniel Horwood <i>General Counsel and Secretary</i> | — | 139,052 (4) | \$ 1.22 | 12/3/2029 | — | — |
| Dean S. Irwin <i>Former Chief Executive Officer</i> | 111,110 (2) | — | \$ 28.94 | 6/4/2028 | 18,428 (5) | \$ 20,824 |

- (1) Market value of the unvested restricted stock units identified in this column is based on a closing price of \$1.13 per share of the Company’s common stock as of December 31, 2019. These amounts do not correspond to the actual value that may be realized by the Named Executive Officers.
- (2) One-third of the shares subject to the option vested on June 4, 2019 and one thirty-sixth of the shares subject to the option shall vest monthly thereafter, in each case subject to continued service.
- (3) One-twelfth of the shares subject to the option shall vest every month after December 3, 2019, in each case subject to continued service.
- (4) One-thirty sixth of the shares subject to the option shall vest every month after December 3, 2019, in each case subject to continued service.
- (5) Restricted stock units vest according to the following schedule: 1/3 of the total number of shares underlying the RSUs granted vested on November 20, 2019, and 1/6th of the total number of shares underlying the RSUs will vest on each May 20 and November 20 thereafter, in each case subject to continued service.

Perquisites, Health, Welfare and Retirement Benefits

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. We provide a 401(k) savings plan to our employees, including our current named executive officers, as discussed in the section below entitled “401(k) Savings Plan.”

We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances and as noted in the Summary Compensation Table above. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

401(k) Savings Plan

We maintain a tax-qualified retirement plan that provides eligible employees, including named executive officers, with an opportunity to save for retirement on a tax advantaged basis. All participants' interests in their deferrals are 100% vested when contributed. Pre-tax and after-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participant's directions. The Company, in its sole discretion, may make certain contributions to the plan. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Internal Revenue Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan, and all contributions, if any, are deductible by us when made. The Company began matching contributions to this plan for all eligible employees in 2019 when the 401(k) plan was implemented.

Equity Compensation Plan Information

The following table summarizes information about our equity compensation plans as of December 31, 2019 with respect to shares of our common stock that may be issued under our existing equity compensation plans.

| | Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a) | Weighted-average Exercise Price of Outstanding Options, Warrants and Rights (b)(1) | Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c) |
|--|---|--|---|
| Equity compensation plans approved by security holders(2)(3)(4): | 3,411,009 | \$ 15.50 | 1,399,435 |
| Equity compensation plans not approved by security holders: | — | — | — |
| Total | 3,411,009 | \$ 15.50 | 1,399,435 |

- (1) The weighted average exercise price is based solely on outstanding options.
- (2) Includes our 2018 Equity Incentive Plan, or 2018 Plan, our 2018 Stock Compensation Plan, or Compensation Plan, and our 2018 Employee Stock Purchase Plan, or ESPP.
- (3) The number of shares reserved for issuance under our 2018 Plan also includes (a) those shares reserved but unissued under the Compensation Plan as of the date of stockholder approval of the 2018 Plan and (b) shares of common stock subject to or issued pursuant to awards granted under the Compensation Plan that, after the date of stockholder approval of the 2018 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2018 Plan pursuant to (a) and (b) is 3,300,000 shares). The number of shares available for issuance under the Company's 2018 Plan also includes an annual increase on the first day of each fiscal year beginning with our 2019 fiscal year, equal to the least of i) 1,632,134 shares; ii) five percent (5%) of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or iii) such other amount as our board of directors may determine.
- (4) The number of shares available for issuance under the Company's ESPP also includes an annual increase on the first day of each fiscal year beginning with our 2019 fiscal year, equal to the least of i) 296,752 shares; ii) one and a quarter percent (1.25%) of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or iii) such other amount as our board of directors may determine.

Director Compensation

In connection with our initial public offering, our board of directors retained Compensia, Inc., a national compensation consultant, to provide our board of directors with an analysis of market data compiled from certain comparable public companies and assistance in determining compensation of directors. Our board of directors adopted our Outside Director Compensation Policy which provides that each non-employee director is entitled to receive the following compensation for their services: Each director may elect to receive all or a portion of the retainer compensation in stock options, rather than cash. If a director elects to receive stock options, the option is granted on January 5 of the calendar year for which the compensation will be received, and vests on a quarterly basis, subject to the continued service of the director. In addition, each director can receive a maximum of 50,000 options per calendar year as retainer compensation, and any remaining retainer compensation is payable in cash.

- \$40,000 retainer per year for each non-employee director;
- \$40,000 retainer per year for service as non-employee chairman of the board of directors;
- \$30,000 retainer per year for service as lead non-employee director;
- \$20,000 retainer per year for the chairman of the audit committee or \$10,000 retainer per year for each other member of the audit committee;
- \$15,000 retainer per year for the chairman of the compensation committee or \$7,000 retainer per year for each other member of the compensation committee; and
- \$8,500 retainer per year for the chairman of the nominating and corporate governance committee or \$4,500 retainer per year for each other member of the nominating and corporate governance committee.

In addition to the retainer compensation structure described above, our Outside Director Compensation Policy provides the following equity incentive compensation program for non-employee directors. Each non-employee director who first joins us (other than a director who becomes a non-employee director as a result of terminating employment with us) automatically is granted on the first trading date on or after his or her start date as a non-employee director a one-time, initial restricted stock unit award with a value of \$140,000. Further, on the date of each of our annual stockholder meetings, each non-employee director who is continuing as a director following our annual stockholder meeting automatically will be granted an annual restricted stock unit award with a value of \$100,000. Unless otherwise determined by our board of directors or our compensation committee, the number of restricted stock units subject to such awards will be determined based on the per share fair market value of our common stock on the applicable grant date. Each initial restricted stock unit award vests as to 1/3rd of the award on each of the first three anniversaries of the date the director's service as a non-employee director started, subject to continued service through each relevant vesting date. Each annual restricted stock unit award will vest as to 100% of the underlying shares on the earlier of the one-year anniversary of the award's grant date or the day before the date of our annual stockholder meeting next following the award's grant date, subject to continued service through such date. In the event of a change in control of our company, all equity awards granted to a non-employee director (including those granted pursuant to our Outside Director Compensation Policy) will fully vest and become immediately exercisable, subject to continued service through such date.

For compensation awarded following our initial public offering, in any fiscal year, a non-employee director may be paid, issued or granted cash compensation and equity awards with a total value of no greater than \$500,000 (with the value of an equity award based on its grant date fair value for purposes of this limit), or the annual director limit. Equity awards or cash compensation granted to a non-employee director while he or she was an employee or consultant (other than a non-employee director) will not count toward the annual director limit.

Our Outside Director Compensation Policy also provides for the reimbursement of our non-employee directors for reasonable, customary and documented travel expenses to attend meetings of our board of directors and committees of our board of directors.

Compensation for our non-employee directors is not limited to the equity awards and payments set forth in our Outside Director Compensation Policy. Our non-employee directors remain eligible to receive equity awards and cash or other compensation outside of the Outside Director Compensation Policy, as may be provided from time to time at the discretion of our board of directors.

2019 Director Compensation Table

The following table sets forth information regarding compensation earned or paid to our directors during the year ended December 31, 2019.

| | Fees Earned or Paid in Cash (\$) | Stock Awards \$(1) | Total (\$) |
|-----------------------------|--|--------------------------|---------------|
| Martin Colomatto (2) | 98,859 | 99,998 | 198,857 |
| Maurice Buchbinder (3) | 44,500 | 99,998 | 144,498 |
| William R. Enquist, Jr. (4) | 51,500 | 99,998 | 151,498 |
| Dean Irwin (5) | 6,957 | — | 6,957 |
| Richard Mejia, Jr. (6) | 67,000 | 99,998 | 166,998 |
| Mark E. Saad (7) | 58,500 | 99,998 | 158,498 |

- (1) Amounts represent the aggregate grant date fair value of the awards calculated in accordance with Financial Accounting Standards Board ASC Topic 718, Stock Compensation, without regard to estimated forfeitures. See Note 12 of the notes to our audited financial statements included in our annual report on Form 10-K for the year ended December 31, 2019 for a discussion of valuation assumptions made in determining the grant date fair value and compensation expense of our awards.
- (2) Mr. Colomatto had 42,000 options to purchase shares of our common stock outstanding and 35,340 restricted stock units outstanding as of December 31, 2019.
- (3) Dr. Buchbinder had 42,000 options to purchase shares of our common stock outstanding and 35,340 restricted stock units outstanding as of December 31, 2019.
- (4) Mr. Enquist had no options to purchase shares of our common stock outstanding and 35,340 restricted stock units outstanding as of December 31, 2019.
- (5) Mr. Irwin resigned as a director on October 14, 2019. Mr. Irwin had 111,110 options to purchase shares of our common stock outstanding and no restricted stock units as of December 31, 2019.
- (6) Mr. Mejia had no options to purchase shares of our common stock outstanding and 35,340 restricted stock units outstanding as of December 31, 2019.
- (7) Mr. Saad had no options to purchase shares of our common stock outstanding and 35,340 restricted stock units outstanding as of December 31, 2019.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 6, 2020 by:

- each person, or group of affiliated persons, who we know to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage ownership information shown in the table is based on an aggregate of 13,770,349 shares of our common stock outstanding as of March 6, 2020.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to: i) the exercise of stock options that are either immediately exercisable or exercisable on or before May 5, 2020, which is 60 days after March 6, 2020 and ii) RSUs held by that person that will vest within 60 days of March 6, 2020. These shares are deemed to be outstanding and beneficially owned by the person holding those options and warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

| | Number of Shares of Common Stock Beneficially Owned | Percentage of Common Stock Beneficially Owned |
|---|--|--|
| <i>5% Stockholders:</i> | | |
| Dean Irwin (1) | 3,207,761 | 22.9 |
| Melissa Burstein, M.B.A. (2) | 3,207,761 | 22.9 |
| Martin Burstein, M.B.A. (3) | 1,956,203 | 14.2 |
| <i>Other Directors and Named Executive Officers</i> | | |
| Jeffrey Kraws (4) | 295,566 | 2.1 |
| Andrew Jackson (5) | 268,417 | 1.9 |
| Martin Colombatto (6) | 125,135 | * |
| Maurice Buchbinder (7) | 77,135 | * |
| Daniel Horwood (8) | 67,151 | * |
| Richard Mejia, Jr. (9) | 15,245 | * |
| Mark E. Saad (10) | 15,139 | * |
| William R. Enquist, Jr. (11) | 13,656 | * |
| All directors and executive officers as a group (8 persons)(12) | 877,444 | 6.1 |

- (1) Consists of (i) 261,110 shares of common stock subject to options exercisable within 60 days March 6, 2020, including 111,110 held directly by Mr. Irwin and 150,000 held by Melissa Burstein, Mr. Irwin's wife; and (ii) 2,803,852 shares held of record by the Dean Irwin and Melissa Burstein Family Trust. Mr. Irwin and Ms. Burstein each serve as co-trustees of the Dean Irwin and Melissa Burstein Family Trust. The address of Dean Irwin, Melissa Burstein and the Dean Irwin and Melissa Burstein Family Trust is c/o Phil Tenser, 12520 High Bluff Drive, Suite 240, San Diego, CA 92130.
- (2) Consists of (i) 261,110 shares of common stock subject to options exercisable within 60 days of March 6, 2020, including 150,000 held directly by Ms. Burstein and 111,110 held by Mr. Irwin; and (ii) 2,803,852 shares held of record by the Dean Irwin and Melissa Burstein Family Trust. Mr. Irwin and Ms. Burstein each serve as co-trustees of the Dean Irwin and Melissa Burstein Family Trust. The address of Melissa Burstein, Dean Irwin and the Dean Irwin and Melissa Burstein Family Trust is c/o Phil Tenser, 12520 High Bluff Drive, Suite 240, San Diego, CA 92130.
- (3) Consists of (i) 1,606,203 shares held of record by Martin Burstein Living Trust dated January 28, 2002 (the "M. Burstein Trust"); and (ii) 350,000 shares held of record by Karen Jorgensen Burstein Family Trust Dated November 10, 2000 (the "K. Burstein Trust"). Martin Burstein, a former member of our board of directors, is a trustee of the M. Burstein Trust. Karen Jorgensen Burstein, Martin Burstein's spouse, is a trustee of the K. Burstein Trust. The address of Martin Burstein, the M. Burstein Trust and the K. Burstein Trust is 7393 Melodia Ter., Carlsbad, CA 92011.
- (4) Includes 182,227 shares of common stock subject to options exercisable within 60 days of March 6, 2020.
- (5) Includes 243,215 shares of common stock subject to options exercisable within 60 days of March 6, 2020.
- (6) Includes (i) 54,500 shares of common stock subject to options exercisable within 60 days of March 6, 2020; and (ii) 37,500 shares held of record by M. Colombatto Trust. Martin Colombatto, a member of our board of directors, serves as trustee of the M. Colombatto Trust.
- (7) Includes (i) 42,000 shares of common stock subject to options exercisable within 60 days of March 6, 2020; and (ii) 2,000 shares held of record.
- (8) Includes 57,938 shares of common stock subject to options exercisable within 60 days of March 6, 2020.
- (9) Includes 12,500 shares of common stock subject to options exercisable within 60 days of March 6, 2020.
- (10) Includes 12,394 shares of common stock subject to options exercisable within 60 days of March 6, 2020.

