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, 2018

OR

☐ **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	**38-3661826**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2070 Las Palmas Drive Carlsbad, California	**92011**
(Address of principal executive offices)	**(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	**Name of the exchange on which registered**
Common Stock, $0.0001 par value	**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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

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 September 27, 2018 as reported by the New York Stock Exchange on such date was approximately $157.8 million. The registrant has elected to use September 27, 2018, which was the initial trading date on the New York Stock Exchange, as the calculation date because on June 30, 2018 (the last business day of the registrant's most recently completed second fiscal quarter), the registrant was a privately held company. 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 13, 2019, the registrant has 12,689,251 shares of common stock, par value $0.0001, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Information required by Part III of this Form 10-K is incorporated by reference to the registrant's proxy statement (the "Proxy Statement") for the 2019 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K.

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 or 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. Following the temporary placement period for the DABRA laser system and single-use catheter, together referred to as DABRA, and once our customers decide to continue using DABRA in their facilities, we typically enter into DABRA laser commercial usage agreements or DABRA laser placement acknowledgements with each customer, which we refer to collectively as Usage Agreements. The terms of the Usage Agreements vary by customer, but each Usage Agreement provides for the specific terms of continued use of DABRA, including periodic maintenance fees and do not provide for a minimum purchase obligation. As of December 31, 2018, we had 53 lasers at customer sites under signed Usage Agreements, with varying volumes of purchases. 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. These procedures are typically referred to in the medical community as atherectomy procedures, which the medical community commonly defines as any removal by surgery or specialized catheterization of an atheroma, or blockage, in an artery. Even though the medical community refers to it as atherectomy, DABRA is not currently cleared by the FDA for atherectomy. Nevertheless, third-party health payers can reimburse a procedure performed by a device which is not cleared or approved for a specific indication or procedure, if the physician determines the device and procedure are medically appropriate for a particular patient. Payers and the medical community can take a broader view than FDA in recognizing the scope of appropriate device use. In order to address this perceived uncertainty regarding reimbursement, we currently are pursuing expanded indications for use for DABRA to include 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, and an indication for use for the treatment of in-stent restenosis. To satisfy the FDA's data requirements to support an atherectomy indication, we plan to perform a new study designed to allow the FDA to evaluate the DABRA atherectomy procedure. The first subject is projected to be enrolled and treated in the second quarter of 2019, and we expect to have final results of the trial in the first quarter of 2020. We believe the incremental cost of obtaining the atherectomy indication will not be material.

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 a longer time frame (two years) than our pivotal trial, which had a 180 day follow up. We have case reports of patients with extended freedom from restenosis even out to over four years, which prompted us to study longer-term outcomes more closely. We intend to provide updates on a periodic basis throughout the study.

In addition, we intend to 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 venous and arterial occlusions, or blockages in the veins or arteries. 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, 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 17.6 million people in the U.S. suffer from PAD. 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 push the plaque to the side of the vessel. DABRA was designed to remove the plaque with less trauma in order 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 blockage types without the use of a guidewire. Although DABRA is suitable for use as a monotherapy, or a therapy that uses one type of treatment, it is predominantly used with angioplasty balloons and also can be used adjunct to drug-eluting balloons, stents, and other endovascular treatments. DABRA employs photochemical ablation, 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 photochemically 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. Independent in vivo and in vitro research studies have demonstrated that 308 nanometer excimer laser light, which is the same wavelength used in DABRA, increases T-cell apoptosis, which may produce an immunosuppressive effect. While we have not established the benefits of this potential immunosuppressant effect in the vasculature, or blood vessels such as arteries or veins, we may conduct a study in the future to identify any immunotherapeutic benefits.

The safety and effectiveness of the DABRA laser system and single-use DABRA catheter is supported by our pivotal study, a non-randomized, single-arm, prospective, multi-site study conducted to evaluate plaque photoablation using DABRA in the endovascular treatment of lower extremity vascular disease. The study enrolled 64 patients at four sites with both above-the-knee and below-the-knee lesions. The final study results demonstrated 94% effectiveness in successful crossing of the target lesion based on angiographic analysis, or a medical imaging technique used to visualize the inside of blood vessels, at time of the procedure with 0% reported serious adverse events (SAEs). In a study conducted by Spectranetics Corporation, or Spectranetics, as part of its 510(k) application for its CLiRpath Excimer Laser Catheter device, which was the predicate device for our 510(k) application, Spectranetics reported a 79% crossing success with its catheter device and a 72% procedure success in a total of 47 cases. Cumulatively, Spectranetics reported that there were 16, or 34%, SAEs reported during the six month follow-up period with the most frequently observed event being reintervention, which occurred in six, or 13%, of cases. The endpoints of both studies were at the time of procedure and at 30 days. Although our pivotal study was not head-to-head with the Spectranetics study, and we may not claim superiority of safety or efficacy, we believe that the patient population in our pivotal study that supported our 510(k) application was substantially similar to the patient population in the Spectranetics study mentioned above.