- (11) Includes 10,911 shares of common stock subject to options exercisable within 60 days of March 6, 2020.
- (12) Includes 39,500 shares of common stock held and (ii) 615,685 shares of common stock subject to options exercisable within 60 days of March 6, 2020.

Unless otherwise noted above, the address of each of the individuals and entities named in the table below is c/o Ra Medical Systems, Inc., 2070 Las Palmas Drive, Carlsbad, California 92011. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of ownership and changes of ownership on Forms 3, 4 and 5 with the SEC. Such directors, executive officers and 10% stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

Based solely on our review of the copies of such forms, and written representations that we have received from certain reporting persons that they filed all required reports, we believe that all of our officers, directors and greater than 10% stockholders complied with all Section 16(a) filing requirements applicable to them with respect to transactions during 2019, except that the vesting of restricted stock units on July 18, 2019 of Jeffrey Kraws was inadvertently reported one day late in a Form 4 on July 23, 2019.

Company Website

We maintain a website at www.ramed.com. Information contained on, or that can be accessed through, our website is not intended to be incorporated by reference into this proxy statement, and references to our website address in this proxy statement are inactive textual references only.

Availability of Bylaws

A copy of our bylaws may be obtained by accessing Ra Medical Systems' filings on the SEC's website at www.sec.gov. You may also contact our corporate secretary at our principal executive offices for a copy of the relevant bylaw provisions regarding the requirements for making stockholder proposals and nominating director candidates.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Person Transactions

The following is a summary of transactions since January 1, 2018 to which we have been a party in which the amount involved exceeded \$120,000 and in which any of our executive officers, directors, promoters or beneficial holders of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section of this proxy statement titled “*Executive Compensation*.”

Certain Family Relationships

Dean Irwin’s wife, Melissa Burstein, served as Executive Vice President and was a member of our board of directors until March 2019. For the year ended December 31, 2018, as previously disclosed on our definitive proxy statement on Schedule 14A filed with the SEC on April 19, 2019, Ms. Burstein received a salary of \$202,570, bonuses totaling \$417,000, stock awards with an aggregate grant date fair value of \$4,308,008, option awards with an aggregate grant date fair value of \$1,936,500, a \$6,000 car allowance, and \$25,704 for a health insurance plan paid for by us on behalf of Ms. Burstein. Mr. Irwin is covered by Ms. Burstein’s health insurance plan. For the year ended December 31, 2019, Ms. Burstein received a salary of \$237,561, a \$1,500 car allowance, a \$1,939 reimbursement for COBRA premiums, \$8,882 for a health insurance plan paid for by us on behalf of Ms. Burstein, and a severance payment of \$230,000.

Additionally, Martin Burstein, who served as a member of our board of directors until he resigned upon the effectiveness of our initial public offering in September 2018, is Mr. Irwin’s father-in-law. For the year ended December 31, 2018, as previously disclosed on our definitive proxy statement on Schedule 14A filed with the SEC on April 19, 2019, Mr. Burstein received stock awards with an aggregate grant date fair value of \$5,187,495 and option awards with an aggregate grant date fair value of \$2,478,720.

Ray Hartman, the brother-in-law of Mark Saad, is a partner of Cooley LLP. For the year ended December 31, 2019, we paid Cooley LLP \$403,827 for legal services rendered, in a matter for which Cooley LLP no longer represents us.

Indemnification of Officers and Directors

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. The indemnification agreements and our amended and restated certificate of incorporation and amended and restated bylaws require us to indemnify our directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law.

Policies and Procedures for Transactions with Related Persons

Our audit committee has the primary responsibility for reviewing and approving or disapproving “related party transactions,” which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed \$120,000 and in which a related person has or will have a direct or indirect material interest. The charter of our audit committee provides that our audit committee shall review and approve or disapprove in advance any related party transaction.

Our board of directors and audit committee have adopted a formal written policy that our executive officers, directors, holders of more than 5% of any class of our voting securities, and any member of the immediate family of any of the foregoing persons, are not permitted to enter into any transaction with us for which disclosure would be required under Item 404 of Regulation S-K, referred to as a related person transaction, without the review and approval or ratification of our audit committee, or other independent members of our board of directors if it is inappropriate for our audit committee to review such transaction due to a conflict of interest. Any related person transaction must be presented to our audit committee for review, consideration and approval or ratification. In approving or rejecting any such related person transaction, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person’s interest in the transaction.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**Fees Paid to the Independent Registered Public Accounting Firm**

The following table represents aggregate fees for services provided to us in the fiscal years ended December 31, 2019 and 2018 by Deloitte & Touche LLP, our independent registered public accounting firm. Following the creation of our audit committee in 2018, all fees paid to the independent registered public accounting firm were pre-approved by the audit committee:

| | Fiscal Year Ended | |
|--------------------|-------------------|--------------|
| | 2019 | 2018 |
| Audit Fees (1) | \$ 925,105 | \$ 1,604,415 |
| Audit-Related Fees | — | — |
| Tax Fees (2) | — | — |
| All Other Fees (3) | — | — |
| Total Fees | \$ 925,105 | \$ 1,604,415 |

- (1) "Audit Fees" consist of fees billed for professional services rendered in connection with the audit of our annual financial statements, review of our quarterly financial statements, and services that are normally provided by Deloitte & Touche LLP in connection with statutory and regulatory filings or engagements for those fiscal years. Fees for 2018 also included fees billed for professional services rendered in connection with our Form S-1 and Form S-8 registration statements related to our initial public offering of common stock completed in 2018.
- (2) "Tax Fees" consist of permissible tax compliance and tax advisory service fees. Deloitte & Touche LLP did not bill us for any tax fees for the years ended December 31, 2019 and December 31, 2018.
- (3) "All Other Fees" consist of fees billed for services other than the services reported in Audit Fees and Tax Fees. Deloitte & Touche LLP did not bill us for any other fees for the years ended December 31, 2019 and December 31, 2018.

Auditor Independence

In 2019, there were no other professional services provided by Deloitte & Touche LLP that would have required our audit committee to consider their compatibility with maintaining the independence of Deloitte & Touche LLP.

Pre-Approval Policy

Our audit committee's policy is to pre-approve all audit and permissible non-audit services provided by the independent accountants and the related estimated fees. These services may include audit services, audit-related services, tax services and other services. Our audit committee generally pre-approves particular services or categories of services on a case-by-case basis. The independent registered public accounting firm and management are required to periodically report to our audit committee regarding the extent of services provided by the independent registered public accounting firm in accordance with these pre-approvals, and the fees for the services performed to date. Following the creation of our audit committee in 2018, all of the services of Deloitte & Touche LLP for 2018 and 2019 described above were pre-approved by our audit committee.

PART IV — FINANCIAL INFORMATION

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report.

(1) Financial Statements.

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(2) Financial Statement Schedules

Schedules not listed above have been omitted because they are not applicable or not required or the information required to be set forth therein is included in the financial statements or notes thereto.

(3) Exhibits.

List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) EXHIBIT INDEX

| Exhibit Number | Description | Incorporated by Reference | | | |
|----------------|--|---------------------------|------------|---------|-------------|
| | | Form | File No. | Exhibit | Filing Date |
| 3.1 | Amended and Restated Certificate of Incorporation of the Registrant. | 8-K | 001-38677 | 3.1 | 10/1/2018 |
| 3.2 | Amended and Restated Bylaws of the Registrant. | 8-K | 001-38677 | 3.2 | 10/1/2018 |
| 4.1 | Specimen common stock certificate of the Registrant. | S-1 | 333-226191 | 4.1 | 7/16/2018 |
| 4.2 | Description of Capital Stock | | | | |
| 10.1 | Lease Agreement by and between the Registrant and Lloyd Wells Gift Trust dated November 24, 1987, for the premises located at 2070 Las Palmas Drive, Carlsbad, California 92011 dated as of August 17, 2017. | S-1 | 333-226191 | 10.1 | 7/16/2018 |
| 10.2+ | Form of Indemnification Agreement between the Registrant and each of its directors and executive officers. | S-1 | 333-226191 | 10.2 | 8/24/2018 |
| 10.3+ | Ra Medical Systems, Inc. 2018 Stock Compensation Plan and Forms of Award Agreement thereunder. | S-1 | 333-226191 | 10.3 | 7/16/2018 |
| 10.4+ | Ra Medical Systems, Inc. 2018 Equity Incentive Plan and Forms of Award Agreement thereunder. | S-1 | 333-226191 | 10.4 | 9/17/2018 |
| 10.5+ | Ra Medical Systems, Inc. 2018 Employee Stock Purchase Plan. | S-1 | 333-226191 | 10.5 | 9/17/2018 |
| 10.6+ | Ra Medical Systems, Inc. Executive Incentive Compensation Plan. | S-1 | 333-226191 | 10.6 | 8/24/2018 |
| 10.7+ | Ra Medical Systems, Inc. Form of At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement for executive officers. | S-1 | 333-226191 | 10.7 | 7/16/2018 |
| 10.8+ | Change in Control and Severance Agreement, by and between the Registrant and Andrew Jackson, dated as of July 13, 2018. | S-1 | 333-226191 | 10.11 | 7/16/2018 |

| Exhibit Number | Description | Incorporated by Reference | | | |
|----------------|--|---------------------------|------------|---------|-------------|
| | | Form | File No. | Exhibit | Filing Date |
| 10.9+ | Change in Control and Severance Agreement, by and between the Registrant and Jeffrey Kraws, dated as of July 13, 2018. | S-1 | 333-226191 | 10.10 | 7/16/2018 |
| 10.10+ | Change in Control and Severance Agreement, by and between the Registrant and Daniel Horwood, dated as of October 24, 2018. | 10-Q | 001-38677 | 10.1 | 11/14/2018 |
| 10.11+ | Confirmatory Employment Letter, by and between the Registrant and Andrew Jackson, dated as of July 13, 2018. | S-1 | 333-226191 | 10.15 | 7/16/2018 |
| 10.12+ | Confirmatory Employment Letter, by and between the Registrant and Jeffrey Kraws, dated as of September 12, 2018. | S-1 | 333-226191 | 10.14 | 9/17/2018 |
| 10.13+ | Employment Letter by and between the Registrant and Daniel Horwood, dated as of October 12, 2018. | 10-Q | 001-38677 | 10.2 | 11/14/2018 |
| 23.1* | Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm. | | | | |
| 24.1* | Power of Attorney (contained on signature page). | | | | |
| 31 | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | |
| 32 *^ | Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | |
| 101.INS* | XBRL Instance Document. | | | | |
| 101.SCH* | XBRL Taxonomy Extension Schema Document. | | | | |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document. | | | | |

| Exhibit Number | Description | Incorporated by Reference | | | |
|-------------------|--|---------------------------|----------|---------|-------------|
| | | Form | File No. | Exhibit | Filing Date |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document | | | | |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document | | | | |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document | | | | |

* Filed herewith.

^ The information in this exhibit is furnished and deemed not filed with the Securities and Exchange Commission for purposes of section 18 of the Exchange Act of 1934, as amended (Exchange Act), and is not to be incorporated by reference into any filing of Ra Medical Systems, Inc. under the Securities Act of 1933, as amended (Securities Act), or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

+ Indicates a management contract or compensatory plan.

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.

RA MEDICAL SYSTEMS, INC.

(Registrant)

Date: March 11, 2020

By: /s/ Andrew Jackson

Andrew Jackson

Interim Chief Executive Officer and Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Andrew Jackson and Daniel Horwood, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, to sign any and all amendments (including post-effective 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, granting unto each of said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each of said attorneys-in-facts and agents, or his substitute or substitutes, or any of them, shall do or cause to be done by virtue hereof.

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:

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|---|----------------|
| <u>/s/ Andrew Jackson</u> Andrew Jackson | Interim Chief Executive Officer and Chief Financial Officer (Principal Executive Officer and Principal Financial and Accounting Officer) | March 11, 2020 |
| <u>/s/ Martin Colomatto</u> Martin Colomatto | Chairman of the Board of Directors | March 11, 2020 |
| <u>/s/ Maurice Buchbinder, M.D.</u> Maurice Buchbinder, M.D. | Director | March 11, 2020 |
| <u>/s/ William R. Enquist, Jr.</u> William R. Enquist, Jr. | Director | March 11, 2020 |
| <u>/s/ Richard Mejia, Jr.</u> Richard Mejia, Jr. | Director | March 11, 2020 |
| <u>/s/ Mark E. Saad</u> Mark E. Saad | Director | March 11, 2020 |

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Ra Medical Systems, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Ra Medical Systems, Inc. (the "Company") as of December 31, 2019 and 2018, the related statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses and negative cash flows from operations, has a significant accumulated deficit and expects to continue to incur net losses into the foreseeable future that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
March 11, 2020

We have served as the Company's auditor since 2018.

Ra Medical Systems, Inc.
Balance Sheets
(in thousands, except share and per share data)

| | December 31, 2019 | December 31, 2018 |
|---|----------------------|----------------------|
| ASSETS | | |
| Current Assets | | |
| Cash and cash equivalents | \$ 14,584 | \$ 64,315 |
| Short-term investments | 15,993 | — |
| Accounts receivable, net | 786 | 1,320 |
| Inventories | 2,777 | 2,097 |
| Prepaid expenses and other current assets | 1,860 | 1,501 |
| Total current assets | 36,000 | 69,233 |
| Property and equipment, net | 5,050 | 4,757 |
| Operating lease right-of-use-assets | 2,835 | — |
| Other non-current assets | 196 | 45 |
| TOTAL ASSETS | \$ 44,081 | \$ 74,035 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities | | |
| Accounts payable | \$ 1,532 | \$ 1,125 |
| Accrued expenses | 2,642 | 2,809 |
| Current portion of deferred revenue | 2,029 | 1,723 |
| Current portion of equipment financing | 293 | 293 |
| Current portion of operating lease liabilities | 318 | — |
| Total current liabilities | 6,814 | 5,950 |
| Deferred revenue | 1,232 | 767 |
| Equipment financing | 265 | 557 |
| Operating lease liabilities | 2,620 | — |
| Other liabilities | — | 56 |
| Total liabilities | 10,931 | 7,330 |
| Commitments and contingencies (Note 14) | | |
| Stockholders' Equity | | |
| Preferred stock, \$0.0001 par value, 10,000,000 shares authorized at December 31, 2019 and 2018; none issued | — | — |
| Common stock, \$0.0001 par value, 300,000,000 shares authorized at December 31, 2019 and 2018; 13,770,349 and 12,689,251 issued and outstanding at December 31, 2019 and 2018, respectively | 1 | 1 |
| Additional paid-in capital | 150,280 | 126,925 |
| Accumulated deficit | (117,157) | (60,221) |
| Accumulated other comprehensive income | 26 | — |
| Total stockholders' equity | 33,150 | 66,705 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$ 44,081 | \$ 74,035 |

See notes to financial statements.

Ra Medical Systems, Inc.
Statements of Operations
(in thousands, except per share data)

| | Year Ended December 31, | |
|---|-------------------------|------------|
| | 2019 | 2018 |
| Net revenue | | |
| Product sales | \$ 3,859 | \$ 3,159 |
| Service and other | 3,340 | 3,098 |
| Total net revenue | 7,199 | 6,257 |
| Cost of revenue | | |
| Product sales | 5,856 | 2,652 |
| Service and other | 2,994 | 1,554 |
| Total cost of revenue | 8,850 | 4,206 |
| Gross (loss) profit | (1,651) | 2,051 |
| Operating expenses | | |
| Selling, general and administrative | 51,549 | 30,435 |
| Research and development | 4,530 | 2,776 |
| Total operating expenses | 56,079 | 33,211 |
| Operating loss | (57,730) | (31,160) |
| Other income (expense), net | | |
| Interest income | 1,038 | 352 |
| Interest expense | (250) | (14) |
| Total other income (expense), net | 788 | 338 |
| Loss before income tax expense | (56,942) | (30,822) |
| Income tax expense | 15 | 10 |
| Net loss | (56,957) | (30,832) |
| Basic and diluted net loss per share | \$ (4.33) | \$ (3.34) |
| Basic and diluted weighted average common shares outstanding | 13,146 | 9,230 |

See notes to financial statements.

Ra Medical Systems, Inc.
Statements of Comprehensive Loss
(in thousands)

| | <u>Year Ended December 31,</u> | |
|--|--------------------------------|--------------------|
| | <u>2019</u> | <u>2018</u> |
| Net loss | \$ (56,957) | \$ (30,832) |
| Other comprehensive income: | | |
| Unrealized gains related to short-term investments | 26 | — |
| Total other comprehensive income | \$ 26 | \$ — |
| Comprehensive loss | <u>\$ (56,931)</u> | <u>\$ (30,832)</u> |

See notes to financial statements.

Ra Medical Systems, Inc.
Statements of Stockholders' Equity
(in thousands)

| | Common Stock Shares | Common Stock Amount | Additional Paid-in- Capital | Accumulated Other Comprehensive Income | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|--|---------------------------|---------------------------|-----------------------------------|---|------------------------|---|
| Balances at December 31, 2017 | 7,888 | \$ 1 | \$ 21,773 | \$ — | \$ (29,389) | \$ (7,615) |
| Common stock issued, net of underwriters' discount of \$5,338 | 4,801 | — | 78,806 | — | — | 78,806 |
| Initial public offering costs | — | — | (3,556) | — | — | (3,556) |
| Settlement of stock-based compensation liability | — | — | 18,243 | — | — | 18,243 |
| Forfeitures of liability-classified awards | — | — | 1,313 | — | — | 1,313 |
| Stock-based compensation | — | — | 10,346 | — | — | 10,346 |
| Net loss | — | — | — | — | (30,832) | (30,832) |
| Balances at December 31, 2018 | <u>12,689</u> | <u>1</u> | <u>126,925</u> | <u>—</u> | <u>(60,221)</u> | <u>66,705</u> |
| Adoption of accounting standard (See Note 2) | — | — | — | — | 21 | 21 |
| Balances at January 1, 2019 | 12,689 | 1 | 126,925 | — | (60,200) | 66,726 |
| Common stock issued | 1,081 | — | (188) | — | — | (188) |
| Stock-based compensation | — | — | 23,543 | — | — | 23,543 |
| Other comprehensive income | — | — | — | 26 | — | 26 |
| Net loss | — | — | — | — | (56,957) | (56,957) |
| Balances at December 31, 2019 | <u>13,770</u> | <u>\$ 1</u> | <u>\$ 150,280</u> | <u>\$ 26</u> | <u>\$ (117,157)</u> | <u>\$ 33,150</u> |

See notes to financial statements.

Ra Medical Systems, Inc.
Statements of Cash Flows
(in thousands)

| | Year Ended December 31, | |
|--|-------------------------|------------------|
| | 2019 | 2018 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | \$ (56,957) | \$ (30,832) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 1,420 | 624 |
| Operating lease right-of-use-assets amortization | 330 | — |
| Provision for doubtful accounts | 283 | 255 |
| Stock-based compensation | 23,543 | 14,728 |
| Loss on disposal of property and equipment | 123 | — |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 251 | (1,058) |
| Inventories | (2,185) | (3,874) |
| Prepaid expenses and other assets | (338) | (1,386) |
| Accounts payable | 407 | 699 |
| Accrued expenses | (184) | 2,485 |
| Deferred revenue | 417 | 1 |
| Other liabilities | (283) | (150) |
| Net cash used in operating activities | (33,173) | (18,508) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchases of available-for-sale securities | (36,461) | — |
| Proceeds from maturities of available-for-sale securities | 20,697 | — |
| Purchases of property and equipment | (268) | (582) |
| Net cash used in investing activities | (16,032) | (582) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Payments for restricted stock tax liability on settlement | (225) | — |
| Proceeds from issuance of common stock, net of underwriters' discount of \$5,338 in 2018 | 37 | 78,806 |
| Initial public offering costs | — | (3,556) |
| Payments on equipment financing | (338) | (82) |
| Net cash (used in) provided by financing activities | (526) | 75,168 |
| NET CHANGE IN CASH AND CASH EQUIVALENTS | (49,731) | 56,078 |
| CASH AND CASH EQUIVALENTS, beginning of year | 64,315 | 8,237 |
| CASH AND CASH EQUIVALENTS, end of year | \$ 14,584 | \$ 64,315 |
| SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES: | | |
| Settlement of stock-based compensation liability | \$ — | \$ 18,243 |
| Forfeitures of liability-classified awards | \$ — | \$ 1,313 |
| Unpaid property and equipment included in equipment financing | \$ — | \$ 831 |
| Transfer from inventories to property and equipment for lasers | \$ 1,505 | \$ 2,848 |
| SUPPLEMENTAL CASH FLOW INFORMATION: | | |
| Cash payments for interest | \$ 49 | \$ 11 |
| Cash payments for taxes | \$ 30 | \$ 5 |

See notes to financial statements.

Ra Medical Systems, Inc.
Notes to Financial Statements

Note 1—Organization and Nature of Operations

Ra Medical Systems, Inc. (the “Company”) was formed in September 4, 2002, in the state of California and reincorporated in Delaware on July 14, 2018. The Company is a medical device company that develops, manufactures and markets advanced excimer lasers for use in the treatment of vascular and dermatological diseases. The Company’s product development centers around proprietary applications of its advanced excimer laser technology for use as a tool in the treatment of peripheral artery disease (“PAD”) and psoriasis, vitiligo, atopic dermatitis and leukoderma.

Reincorporation—In July 2018, the Company reincorporated in Delaware, the par value of each share of common stock was established to be \$0.0001 and the number of authorized shares of common stock was increased from 10,000,000 to 25,000,000. In connection with the reincorporation, common stock and additional paid-in capital amounts in these financial statements have been adjusted to reflect the par value of common stock. All share information included in these financial statements has been adjusted to reflect this reincorporation.

Initial Public Offering—On October 1, 2018, the Company closed its initial public offering (“IPO”) of 4,485,000 shares of common stock at an offering price to the public of \$17.00 per share, resulting in gross proceeds of approximately \$76.2 million. These amounts include the exercise in full by the underwriters of their option to purchase 585,000 additional shares of common stock at the same price to the public to cover over-allotments. The aggregate net proceeds to the Company from its IPO were \$67.3 million after deducting the underwriters discount and offering costs of \$5.3 million and \$3.6 million, respectively. The Company’s registration statement on Form S-1 relating to its IPO was declared effective by the Securities and Exchange Commission on September 26, 2018.

In connection with the IPO, the Company filed an Amended and Restated Certificate of Incorporation which authorizes the issuance of 300,000,000 shares of common stock with a par value of \$0.0001 and 10,000,000 shares of preferred stock with a par value of \$0.0001.

Going Concern— The financial statements have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty.

The Company has experienced recurring net losses from operations and negative cash flows from operating activities, has a significant accumulated deficit and expects to continue to incur net losses into the foreseeable future. The Company had an accumulated deficit of \$117.2 million at December 31, 2019. In 2019, the Company used \$33.2 million for operating activities. As of December 31, 2019, the Company had cash, cash equivalents and short-term investments of \$30.6 million. Management expects operating losses and negative cash flows to continue for the foreseeable future with the Company’s reduced commercial footprint, and as the Company continues to incur costs related to its atherectomy clinical trial, engineering efforts to improve the shelf-life of its catheters and develop next generation products and legal costs associated with ongoing litigation.

Management estimates that based on the Company’s liquidity resources, there is substantial doubt about the Company’s ability to continue as a going concern within 12 months from the date of issuance of the financial statements.