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. In June 2018, we completed our 12-month commercial launch period, which included initial training, production, and staffing for the marketing of DABRA in the United States. We market DABRA in the U.S. through our direct sales force, comprised of 35 personnel as of December 31, 2018, including sales personnel who place lasers in catheterization laboratories that perform high volumes of endovascular procedures, including plaque removal in peripheral arteries. We have plans to increase sales by further expanding this organization. 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 granted CE mark approval in September 2016 for the endovascular treatment of infrainguinal arteries via atherectomy and for crossing total occlusions, and we sell systems through distributors in select non-U.S. countries.

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 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, and South Korea Ministry of Drug Safety (now called the Ministry of Food and Drug Safety, or MDFS), in the applicable jurisdictions. 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. In addition, we believe excimer laser treatments can put patients into remission from certain diseases. 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 approximately 7.5 million people in the U.S., which accounts for over 2% of the domestic population. 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 1-2% of the population globally. Atopic dermatitis, more commonly known as eczema, is a chronic eczematous skin disease. There are more than 18 million people 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 heart and 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 arterial 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, including cooling, color changes, or sores that do not heal. If untreated, PAD can lead to critical limb ischemia, or CLI, a condition where there is not enough oxygenated blood being delivered to the limb 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

Recent analysis suggests that approximately 18 million people in the U.S. suffer from PAD. 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 and many dismiss symptoms as normal signs of aging. Research indicates only 20-30% of PAD patients are actively being treated.

Without treatment, the disease can result in severe complications and lead to amputation. The most common reason for amputation today is PAD, and up to 180,000 amputations are performed annually in the U.S. Despite the relative under diagnosis and treatment of PAD, the atherectomy devices industry achieved a $1.08 billion market in 2017 and is estimated to grow at CAGR of over 6% from 2018 to 2022. 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 guide wire 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 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. 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 180,000 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. No SAEs were reported in our 2017 pivotal study, which followed 38 subjects for 180 days, or reported in our post-market surveillance for DABRA. 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 photochemical ablation 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. We followed 38 subjects from our pivotal study to 180 days thereafter and all of the subjects were determined to be free of target lesion revascularization, or the need to retreat the lesion.
- ***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 that other products are unable to cross without the use of a guidewire. 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. This significantly increases the number of physicians who are able to perform the procedure compared to surgical alternatives that must be performed by highly-trained vascular surgeons.
- ***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.
- ***Immunotherapeutic Benefits***. Research performed using 308 nanometer laser energy, the wavelength of Pharos, demonstrated increased T-cell apoptosis, which may produce an immunosuppressant effect. Unlike with Pharos, where we can measure the degree and speed of clearance of disease and quantify the remission time, with DABRA we have not established the benefits of this immunosuppressant effect in the vasculature. We may, in the future, conduct a study to identify any immunotherapeutic benefits.

Our Strategy

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

- ***Driving physician awareness of DABRA***. Our program to educate physicians regarding DABRA's value proposition consists of presentations and exhibits at industry conferences, advertising in medical journals, direct visits, webinars, and calls.
- ***Creating patient awareness of DABRA***. We are establishing marketing and support programs with physicians and patient advocacy organizations to create patient awareness of PAD treatment options in order to generate demand for our products.
- ***Expanding DABRA sales***. We provide physicians with clinical training to drive adoption and utilization of DABRA. We believe that a strong sales team to train physicians on the correct use and the benefits of DABRA will increase sales. We expect to continue to expand the clinical sales team through 2019 and beyond.
- ***Extending DABRA to additional indications***. We plan to leverage our product technology and research and development expertise to develop DABRA for additional vascular indications, such as CAD and in-stent restenosis.
- ***Expanding commercial opportunities for DABRA internationally***. We received the right to affix the CE mark to DABRA in the third quarter of 2016, permitting DABRA to be marketed and sold in Europe and other CE mark markets. We plan to expand commercial opportunities for DABRA internationally through obtaining additional regulatory approvals and expanding our relationships with international distributors.
- ***Optimizing existing manufacturing capabilities to generate operating leverage***. We design, develop and manufacture DABRA in-house using components and sub-assemblies provided by third-party suppliers. We believe that by controlling the manufacturing and assembly of our products we are able to innovate more quickly, produce higher quality products, and increase our manufacturing scale in a cost-effective manner. We intend to use our design, engineering, and manufacturing capabilities to further improve the efficiency of our manufacturing process and increase our margins.
- ***Expanding our product offerings***. We believe that we will be able to leverage our technology and sales platform to expand our endovascular offerings with ancillary endovascular devices such as angioplasty balloons, guide catheters, and introducers. We intend to achieve this through our internal development efforts and with selective licenses, alliances or acquisitions of complementary products, technologies or businesses.

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.

We believe that DABRA is the only endovascular device that crosses chronic total occlusions and removes plaque without a guidewire. 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 instead of glass fiber optic construction allowing for the efficient and precise delivery of the laser energy.