Management’s ability to continue as a going concern is dependent upon its ability to raise additional funding. Management’s plans to raise additional capital through public or private equity or debt financings to fulfill its operating and capital requirements for at least 12 months from the date of the issuance of the financial statements. However, the Company may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity securities to raise additional funds, its existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of the Company’s existing stockholders.

Note 2—Significant Accounting Policies

Use of estimates—The financial statements of the Company have been prepared by management in accordance with accounting principles generally accepted in the United States of America. The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and reported disclosures of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates. The Company’s financial statements are based upon a number of estimates, including but not limited to, allowance for doubtful accounts, reserves for warranty costs including product recalls, evaluation of probable loss contingencies, fair value of stock option awards granted and revenue recognition for multiple performance obligations.

Short-term Investments—Investments with original maturities of greater than three months are classified as short-term investments. Debt investments are classified as available-for-sale and realized gains and losses are recorded using the specific identification method. Changes in fair value, excluding other-than-temporary impairments, are recorded in other comprehensive income (“OCI”). Debt investments are impaired when a decline in fair value is judged to be other-than-temporary. Fair value is calculated based on publicly available market information or other estimates determined by management. The Company employs a systematic methodology on a quarterly basis that considers available quantitative and qualitative evidence in evaluating potential impairment of our investments. If the cost of an investment exceeds its fair value, the Company evaluates, among other factors, general market conditions, credit quality of debt instrument issuers, and the duration and extent to which the fair value is less than cost. The Company also evaluates whether it has plans to sell the security or it is more likely than not that the Company will be required to sell the security before recovery. In addition, the Company considers specific adverse conditions related to the financial health of and business outlook for the investee, including industry and sector performance, changes in technology, and operational and financing cash flow factors. Once a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded in other income (expense), net and a new cost basis in the investment is established.

Fair value measurements—Fair value represents the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants and is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier value hierarchy is used to identify inputs used in measuring fair value as follows:

Level 1—Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets.

Level 2—Inputs other than the quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and

Level 3—Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions.

The hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

The Company measures its cash equivalents and short-term investments at fair value.

Fair value of financial instruments—Cash and cash equivalents, trade accounts receivable, accounts payable, accrued expenses, deferred revenue and other current assets and liabilities are reported on the balance sheets at carrying value which approximates fair value due to the short-term maturities of these instruments.

The fair value of the Company’s debt, which is classified as equipment financing liability on the balance sheets, is estimated based on current rates offered to the Company for similar debt and approximates carrying value.

Cash and cash equivalents—The Company considers all short-term, highly liquid investments with original maturities of three months or less to be cash equivalents. Cash equivalents primarily represent funds invested in readily available checking and money market accounts. The Company maintains deposits in financial institutions in excess of federally insured limits.

Accounts receivable, net—Trade accounts receivable are presented net of allowances for doubtful accounts.

The Company sells or leases its lasers to distributors or physicians directly with various forms of financing options. The Company extends credit based on an evaluation of the customers' financial condition generally without requiring collateral. Exposure to losses on trade receivables is expected to vary by customer due to the financial condition of each customer. The Company monitors exposure to credit losses and maintains allowances for anticipated losses considered necessary under the circumstances.

The Company maintains an allowance for doubtful accounts for balances that appear to have specific collection issues. The collection process is based on the age of the invoice and requires attempted contacts with the customer at specified intervals. If, after a specified number of days, the Company has been unsuccessful in its collection efforts, provision for doubtful accounts is recorded for the balance in question. Delinquent accounts receivable are charged against the allowance for doubtful accounts once the Company has determined the amounts are uncollectible. The factors considered in reaching this determination are the apparent financial condition of the customer and the Company's success in contacting and negotiating with the customer. If the financial condition of the Company's customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

The following table shows the allowance for doubtful accounts activity (in thousands):

| | Year Ended December 31, | |
|---------------------------------|----------------------------|---------------|
| | 2019 | 2018 |
| Balance at beginning of period | \$ 214 | \$ 12 |
| Provision for doubtful accounts | 283 | 255 |
| Deductions | (142) | (53) |
| Balance at end of period | \$ 355 | \$ 214 |

Inventories—Inventories are stated at the lower of cost (first-in, first-out method) or net realizable value. Cost includes materials, labor and manufacturing overhead related to the purchase and production of inventories. The Company reduces the carrying value of inventories for those items that are potentially excess, obsolete or slow-moving based on changes in customer demand, technological developments or other economic factors.

Catheters are manufactured in-house and each catheter is tested at various stages of the manufacturing process for adherence to quality standards. Catheters that do not meet functionality specification at each test point are destroyed and immediately written off, with the expense recorded in cost of revenue in the statements of operations. Once manufactured, completed catheters that pass quality assurance, are sent to a third-party for sterilization and sealed in a sterile container. Upon return from the third-party sterilizer, a sample of catheters from each batch are re-tested. If the sample tests are successful, the batch is accepted into finished goods inventory and if the sample tests are unsuccessful, the entire batch is written off, with the expense recorded in cost of revenue in the statements of operations.

Property and equipment, net—Property and equipment are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives as follows:

| | |
|--------------------------------|------------|
| Computer hardware and software | 4-5 years |
| Furniture and fixtures | 5 years |
| Machinery and equipment | 5-10 years |
| Lasers | 3-5 years |
| Automobiles | 5 years |

Leasehold improvements are depreciated over the shorter of the useful life of the leasehold improvement or the term of the underlying property's lease.

When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the account balances and any resulting gain or loss is recognized in income for the period. The cost of repairs and maintenance is expensed as incurred, whereas significant betterments are capitalized.

Impairment of long-lived assets—The Company periodically reviews its long-lived assets for impairment when certain events or changes in circumstances indicate that the carrying value of the long-lived assets may not be recoverable. Should the sum of the undiscounted expected future net cash flows be less than the carrying value, the Company would recognize an impairment loss at that date. The inconsistencies in the DABRA catheter performance, the voluntary product recall and the reduction in the sales force resulted in lower current and expected revenues for the vascular segment, led the Company to accelerate its annual testing for asset impairment into the third quarter of 2019. There were no impairment charges for the years ended December 31, 2019 or 2018.

Product warranty—The Company records estimated product warranty costs at the time of sale. Products are warranted against defects in material and workmanship when properly used for their intended purpose and appropriately maintained. Accordingly, the Company generally replaces catheters that kink or fail to calibrate. The product warranty liability is determined based on historical information such as past experience, product failure rates or number of units repaired, estimated cost of material and labor. The product warranty liability also includes the estimated costs of a product recall. In September 2019, the Company initiated a voluntary recall of its DABRA laser system single-use catheters due to a change in product shelf life labeling.

Product warranties are included for the first year after the sale for laser sales. For lasers, the customer may purchase an extended service contract, which is either negotiated in the contract or sold as a separate component for which revenue is recognized over the term of the agreement.

The warranty accrual is included in accrued expenses in the accompanying balance sheets. Warranty expenses are included in cost of revenue in the accompanying statements of operations. Changes in estimates to previously established warranty accruals result from current period updates to assumptions regarding repair and product recall costs and are included in current period warranty expense.

Revenue recognition— The Company adopted ASC Topic 606 (Topic 606), *Revenue from Contracts with Customers*, on January 1, 2019 using the modified retrospective method to all contract agreements not completed as of January 1, 2019. Results for reporting periods beginning after January 1, 2019 are presented under Topic 606 while, as permitted by Topic 606, prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. The Company recorded a cumulative catch up adjustment to beginning accumulated deficit to reflect the impact of adopting Topic 606. The adoption of Topic 606 did not have a material effect on our results of operations for the year ended December 31, 2019.

The Company generates revenue from the sale of products and services. Product sales consist of the sale of DABRA and Pharos laser systems, the sale of catheters for use with the DABRA laser, and the sale of consumables and replacement parts. The Company's sales agreements generally do not include right-of-return provisions for any form of consideration including partial refund or credit against amounts owed to the Company. Services and other revenue primarily consist of sales of extended warranty and billable services, including repair activity and income from rental of lasers.

The Company determines revenue recognition incorporating the following steps:

- Identification of each contract with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when, or as, performance obligations are satisfied.

The Company accounts for a contract with a customer when it has a legally enforceable contract with the customer, the arrangement identifies the rights of the parties, the contract has commercial substance, and the Company determines it is probable that it will collect the contract consideration. The Company recognizes revenue when control of the promised goods or services transfers to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Taxes collected from customers relating to goods or services and remitted to governmental authorities are excluded from revenue.

Catheter Revenue

The Company enters into a DABRA laser commercial usage agreement or DABRA laser placement acknowledgement with each customer that is supplied a DABRA laser, collectively the “usage agreement”. The usage agreement provides for specific terms of continued use of DABRA laser, including a nominal periodic fee. The terms of a usage agreement typically allow the Company to place a DABRA laser at a customer’s specified location without a specified contract term. Under the usage agreement terms, the Company retains all ownership rights to the DABRA laser and is permitted to request the return of the equipment within 10 business days of notification. While the laser periodic fees are nominal, the laser usage agreements provide the Company the exclusive rights to supply related single-use catheters to the customer which aggregate the majority of the vascular segment revenue. There are no specified minimum purchase commitments for the catheters.

The Company recognizes revenue associated with the usage agreement and catheter supply arrangements in accordance with Topic 606 as the contract primarily includes variable payments, the catheters are priced at their standalone selling price and the laser equipment is insignificant in the context of the contract. Revenue is recognized when the performance obligation is satisfied, which is generally upon shipment of the catheter.

Laser Sales

Laser sales consist of sales of DABRA and Pharos laser systems and are included in product sales in the statements of operations. The Company recognizes revenue on laser sales at the point in time that control transfers to the customer. Control of the product typically transfers upon shipment.

Warranty Service Revenue

The Company typically provides a 12-month warranty with the purchase of its laser systems. Customers can extend the warranty period through the purchase of extended warranty service contracts. Extended warranty service contracts are sold with contract terms ranging from 12 to 60 months and cover periods after the end of the initial 12-month warranty period. The warranty provides the customer with maintenance services in addition to the assurance that the laser product complies with agreed-upon specifications. Therefore, the warranty service is treated as a separate performance obligation from the laser system. Warranty services are a stand-ready obligation, and the Company recognizes revenue on a straight-line basis over the service contract term. Warranty service revenue is included in service and other revenue in the statements of operations.

Deferred revenue, after adoption of Topic 606 on January 1, 2019, was \$2.8 million. Revenue recognized in the year ended December 31, 2019 relating to amounts previously included in deferred revenue was \$1.9 million. The deferred revenue greater than one year will be recognized during the remaining service period through June 2024.

Distributor Transactions

In certain markets outside the U.S., the Company sells products and provides services to customers through distributors that specialize in medical device products. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers. The Company accounts for these transactions in accordance with the Company’s revenue recognition policy described herein.

Contracts with multiple performance obligations

Certain of the Company’s contracts with customers contain multiple performance obligations. For these contracts, the Company accounts for individual products and services as separate performance obligations if they are distinct, which is if (i) a product or service is separately identifiable from other items in the arrangement and (ii) the customer can benefit from the product or service on its own or with other readily available resources. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. The Company determines standalone selling prices based on observable prices of products or services sold separately in comparable circumstances to similar customers.

Significant Financing Component

For multi-year warranty service contracts in which there is a difference between the cash selling price and the consideration in the contract and a significant amount of time between the payment, which is due up-front, and delivery of the services (greater than one year), the Company records an adjustment for significant financing to reflect the time value of money. The Company recognizes revenue associated with the cash selling price and interest expense using the effective interest method as the Company satisfies its performance obligation(s). The amount of interest expense the Company recognizes over the contract term is based on the contract liability balance, which increases for the accrual of interest and decreases as services are provided.

For services contracts that have an original duration of one year or less, the Company uses the practical expedient applicable to such contracts and does not adjust the transaction price for the time value of money.

Practical expedients elected

As part of the Company's adoption of Topic 606, the Company elected to use the following practical expedients:

- not to adjust the promised amount of consideration for the effects of a significant financing component when the Company expects, at contract inception, that the period between the Company's transfer of a promised product or service to a customer and when the customer pays for that product or service will be one year or less;
- to expense costs as incurred for costs to obtain a contract when the amortization period would have been one year or less;
- to exclude government assessed taxes from the transaction price; and
- not to recast revenue for contracts that begin and end in the same fiscal year.

Contract Costs

The Company capitalizes costs to obtain contracts that are considered incremental and recoverable, such as sales commissions. The capitalized costs are amortized to selling, general and administrative expense over the estimated period of benefit of the asset, which is the contract term. The Company elected to use the practical expedient to expense the costs to obtain a contract when the amortization period is less than one year. After the adoption of Topic 606, the Company has contract costs of \$0.4 million capitalized at January 1, 2019 and December 31, 2019.

Rental Income

The Company also adopted ASC Topic 842, *Leases*, on January 1, 2019 using the optional transitional method. There was no adjustment to accumulated deficit at January 1, 2019.

The Company also derives income pursuant to product lease agreements for its Pharos laser systems, as operating leases. Consequently, the Company retains title to the equipment and the equipment remains on Company's balance sheet within property and equipment. Depreciation expense on these leased lasers is recorded to cost of revenues on a straight-line basis. The costs to maintain these leased lasers are charged to cost of revenues as incurred.

These lease arrangements contain one lease component (the laser) and one nonlease component (warranty service) for which the Company elected the practical expedient to not separate the nonlease component from the lease component. The Company accounts for the combined lease component as an operating lease and recognizes lease income on a straight-line basis over the lease term. Rental income from lease arrangements for the years ended December 31, 2019 and 2018 was \$0.7 million and \$0.5 million, respectively.

Shipping and handling costs—Shipping and handling charged to customers is included in net product sales. Shipping and handling costs are included in selling, general and administrative expenses in the accompanying statements of operations. Shipping and handling costs were \$0.5 million and \$0.6 million for the years ended December 31, 2019 and 2018, respectively.

Advertising expense—The Company charges advertising costs to expense as incurred. Advertising expense for the years ended December 31, 2019 and 2018, amounted to \$0.1 million and \$40,000, respectively.

Research and development—Major components of research and development costs include personnel compensation expenses, stock-based compensation, consulting, materials and clinical trial expenses. Research and development expenses are charged to operations in the period they are incurred.

Patents—The Company expenses patent costs, including related legal costs, as incurred and records such costs within selling, general and administrative expense in the accompanying statements of operations.

Stock-based compensation—The Company evaluates whether an award should be classified and accounted for as a liability award or equity award for all stock-based compensation awards granted.

Stock-based compensation for liability awards issued to employees, directors, consultants, and other service providers were measured based on fair value of the award using the Black Scholes option pricing model. Changes in the fair value of a liability incurred under a share-based payment arrangement that occur during the requisite service period are recognized as compensation cost over that period. The percentage of the fair value that is accrued as compensation cost at the end of each period is equal to the percentage of the requisite service that has been rendered at that date. Any difference between the amount for which a liability award is settled and its fair value at the settlement date is recorded as an adjustment to compensation cost in the period of settlement. There were no liability awards outstanding at December 31, 2019 or 2018.

Stock-based compensation expense for equity instruments issued to employees and directors is measured based on estimating the fair value of each stock option on the date of grant using the Black Scholes option pricing model. Equity instruments issued to nonemployee consultants and service providers are valued using the Black Scholes option pricing model and are subject to revaluation as the underlying equity instruments vest. The Company recognizes forfeitures as they occur.

The Company recognizes stock-based compensation expense as follows:

| | <u>Employees</u> | <u>Nonemployees</u> |
|--|---|---|
| Service condition only | Straight-line | In the same period and in the same manner as if the Company paid cash for services. |
| Performance criterion is probable of being met: | | |
| Service criterion is complete | Recognize the grant date fair value of the award once the performance criterion is considered probable of occurrence | Recognize the grant date fair value of the award once the performance criterion is considered probable of occurrence |
| Service criterion is not complete | Straight-line | Straight-line unless a performance condition is not probable |
| Performance criterion is not probable of being met | No expense is recognized until the performance criterion is considered probable, at which point expense is recognized per above | No expense is recognized until the performance criterion is considered probable, at which point expense is recognized per above |

Income taxes—The Company accounts for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences reverse. Any resulting net deferred tax assets are evaluated for recoverability and, accordingly, a valuation allowance is provided when it is more likely than not that all or some portion of the deferred tax asset will not be realized.

The Company accounts for uncertainty in income taxes using a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining whether it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. An uncertain tax position is considered effectively settled on completion of an examination by a taxing authority if certain other conditions are satisfied. Should the Company incur interest and penalties relating to tax uncertainties, such amounts would be classified as a component of interest expense and other expense, respectively.

Concentrations of credit risk—Credit risk represents the accounting loss that would be recognized at the reporting date if counterparties failed completely to perform as contracted. Concentrations of credit risk that arise from financial instruments exist for groups of customers or counterparties when they have similar economic characteristics that would cause their ability to meet contractual obligations to be similarly affected by changes in economic or other conditions described below.

Financial instruments, which potentially subject the Company to concentration of credit risk, consist of cash, cash equivalents and short-term investments balances maintained in excess of Federal Depository Insurance Corporation limits, and accounts receivable which have no collateral or security. The Company monitors the financial condition of the banks in which it currently has deposits. The Company has not experienced any significant losses in this respect and believes that it is not exposed to any significant related risk.

Exposure to losses on accounts receivable is dependent on the individual customer's financial condition. The Company monitors its exposure to credit losses and reserves for those accounts receivable that it deems to be not collectible.

One of the Company's customers represented 10% of accounts receivable as of December 31, 2019 and 2018.

No individual customer represented greater than 10% of total net revenue for the years ended December 31, 2019 or 2018.

Recently Adopted Accounting Pronouncements—As an emerging growth company, the Company may elect to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than public companies must adopt the standards. The Company has elected to take advantage of the extended transition period afforded by the JOBS Act and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies, which are the dates included below.

In May 2014, FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)*, and issued subsequent amendments to the initial guidance in August 2015, March 2016, April 2016 and May 2016 within ASU 2015-14, ASU 2016-08, ASU 2016-10 and ASU 2016-12, respectively. ASU 2014-09 supersedes nearly all existing revenue recognition guidance under generally accepted accounting principles in the United States ("US GAAP"). The core principle of ASU 2014-09 is to recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services. The Company adopted this accounting standard in the first quarter of fiscal year 2019 using the modified retrospective method. The Company recorded an adjustment to accumulated deficit in the first quarter of 2019 for the following items; (i) differences in the amount of revenue recognized for the Company's revenue streams as a result of allocating revenue based on standalone selling prices to the Company's various performance obligations, (ii) capitalization of incremental contract acquisition costs, such as sales commissions paid in connection with product sales with multi-year service contracts, which will be amortized over the contract service period and (iii) recognized a significant financing component for multi-year service contracts for customers who pay more than one year in advance of receiving the service. The Company recognized the significant financing component over the contract service period. The Company recorded a \$21,000 reduction to accumulated deficit as a result of the adoption of Topic 606.

In February 2016, FASB issued ASU 2016-02, *Leases (Topic 842)* (“ASU 2016-02”). This update requires lessees to recognize, on the balance sheet, a lease liability and a lease asset for all leases with a term greater than 12 months, including operating leases. The update also expands the required quantitative and qualitative disclosures surrounding leases. Under the new standard, the Company will have to recognize, on the balance sheet, a liability representing its lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. ASU 2016-02 is effective for the Company beginning January 1, 2020, with early adoption permitted. Lessor accounting under ASU 2016-02 is similar to the current model but updated to align with certain changes to the lessee model. Lessors will continue to classify leases as operating, direct financing or sales-type leases. In addition, the new standard requires that lease and nonlease components of a contract be bifurcated, with nonlease components subject to the new revenue recognition standard effective upon adoption of the new leasing standard. Lessors are allowed to elect to account for the lease and nonlease components as a single combined lease component if (i) the timing and pattern of the revenue recognition is the same, and (ii) the combined lease component would continue to be classified as an operating lease.

The Company adopted the standard using the optional transition method provided by ASC Update No. 2018-11 *Leases (Topic 842): Targeted Improvements*. Under this method, the Company applied the new leasing rules on January 1, 2019. As part of the adoption, the Company elected the package of practical expedients permitted under the new lease standard, which among other things, allowed the Company to carry forward the historical lease classification. The Company also elected the practical expedient to combine lease and non-lease components. The Company recognized right-of-use assets and lease liabilities of \$3.2 million upon adoption of ASU 2016-02. The new lease standard did not change the Company’s accounting for leases in which the Company is the lessor.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. ASU 2018-07 expands the scope of Topic 718, *Compensation—Stock Compensation*, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU 2018-07 supersedes Subtopic 505-50, *Equity—Equity-Based Payments to Non-Employees*. The amendments are effective for fiscal years beginning after December 15, 2019. Early adoption is permitted, but no earlier than a company’s adoption date of Topic 606, *Revenue from Contracts with Customers*. The Company adopted this guidance on January 1, 2020 and there was no impact on the financial statements and related disclosures.

Recently Issued Accounting Pronouncements—In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820) - Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, which is designed to improve the effectiveness of disclosures by removing, modifying and adding disclosures related to fair value measurements. ASU No. 2018-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and the ASU allows for early adoption in any interim period after issuance of the update. The Company does not expect the effects of the adoption of this ASU to have a material impact on the Company’s financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326)*, to require the measurement of expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions and reasonable forecasts and applies to all financial assets, including trade receivables. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. ASU No. 2016-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company adopted this guidance on January 1, 2020. The Company does not expect the effects of the adoption of this ASU to have a material impact on the Company’s financial statements.

Note 3—Short-term Investments

A summary of debt securities by major security type is as follows as of December 31, 2019 (in thousands):

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|--|-------------------|------------------------------|-------------------------------|------------------|
| Debt Securities-available-for-sale: | | | | |
| U.S. agency securities | \$ 1,000 | \$ — | \$ — | \$ 1,000 |
| U.S. government securities | 14,967 | 26 | — | 14,993 |
| Total debt securities | <u>\$ 15,967</u> | <u>\$ 26</u> | <u>\$ —</u> | <u>\$ 15,993</u> |

All debt securities are due in less than one year.

The following table presents the hierarchy for assets measured at fair value on a recurring basis (in thousands):

| | Total Fair Value | Quoted Market Prices for Identical Assets (Level 1) | Other Observable Inputs (Level 2) | Unobservable Inputs (Level 3) |
|--------------------------------|---------------------|--|--|-------------------------------------|
| As of December 31, 2019 | | | | |
| Money market funds | \$ 13,219 | \$ 13,219 | \$ — | \$ — |
| U.S. government securities | \$ 14,993 | \$ 14,993 | \$ — | \$ — |
| U.S. agency securities | \$ 1,000 | \$ — | \$ 1,000 | \$ — |
| As of December 31, 2018 | | | | |
| Money market funds | \$ 61,134 | \$ 61,134 | \$ — | \$ — |

Note 4—Inventories

Inventories consisted of the following (in thousands):

| | December 31, | |
|--------------------|-----------------|-----------------|
| | 2019 | 2018 |
| Raw materials | \$ 2,300 | \$ 1,333 |
| Work in process | 215 | 88 |
| Finished goods | 262 | 676 |
| Inventories | <u>\$ 2,777</u> | <u>\$ 2,097</u> |

Note 5—Property and Equipment, net

Property and equipment consisted of the following (in thousands):

| | December 31, | |
|------------------------------------|-----------------|-----------------|
| | 2019 | 2018 |
| Lasers | \$ 4,671 | \$ 3,254 |
| Machinery and equipment | 841 | 1,135 |
| Automobiles | 1,109 | 1,115 |
| Computer hardware and software | 348 | 366 |
| Leasehold improvements | 119 | 104 |
| Furniture and fixtures | 48 | 82 |
| Construction in progress | 23 | 14 |
| Property and equipment, gross | 7,159 | 6,070 |
| Accumulated depreciation | (2,109) | (1,313) |
| Property and equipment, net | <u>\$ 5,050</u> | <u>\$ 4,757</u> |

Depreciation expense was \$1.4 million and \$0.6 million for the years ended December 31, 2019 and 2018, respectively.

Note 6—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

| | December 31, | |
|-----------------------------------|-----------------|-----------------|
| | 2019 | 2018 |
| Compensation and related benefits | \$ 1,163 | \$ 1,734 |
| Accrued warranty (Note 7) | 338 | 112 |
| Accrued services | 1,141 | 963 |
| Accrued expenses | \$ 2,642 | \$ 2,809 |

Note 7—Accrued Warranty

Activity in the product warranty accrual is included in accrued expenses above and consists of the following (in thousands):

| | Year ended December 31, | |
|---|-------------------------|---------------|
| | 2019 | 2018 |
| Balanced at beginning of period | \$ 112 | \$ 87 |
| Increase in warranty accrual | 889 | 287 |
| Change in liability for pre-existing warranties | (28) | — |
| Claims satisfied | (635) | (262) |
| Accrued warranty | \$ 338 | \$ 112 |

Warranty expense was \$0.9 million and \$0.3 million for the years ended December 31, 2019 and 2018, respectively. The year ended December 31, 2019 includes \$0.2 million relating to the voluntary recall of catheters, which occurred in September 2019. Warranty expense is included in cost of revenue in the accompanying statements of operations.

Note 8—Leases

The Company recognized non-cash right-of-use assets and lease liabilities of \$3.2 million upon adoption of ASU 2016-02 on January 1, 2019. The Company has two operating leases for office and manufacturing space which requires it to pay base rent and certain utilities. Monthly rent expense is recognized on a straight-line basis over the term of the leases, which expire in 2027 and 2021.

At December 31, 2019 the weighted average remaining lease term was eight years. The operating leases are included in the balance sheet at the present value of the lease payments at a 7% discount rate using the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and amount equal to the lease payments in a similar economic environment as the leases do not provide an implicit rate.

For the year ended December 31, 2019, operating lease expense and cash paid was \$0.5 million. Operating lease right-of-use assets amortization was \$0.3 million for the year ended December 31, 2019. Variable costs are de minimis. Rent expense was \$0.4 million for the year ended December 31, 2018.

The following table presents the lease liabilities within the balance sheet, related to the Company's operating leases as of December 31, 2019 (in thousands):

| Years Ending December 31, | | |
|--|----|--------------|
| 2020 | \$ | 514 |
| 2021 | | 528 |
| 2022 | | 432 |
| 2023 | | 445 |
| 2024 | | 459 |
| Thereafter | | 1,459 |
| Total operating lease payments | \$ | <u>3,837</u> |
| Less: imputed interest | | (899) |
| Total operating lease liabilities | \$ | <u>2,938</u> |

The following table presents the future minimum rental payments due as of December 31, 2018 (in thousands):

| Years Ending December 31, | | |
|----------------------------------|----|--------------|
| 2019 | \$ | 500 |
| 2020 | | 514 |
| 2021 | | 528 |
| 2022 | | 432 |
| 2023 | | 445 |
| Thereafter | | 1,918 |
| Total | \$ | <u>4,337</u> |

Note 9—Equipment Financing

During 2018, the Company entered into four loan agreements to finance 25 automobiles. The loans expire in 2021 and bear interest at a weighted average interest rate of 6.5%. These loans are secured by the automobiles. Interest expense for the years ended December 31, 2019 and 2018 was \$48,000 and \$8,000, respectively. The outstanding balance at December 31, 2019 was \$0.6 million and included in equipment financing.

Future maturities are as follows (in thousands):

| Years ending December 31, | | |
|----------------------------------|----|------------|
| 2020 | \$ | 293 |
| 2021 | | 265 |
| Total | \$ | <u>558</u> |

Note 10—Loss per Share

The Company calculates basic loss per share by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted loss per share would reflect the effects of potentially dilutive securities, if any.

Anti-dilutive common share equivalents excluded from the computation of diluted net loss per share at December 31, 2019 consisted of stock options of 3,139,537, restricted stock units of 271,472 and Employee Stock Purchase Plan shares of 61,840.

Note 11—Stockholders' Equity

Common stock—The Company has one class of stock outstanding: common shares. The Company issued 316,080 shares of stock in exchange for \$7.9 million that related to the private placements which took place in 2018.

The Company's Registration Statement on Form S-1 for its initial public offering was effective September 26, 2018 and the transaction closed on October 1, 2018, at which time the Company issued 4,485,000 shares of common stock in exchange for net proceeds of approximately \$67.3 million after deducting underwriting discounts and commissions and offering expenses payable by the Company.

Preferred stock— At December 31, 2019 and 2018, the Company has no shares of preferred stock outstanding.

Note 12—Stock-Based Compensation

In 2003, the Company adopted a stock option plan (the “2003 Plan”), which authorized the board of directors to grant stock option awards to eligible employees, directors, consultants and service providers (together the “Optionees”) of the Company. In April 2012, such plan expired. In 2014, the Company established the 2014 Stock Option Plan (the “2014 Plan”) whereby 1,000,000 shares of the Company’s common stock were reserved for issuance to eligible Optionees. The 2014 Plan provided for the grant of incentive stock options, non-statutory stock options, stock bonuses and rights to acquire restricted stock. Option awards under the 2014 Plan expired up to a maximum of 10 years from the date of the grant. On May 17, 2018, the Company’s board of directors terminated the 2014 Plan.

Obligations under the 2003 Plan and 2014 Plan included time and performance-based awards. For time-based awards, vesting generally occurred over the service period of up to four years. Performance based awards vested at the time that the underlying performance conditions were met.

In 2018, the Company concluded that option awards communicated to Optionees (the “Communicated Option Awards”) under the 2003 Plan and 2014 Plan were not validly authorized and therefore were not valid outstanding option awards. Although the Communicated Option Awards were not outstanding options, the Company believed the Communicated Option Awards represented a contractual obligation to the Optionees and therefore the Company classified the Communicated Option Awards as liabilities in the financial statements which were remeasured at fair value each reporting period.

On June 4, 2018, the 2014 Plan was replaced with the 2018 Stock Compensation Plan (the “Compensation Plan”) whereby 3,300,000 shares of the Company’s common stock were reserved for issuance. On June 4, 2018, the Company’s board of directors authorized 1,901,900 replacement equity awards of stock options and, on June 8, 2018, 1,340,832 restricted stock units (collectively, the “Replacement Awards”) to the Optionees. On various dates in June 2018, but after the board of directors’ authorization, the Replacement Awards were communicated to the Optionees in exchange for the cancellation of, and waiver to any claims related to, the Communicated Option Awards granted under the 2003 Plan and 2014 Plan which were determined to be not validly authorized. The issuance of the Replacement Awards and cancellation of the Communicated Option Awards was treated as a modification. The modification date is the date of the grant of the Replacement Awards, such date being June 4, 2018, for options and June 8, 2018, for restricted stock unit awards. The Company is recognizing the remaining unrecognized compensation cost, as well as any incremental compensation cost of the Replacement Awards of \$17.2 million, over the remaining service period of the Replacement Awards, as described below. As the Replacement Awards have been determined to be equity-classified awards, the Company no longer records such awards as liabilities. The Compensation Plan terminated in connection with the adoption of the Company’s 2018 Equity Incentive Plan, described below, and, accordingly no new awards are available for issuance under this plan. The Compensation Plan continues to govern awards granted thereunder.

Stock options granted under the Compensation Plan, including those granted as a component of the Replacement Awards, generally vest 33% on the first anniversary of the grant date with the balance vesting monthly over the remaining two years. The restricted stock units granted under the Compensation Plan, including those granted as a component of the Replacement Awards, include a service condition and a performance condition. The service condition generally begins on the grant date and continues through January 2020 and the restricted stock units vest at various times commencing March 27, 2019 until January 2020. The performance condition related to the Company completing its IPO and the vesting of the restricted stock units were contingent upon the achievement of such IPO, which was achieved on October 1, 2018.

The restricted stock units granted under the Compensation Plan, including those granted as a component of the Replacement Awards, include a service condition and a performance condition. The service condition generally begins on the grant date and continues through January 2020 and the restricted stock units vest at various times commencing the day following the expiration of the lock-up until January 2020. The performance condition related to the Company completing its IPO and the vesting of the restricted stock units were contingent upon the achievement of such IPO, which was achieved on October 1, 2018. Stock options granted under the 2018 Plan generally vest 25% on the first anniversary of the vesting commencement date with the balance vesting monthly over the remaining three years. Restricted stock units granted under the 2018 plan generally have a vesting schedule with one third of the total number of shares underlying the restricted stock units vesting on the first anniversary of the vesting commencement date and one sixth of the total shares vesting every six months thereafter such that the award will be fully vested on the third anniversary of the vesting commencement date.

In September 2018, the Company's board of directors adopted, and the Company's stockholders approved, the Company's 2018 Equity Incentive Plan (the "2018 Plan"). The 2018 Plan became effective on September 25, 2018. As of December 31, 2019, 953,275 shares of common stock are reserved for future issuance pursuant to the Company's 2018 Plan. In addition, the shares reserved for issuance under the 2018 Plan include (1) those shares reserved but unissued under the Compensation Plan as of the date of stockholder approval of the 2018 Plan and (2) shares of common stock subject to or issued pursuant to awards granted under the Compensation Plan that, after the date of stockholder approval of the 2018 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2018 Plan pursuant to (1) and (2) is 3,300,000 shares). The 2018 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code to the Company's employees and any of the Company's parent and subsidiary corporations' employees, if applicable, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to the Company's employees, directors and consultants and the Company's parent and subsidiary corporations' employees, if applicable, and consultants. The number of shares available for issuance under the Company's 2018 Plan also includes an annual increase on the first day of each fiscal year beginning with our 2019 fiscal year, equal to the least of 1) 1,632,134 shares; 2) five percent (5%) of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or 3) such other amount as our board of directors may determine.

A summary of the activity and related information of the Communicated Option Awards classified as liabilities and communicated during the year ended December 31, 2018, is presented below:

| | Liability- Classified Awards (in shares) | Weighted Average Exercise Price | Weighted Average Remaining Life (in years) | Aggregate Intrinsic Value (in thousands) |
|---|---|--|--|---|
| Outstanding at December 31, 2017 | 933,500 | \$ 3.92 | 4.86 | \$ 19,676 |
| Granted | 170,000 | 25.00 | | |
| Forfeited | (67,000) | 5.33 | | |
| Cancelled and settled with Replacement Awards | (1,036,500) | 7.29 | — | 22,442 |
| Outstanding at December 31, 2018 | — | \$ — | — | \$ — |
| Exercisable at December 31, 2018 | — | \$ — | — | \$ — |
| Vested and expected to vest at December 31, 2018 | — | \$ — | — | \$ — |

A summary of the activity and related information of the stock options issued is presented below:

| | Stock Options | Weighted Average Exercise Price | Weighted Average Remaining Life (in years) | Aggregate Intrinsic Value (in thousands) |
|---|------------------|---------------------------------|--|--|
| Outstanding at December 31, 2017 | — | \$ — | — | \$ — |
| Granted | 1,945,900 | 28.47 | | |
| Forfeited | (25,800) | 19.27 | | |
| Outstanding at December 31, 2018 | <u>1,920,100</u> | <u>\$ 28.59</u> | <u>9.43</u> | <u>\$ —</u> |
| Granted | 1,521,335 | 1.22 | | |
| Forfeited | (301,898) | 26.81 | | |
| Outstanding at December 31, 2019 | <u>3,139,537</u> | <u>\$ 15.50</u> | <u>8.09</u> | <u>\$ —</u> |
| Exercisable at December 31, 2019 | <u>1,116,888</u> | <u>\$ 28.92</u> | <u>5.44</u> | <u>\$ —</u> |
| Vested and expected to vest at December 31, 2019 | <u>3,139,537</u> | <u>\$ 15.50</u> | <u>8.09</u> | <u>\$ —</u> |

A summary of the activity and related information of the restricted stock units is presented below:

| | Restricted Stock Units | Weighted Average Grant Date Fair Value |
|---|------------------------|--|
| Outstanding at December 31, 2017 | — | \$ — |
| Granted | 1,502,666 | 26.86 |
| Forfeited | (8,555) | 16.99 |
| Outstanding at December 31, 2018 | <u>1,494,111</u> | <u>\$ 26.91</u> |
| Granted | 300,003 | 3.95 |
| Vested and released | (1,206,743) | 27.93 |
| Forfeited | (315,899) | 19.91 |
| Outstanding at December 31, 2019 | <u>271,472</u> | <u>\$ 5.15</u> |

Stock-based compensation expense recorded in operating expenses was as follows (in thousands):

| | Year Ended December 31, | |
|---|-------------------------|------------------|
| | 2019 | 2018 |
| Selling, general and administrative | \$ 20,392 | \$ 11,936 |
| Research and development | 1,537 | 1,951 |
| Stock-based compensation in operating expenses | <u>\$ 21,929</u> | <u>\$ 13,887</u> |

Stock-based compensation amounts of \$1.6 million and \$0.6 million were capitalized to property and equipment and inventory during the years ended December 31, 2019 and 2018, respectively.

Unrecognized compensation expense for stock options issued as of December 31, 2019 was \$4.8 million and is expected to be recognized over a weighted-average period of 1.6 years. Unrecognized compensation expense for the restricted stock units as of December 31, 2019 was \$1.0 million and is expected to be recognized over a weighted-average period of 1.7 years.

The Communicated Option Awards were presented as a stock-based compensation liability, until June 4, 2018, when they were settled and reclassified to equity. The Communicated Option Awards were revalued at each reporting period with the change in fair value recorded to compensation expense.

The fair value of the Communicated Option Awards classified as liabilities was estimated using the Black Scholes option pricing model and the weighted-average assumptions used in the model are noted in the following table:

| | <u>Year Ended December 31, 2018</u> |
|--------------------------|---|
| Risk-free interest rate | 2.49 % |
| Volatility | 34.13 % |
| Expected dividend yield | 0.00 % |
| Expected life (in years) | 2.9 |

The weighted-average fair value for Communicated Option Awards granted during 2018 was \$12.91. The Company's shares were not traded on any public market during the term of the Communicated Option Awards. The common stock value as of the date of grant was based on the share price of recent equity issuances, if available. If there were no such recent transactions, the Company's share valuation was estimated. As of the date of the modification of the Communicated Option Awards, which resulted in the settlement of the stock-based compensation liability, the common stock price was estimated utilizing a hybrid method, a combination of the Probability Weighted Expected Return Method ("PWERM") and Option Pricing Model ("OPM"). The estimate incorporated a near-term IPO scenario using PWERM weighted at 80%. Other near-term exit events, a long-term stay private case, and dissolution were all considered as non-IPO scenarios using OPM, and were weighted at 20%. The estimate also reflected a 10% and 15% discount for lack of marketability under PWERM and OPM, respectively. The risk-free interest rate approximates the implied yield available on United States Treasury securities with an equivalent remaining term. Expected volatility is based on the historical volatilities of certain "guideline" companies. Expected dividend yield is based on dividends historically paid by the Company. The expected life is based on the "simplified" method using the average of the term and vesting period.

The fair value of the stock options issued under the 2018 Plan was estimated using the Black Scholes option pricing model and the weighted-average assumptions used in the model are noted in the following table:

| | <u>Year Ended December 31,</u> | |
|--------------------------|------------------------------------|-------------|
| | <u>2019</u> | <u>2018</u> |
| Risk-free interest rate | 1.6 % | 2.89 % |
| Volatility | 59.26 % | 42.64 % |
| Expected dividend yield | 0.00 % | 0.00 % |
| Expected life (in years) | 5.9 | 6.5 |

The weighted average fair value for the stock options granted during 2018 was \$12.70. The Company's shares were not traded in any public market at the stock option grant dates during the first nine months of 2018. For purposes of determining the fair value of the Company's common stock for the grants made in June 2018, the Company utilized a hybrid method, a combination of the PWERM and OPM as described above. The risk-free interest rate approximates the implied yield available on United States Treasury securities with an equivalent remaining term. Expected volatility is based on the historical volatilities of certain "guideline" companies. Expected dividend yield is based on dividends historically paid by the Company. The expected life is based on the "simplified" method using the average of the term and vesting period.

The Company's 2018 Employee Stock Purchase Plan (ESPP) became effective in September 2018. A total of 446,160 shares of common stock were available for sale under our ESPP as of December 31, 2019. Under the Company's ESPP, eligible employees are allowed to purchase the Company's stock at a discounted price, which is 85% of the lower market price of the Company's common stock at the beginning or at the end of the six-month purchase period. The Company issued 9,207 shares in exchange for \$37,000 in the year ended December 31, 2019 under the ESPP. The number of shares of common stock that will be available for sale under the ESPP also includes an annual increase on the first day of each fiscal year beginning with our 2019 fiscal year, equal to the least of (1) 296,752 shares; (2) one and one quarter percent (1.25%) of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or (3) such other amount as the administrator may determine.

Note 13—Income Taxes

A reconciliation of the differences between the United States statutory federal income tax rate and the effective tax rate as provided in the statements of operations is as follows:

| | Year Ended December 31, | |
|---|-------------------------|----------|
| | 2019 | 2018 |
| Tax computed at the federal statutory rate | 21.0 % | 21.0 % |
| State income taxes, net of federal benefits | 1.9 | 2.7 |
| Nondeductible expenses | (0.4) | (2.0) |
| Stock-based compensation | (9.5) | (2.2) |
| Change in valuation allowance | (13.0) | (19.5) |
| | <u>—</u> | <u>—</u> |

The federal and state income tax provision is summarized as follows (in thousands):

| | Year Ended December 31, | |
|---------------------------|-------------------------|--------------|
| | 2019 | 2018 |
| Current | | |
| Federal | \$ — | \$ — |
| State | 15 | 10 |
| | <u>15</u> | <u>10</u> |
| Deferred | | |
| Federal | — | — |
| State | — | — |
| | <u>—</u> | <u>—</u> |
| Income tax expense | <u>\$ 15</u> | <u>\$ 10</u> |

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for tax purposes, and (b) operating losses and tax credit carryforwards.

The tax effects of significant components of the Company's deferred tax assets (liabilities) are as follows (in thousands):

| | December 31, | |
|--------------------------------------|-------------------|------------------|
| | 2019 | 2018 |
| Deferred Tax Assets: | | |
| Net operating loss carryforwards | \$ 16,096 | \$ 6,990 |
| Operating lease liabilities | 766 | — |
| Other accruals | 61 | 88 |
| Reserves | 301 | 203 |
| Deferred revenue | 850 | 661 |
| Intangible assets | 253 | 353 |
| Stock-based compensation | 4,821 | 6,464 |
| Total gross deferred tax assets | <u>\$ 23,148</u> | <u>\$ 14,759</u> |
| Deferred Tax Liabilities: | | |
| Property and equipment | (1,026) | (888) |
| Operating lease right-of-use assets | (739) | — |
| Other | (92) | — |
| Total gross deferred tax liabilities | <u>\$ (1,857)</u> | <u>\$ (888)</u> |
| Valuation allowance | <u>(21,291)</u> | <u>(13,871)</u> |
| Total deferred taxes | <u>\$ —</u> | <u>\$ —</u> |

At December 31, 2019, the Company had available federal and state net operating loss carryforwards of approximately \$63.7 million and \$66.0 million, respectively, which may be used to offset future federal and state taxable earnings. The federal and state net operating losses begin expiring in 2029. Use of these net operating loss carryforwards may be significantly limited under the tax rules regarding the use of losses following an ownership change under Internal Revenue Code (“IRC”) Section 382. The Company has completed an IRC Section 382 analysis regarding the limitation of net operating losses through June 30, 2019 and has determined that no ownership change has occurred.

As of December 31, 2019, the Company does not have any unrecognized tax benefits. The Company does not anticipate that the amount of unrecognized tax benefits will significantly increase in the next 12 months. There were no interest and penalties accrued as of December 31, 2019. The Company files U.S. federal and various states income tax returns, which are subject to examination by the taxing authorities for years 2015 and later. However, the federal net operating loss carryover may be adjusted three years from the date the loss is utilized on an income tax return.

ASC 740, *Income Taxes*, requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is “more likely than not.” Realization of the future tax benefits is dependent on the Company’s ability to generate sufficient taxable income within the carryforward period. Because of the Company’s recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is not currently more likely than not to be realized and, accordingly, has provided a full valuation allowance at December 31, 2019 and 2018.

Note 14—Commitments and Contingencies

Legal—In the normal course of business, the Company is at times subject to pending and threatened legal actions. In management’s opinion, any potential loss resulting from the resolution of these matters will not have a material effect on the results of operations, financial position or cash flows of the Company.

Securities Litigation

On June 7, 2019, a putative securities class action complaint captioned *Derr v. Ra Medical Systems, Inc., et. al.*, (Civil Action no. 19CV1079 LAB NLS) was filed in the United States District Court for the Southern District of California against the Company, certain current and former officers and directors, and certain underwriters of the Company’s IPO. The complaint alleged that the defendants made material misstatements or omissions in the Company’s registration statement in violation of Sections 11 and 15 of the Securities Act of 1933. On September 5, 2019, the court appointed Lead Plaintiffs. On January 13, 2020, the Lead Plaintiffs filed an amended complaint. In addition to the Securities Act violations alleged in the original complaint, the amended complaint alleges that the defendants made material misstatements or omissions between September 27, 2018 and November 27, 2019, inclusive, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. The defendants have until March 13, 2020 to file their responsive pleadings or motions. Management intends to vigorously defend the Company against this lawsuit. At this time, the Company cannot predict how a court or jury will rule on the merits of the claims and/or the scope of the potential loss in the event of an adverse outcome. Should the Company ultimately be found liable, the liability could have a material adverse effect on the Company’s financial condition and its results of operations for the period or periods in which it is incurred. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

On October 1, 2019, a shareholder derivative complaint captioned *Noel Borg v. Dean Irwin, et. al* (Civil Action no. 1:99-cm-09999) was filed in the United States District Court for the District of Delaware against certain current and former officers and directors, purportedly on behalf of the Company, which is named as a nominal defendant in the action. The complaint alleges breaches of fiduciary duty, unjust enrichment, waste, and violations of Section 14(a) of the Securities Exchange Act of 1934. On October 21, 2019, pursuant to the parties’ stipulation, the court stayed the derivative lawsuit until the related class action is resolved. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

Governmental Investigations

As previously announced in the Form 8-K filed on August 12, 2019, the Audit Committee of Ra Medical's Board of Directors (the "Audit Committee") conducted an investigation of certain allegations raised by a former employee. The Company announced the Audit Committee's findings in the Form 8-K filed on October 31, 2019. The primary investigative findings were: (i) the DABRA catheter frequently failed to calibrate and occasionally overheated, posing a risk of injury to physicians and patients; (ii) the Company's explanations regarding its fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because they did not explicitly reference inconsistent DABRA catheter performance and catheter failures; (iii) the Company failed to timely make at least two Medical Device Reports, or MDRs, to the FDA; (iv) the Company, out of a concern for the DABRA catheters' performance, engaged in systematic efforts to replace product held by customers, which constituted product recalls, but were not documented as such; (v) the Company lack documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, and as to three physicians did not accurately reflect the purpose and nature of approximately \$300,000 of payments, which could be perceived as an improper attempt to obtain business or to gain special advantage; (vi) while the indication for use in the 510(k) clearance the Company obtained for the DABRA system is not for atherectomy, the Company's salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes; (vii) the Company's determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects; and (viii) the Company received complaints regarding regulatory or compliance concerns that, because they implicated executive officers, should have been brought to the attention of the Board or the Audit Committee, but were not. The Audit Committee, in reviewing the allegations, identified certain behavior inconsistent with the Company's Code of Ethics and Conduct and related policies.

As also previously announced, the Company voluntarily contacted the Securities and Exchange Commission's (the "SEC") Enforcement Division regarding the Audit Committee's investigation. On November 13, 2019, the SEC notified the Company that it is conducting an investigation. The Company has been, and intends to continue, cooperating with the SEC in this investigation.

In October 2019, the Department of Justice, or DOJ, served the Company with a Civil Investigative Demand ("CID") seeking information with respect to a False Claims Act investigation concerning whether the Company fraudulently obtained 510(k) marketing clearance for the Company's devices marketed under the trade name DABRA, whether the Company marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether the Company paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. In response to the DOJ's CID, the Company reviewed the facts and circumstances of the clinical study used to support its 510(k) marketing clearance and has now completed such review. Following this review, the Company believes there is (i) adequate evidence to support the safety and efficacy reported in the study submitted with the 510(k) application, and (ii) no observations that would have a major impact on the reported results of the study. The Company has been, and intends to continue, cooperating with the DOJ in its investigation.

On November 21, 2019, the Company became aware that the Criminal Division, Fraud Section of the U.S. Department of Justice has an open investigation related to the Company. At this time, it is unclear if the Company is a target in this investigation. The Company has been, and intends to continue, cooperating with the DOJ in its investigation.

The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

Other Litigation

On August 30, 2018, Strata Skin Sciences, Inc. ("Strata") and Uri Geiger, a member of the board of directors of Strata Skin Sciences, Inc. (collectively "Strata") filed an action against the Company in Court of Common Pleas of, Montgomery County, Pennsylvania (Civil Action No. 18-21421) (the "Pennsylvania Case"), requesting declaratory relief that: (1) Strata and Mr. Geiger are not liable for tortious interference, defamation, libel, or unfair competition based on an e-mail by Mr. Geiger to an investment bank (the "Geiger Email"); (2) Strata and Mr. Geiger made no actionable statements about the Company to such investment bank; (3) the Company cannot enforce the 2011 settlement and release agreement between the Company and PhotoMedex, Inc. ("Settlement Agreement") against Strata; and (4) that any dispute regarding the Geiger Email does not relate to the Settlement Agreement. The action

filed by Strata and Mr. Geiger does not request any monetary damages. The Company believes that the action by Strata and Mr. Geiger was filed as a response to a letter that the Company sent to Strata on August 22, 2018 demanding that Strata and Mr. Geiger cease and desist from making statements about alleged patent infringement and affirmatively retract the statements made in the Geiger Email. The Company was served with the action on August 31, 2018, and responded with preliminary objections to the action on September 19, 2018. The court overruled the Company's preliminary arguments on April 29, 2019. The Company filed a motion for partial summary judgment on December 9, 2019 for the court to rule that Strata is bound by the Settlement Agreement. Strata filed a motion on February 4, 2020 asking the court to enforce a settlement agreement to which Strata believes the Company agreed, despite such agreement never having been signed. A hearing on the motion for partial summary judgment and the motion to enforce a settlement is scheduled for March 20, 2020. The Company believes that Strata's action in the Pennsylvania Case lacks merit, and plans to vigorously oppose the action on procedural and substantive grounds within the prescribed time limits. No loss is probable or reasonably possible as of December 31, 2019.

On May 16, 2019, the Company filed an action against Strata, Mr. Geiger and Accelmed Growth Partners, L.P. (collectively, the "Strata Parties") in the United States District Court for the Southern District of California (Civil Action No. 19-cv-0920-AJB-MSB (the "California Case")) alleging (1) breach of the Settlement Agreement, (2) intentional interference in contractual relations, (3) intentional interference in prospective economic relations, and (4) trade libel. In the California Case, the Company alleges, among other things, that the statements in the Geiger Email regarding alleged patent infringement constitute a breach of the Settlement Agreement, that the Strata Parties employed deceptive practices designed to delay the Company's initial public offering and reduce the amount of capital raised by the Company, and that statements in the Geiger Email regarding patent infringement, off label promotion and reimbursement constitute trade libel. The Company seeks an injunction barring the Strata Parties from continuing the alleged conduct, monetary damages, and other available legal and equitable relief. The Company amended its complaint on July 25, 2019 to allege violations of the Lanham Act's prohibition on false advertising. The Strata Parties filed motions to dismiss on August 25, 2019, and the Company responded with its oppositions to the motions to dismiss on September 27, 2019. On February 28, 2020, the Company filed a supplemental complaint to include additional allegations of violations of the Lanham Act. The Company and the Strata Parties filed a joint motion to treat the pending motions to dismiss as if they were directed at this supplemental complaint. On March 6, 2020, the court denied the motion but indicated that the Company may file a new amended complaint with these additional allegations, rather than a supplemental complaint.

On February 12, 2020, Dean Irwin, the Company's former Chief Executive Officer, filed a Demand for Arbitration, alleging that the Company attempted to coerce him into signing a non-standard separation agreement and release of claims, contrary to the terms of his Severance Agreement. Mr. Irwin claims that he was willing to sign the Company's standard separation agreement and release of claims. Based on this allegation, Mr. Irwin is claiming nonpayment of wages, penalties for nonpayment of wages, failure to provide wage statements, breach of contract, and breach of implied covenant of good faith and fair dealing. The Company believes that Mr. Irwin's allegations lack merit, and plans to vigorously defend the action.

401(k) —In January 2019, the Company established a defined contribution plan under Section 401(k) of the Internal Revenue Code ("401(k) Plan") that the Company administers for participating employees' contributions. All full-time employees are eligible under the 401(k) Plan. The Company will make contributions, based on a match of 100% of each employee's contribution up to 3% and 50% of contributions between 3% and 5%, with the match-eligible contribution being limited to 4% of the employee's eligible compensation. The Company match expense was \$0.3 million for the year ended December 31, 2019.

Note 15—Segment Information

The Company has organized its business into two operating segments based on the product specialties: the vascular segment and the dermatology segment.

In deciding how to allocate resources and assess performance, the Company's chief operating decision maker regularly evaluates the sales and gross profit of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to the Company and not specific to a particular segment; therefore, these amounts are not evaluated by the Company's chief operating decision maker on a segmented basis.

The following tables summarize segment performance (in thousands):

| | Year Ended December 31, | |
|----------------------------|-------------------------|-----------------|
| | 2019 | 2018 |
| Vascular | \$ 1,275 | \$ 1,552 |
| Dermatology | 5,924 | 4,705 |
| Net revenue | \$ 7,199 | \$ 6,257 |
| Vascular | \$ 4,036 | \$ 1,521 |
| Dermatology | 4,814 | 2,685 |
| Cost of revenue | \$ 8,850 | \$ 4,206 |
| Vascular | \$ (2,761) | \$ 31 |
| Dermatology | 1,110 | 2,020 |
| Gross (loss) profit | \$ (1,651) | \$ 2,051 |

Generally, all assets are common assets, except for lasers, which are a subset of property and equipment. The net book value of the lasers aggregated in the vascular segment was \$2.6 million and \$2.2 million as of December 31, 2019 and 2018, respectively. The net book value of the lasers placed with customers aggregated in the dermatology segment was \$0.9 million and \$0.7 million as of December 31, 2019 and 2018, respectively.

Net revenue, classified by the major geographic areas in which our customers are located, was as follows (in thousands):

| | Year Ended December 31, | |
|---------------------|-------------------------|-----------------|
| | 2019 | 2018 |
| United States | \$ 6,568 | \$ 5,835 |
| All other countries | 631 | 422 |
| Net revenue | \$ 7,199 | \$ 6,257 |

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes certain terms of our capital stock and certain provisions of our amended and restated certificate of incorporation. We have adopted an amended and restated certificate of incorporation and amended and restated bylaws, and this description summarizes certain of the provisions that are included in those documents. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, copies of which are filed with the SEC as exhibits to this Annual Report on Form 10-K, and to the applicable provisions of Delaware law.

Our authorized capital stock consists of 310,000,000 shares of capital stock, of which 300,000,000 shares are designated as common stock, \$0.0001 par value per share, and 10,000,000 shares are designated as preferred stock, \$0.0001 par value per share. Our board of directors is authorized, without stockholder approval, except as required by the listing standards of the NYSE, to issue shares of our preferred stock. As of March 6, 2020, there were 13,770,349 shares of common stock issued and outstanding and there were 77 holders of record of our common stock.

Common Stock

The holders of common stock are entitled to one vote per share on all matters submitted to a vote of our stockholders and do not have cumulative voting rights. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. Subject to preferences that may be applicable to any preferred stock outstanding at the time, the holders of outstanding shares of common stock are entitled to receive ratably any dividends declared by our board of directors out of assets legally available. See the section captioned “*Dividend Policy*” for additional information. Upon our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any then outstanding shares of preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock.

Preferred Stock

Pursuant to our amended and restated certificate of incorporation, our board of directors has the authority, without further action by the stockholders, to issue from time to time up to 10,000,000 shares of preferred stock in one or more series. Our board of directors may designate the rights, preferences, privileges and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, redemption rights, liquidation preference, sinking fund terms and the number of shares constituting any series or the designation of any series. The issuance of preferred stock could have the effect of restricting dividends on the common stock, diluting the voting power of the common stock, impairing the liquidation rights of the common stock or delaying, deterring or preventing a change in control. Such issuance could have the effect of decreasing the market price of the common stock. We currently have no plans to issue any shares of preferred stock.

Anti-Takeover Effects of Delaware law and our Certificate of Incorporation and Bylaws

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions and certain provisions of Delaware law, which are summarized below, may have the effect of discouraging takeover bids, coercive or otherwise. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Issuance of Undesignated Preferred Stock. As discussed above under “*Description of Capital Stock—Preferred Stock*,” our board of directors has the ability to designate and issue preferred stock with voting or other rights or preferences that could deter hostile takeovers or delay changes in our control or management.

Limits on Ability of Stockholders to Act by Written Consent or Call a Special Meeting. Our amended and restated certificate of incorporation provides that our stockholders may not act by written consent. This limit on the ability of stockholders to act by written consent may lengthen the amount of time required to take stockholder actions. As a result, the holders of a majority of our capital stock would not be able to amend the amended and restated bylaws or remove directors without holding a meeting of stockholders called in accordance with the amended and restated bylaws. In addition, our amended and restated bylaws provide that special meetings of the stockholders may be called only by the chairperson of the board, our chief executive officer or president (in the absence of a chief executive officer) or a majority of our board of directors. A stockholder may not call a special meeting, which may delay the ability of our stockholders to force

consideration of a proposal or for holders controlling a majority of our capital stock to take any action, including the removal of directors.

Advance Requirements for Advance Notification of Stockholder Nominations and Proposals. Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of the board of directors. These advance notice procedures may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed and may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempt to obtain control of our company.

Board Classification. Our amended and restated certificate of incorporation provides that our board of directors are divided into three classes, one class of which is elected each year by our stockholders. The directors in each class will serve for a three-year term. For more information on the classified board of directors, see Part III, “*Directors, Executive Officers and Corporate Governance*.” Our classified board of directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us because it generally makes it more difficult for stockholders to replace a majority of the directors.

Election and Removal of Directors. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that establish specific procedures for appointing and removing members of our board of directors. Under our amended and restated certificate of incorporation and amended and restated bylaws, vacancies and newly created directorships on our board of directors may be filled only by a majority of the directors then serving on the board of directors.

Under our amended and restated certificate of incorporation and amended and restated bylaws, directors may be removed only for cause by the affirmative vote of the holders of a majority of the shares then entitled to vote at an election of directors.

No Cumulative Voting. The Delaware General Corporation Law provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless our amended and restated certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation and amended and restated bylaws do not expressly provide for cumulative voting. Without cumulative voting, a minority stockholder may not be able to gain as many seats on our board of directors as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence our board of directors’ decision regarding a takeover.

Amendment of Charter Provision. Any amendment of the above provisions in our amended and restated certificate of incorporation would require approval by holders of at least 66 2/3% of our then outstanding capital stock entitled to vote, voting together as a single class.

Delaware Anti-Takeover Statute. We are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation’s outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board

of directors does not approve in advance. We also anticipate that Section 203 may discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

The provisions of Delaware law and the provisions of our amended and restated certificate of incorporation and amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts.

These provisions might also have the effect of preventing changes in our management. It is also possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

Choice of Forum. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty; (iii) any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate or our amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; and (v) any action asserting a claim against us that is governed by the internal-affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219, and its telephone number is 718-921-8300. Our shares of common stock are issued in uncertificated form only, subject to limited circumstances.

Market Listing

Our common stock is listed on the New York Stock Exchange under the symbol "RMED."

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-227696 and 333-230332 on Form S-8 of our report dated March 11, 2020, relating to the financial statements of Ra Medical Systems, Inc., appearing in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
March 11, 2020

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002

I, Andrew Jackson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ra Medical 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.

Date: March 11, 2020

By: /s/ Andrew Jackson

Andrew Jackson
Interim Chief Executive Officer and Chief Financial Officer
(Principal executive officer and principal financial officer)

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Andrew Jackson, hereby certify that, to my knowledge:

- (i) the Company's Annual Report on Form 10-K for the year ended December 31, 2019 to which this Certification is attached as Exhibit 32 (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act, and
- (ii) that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Ra Medical Systems, Inc.

Date: March 11, 2020

By: /s/ Andrew Jackson
Andrew Jackson
Interim Chief Executive Officer and Chief Financial Officer
(Principal executive officer and principal financial officer)

This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Ra Medical Systems, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.