The DABRA catheter is a single-use, 5 French gauge catheter that 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 all types 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 photochemical ablation, 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 nm excimer laser source that produces 308 nanometer ultraviolet-B photons that are directed to the catheter through a lens to photochemically ablate 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 110 pounds, 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 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. Procedures performed using DABRA have an approximate two and a half minute total lasing time. 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 patients 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 and contained data on 64 patients. The final study results demonstrated 94% effectiveness with 0% reported SAEs. 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%. In a study conducted by Spectranetics as part of its 510(k) application for its CLiRpath Excimer Laser Catheter device, which was the predicate device for our 510(k) application, Spectranetics reported a 79% crossing success with its catheter device and a 72% procedure success in a total of 47 cases. Cumulatively, Spectranetics reported that there were 16, or 34%, SAEs reported during the six month follow-up period with the most frequently observed event being reintervention, which occurred in six, or 13%, of cases.

The endpoints were at the time of procedure, at 30 and 180 days. Although our pivotal study was not head-to-head with the Spectranetics study, and we may not claim superiority of safety or efficacy, we believe that the patient population in our pivotal study that supported our 510(k) application was substantially similar to the patient population in the Spectranetics study. The following is a summary of our clinical study for DABRA:

	Patients (64)		Age					
			M		F			
	M	F	Mean	Median	Mean	Median	Patient Successes	# of Serious Adverse Events
Totals:	48	16	71	69	75	77	60	—

Lesion Locations	Number of Lesions
CFA	2
Iliac	1
Proximal SFA	12
Mid SFA	30
Popliteal	14
Peroneal	2
TP Trunk	2
Anterior Tibial	8
Posterior Tibial	1

Although not prespecified in our protocol, we followed 38 subjects from our pivotal study to 180 days after treatment. Using various methods of evaluation, all of the subjects were determined to be free of target lesion revascularization or the need to retreat the lesion.

Because of the lack of prespecification of the collection of the luminal patency data, including method of evaluation, the data would not be sufficient for an atherectomy indication for use. We intend to pursue an expanded indication for use for DABRA for atherectomy procedures to improve luminal patency. We plan to perform a new study designed to allow the FDA to evaluate the DABRA atherectomy procedure. The first subject is projected to be enrolled and treated in the second quarter of 2019, and we expect to have final results of the trial in the first quarter of 2020. We believe the incremental cost of obtaining the atherectomy indication will not be material.

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.

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 approximately 7.5 million people in the U.S., which accounts for over 2% of the domestic population. Globally, this skin condition is estimated to afflict over 125 million people. Direct and indirect healthcare costs related to psoriasis in the U.S. alone are roughly $11.25 billion annually. Lost time from work accounts for an additional $11.2 billion per year, as the majority of psoriasis patients miss an average of 26 days of work a year due to their disease. Currently, 17.8 million people 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 1% to 2% of the population globally. Alopecia areata affects about 2% of the population in the U.S., or about six million people. There are approximately 30,000 CTCL sufferers in North America.

Customers

No single customer represented more than 10% of our total revenue for 2018 or 2017.

Sales and Marketing

We market and sell DABRA and Pharos primarily through our direct sales force in the U.S. As of December 31, 2018, we had a 39-person direct sales force in the U.S. with 35 persons focused on vascular and four persons focused on dermatology. Our sales force is organized by geographic sales territories, and each territory is managed by a sales manager who acts as the primary customer contact. We plan to continue to increase the size of our sales organization to expand our installed unit base and to increase utilization of the DABRA and Pharos. Our initial focus for DABRA is high-volume OBLs. We partner with distributors for DABRA and Pharos in select geographies outside of the U.S.

Our marketing department currently consists of six professionals. 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 PAD 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 reimbursable using existing CPT codes. At this time the Company believes that the existing CPT codes are generally adequate to describe the procedures using the Company's products. The Company believes that there is no current need to apply for separate product specific CPT codes. 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 and reimbursement policy for services and products exists among third-party payors in the U.S. 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.

Procedures performed using DABRA and Pharos are generally reimbursed using the CPT codes summarized below. The 2019 Medicare non-facility (free-standing OBL catheterization laboratory), facility (hospital outpatient), and facility (physician) reimbursement amounts are included in the table below. The non-facility reimbursement amounts are the payment rates for services performed in the OBL setting. The reimbursement in the non-facility setting captures the physician's professional fees as well as the OBL technical practice expenses for equipment, supplies and other office expenses.

2019 Medicare National Payment Amounts

DABRA LASER (Endovascular)

CPT Code	Non-Facility (Free-Standing OBL Cath Lab) Reimbursement Amount	Facility (Hospital Outpatient) Reimbursement Amount	Facility (Physician) Reimbursement Amount	Procedure
37225	$ 12,443.94	$ 9,669	$ 634.65	Fem/popl revasc w/ather
37227	$ 16,033.80	$ 15,355	$ 762.95	Fem/popl revasc stnt & ather
37229	$ 12,450.79	$ 15,355	$ 740.96	Tib/per revasc w/ather
37231	$ 15,230.12	$ 15,355	$ 798.63	Tib/per revasc stent & ather
37233	$ 1,366.96	N/A	$ 343.45	Tib/per revasc w/ather add-on
37235	$ 4,291.18	N/A	$ 420.94	Tib/per revasc stnt & ather

PHAROS LASER (Dermatology)

CPT Code	Non-Facility (Free-Standing OBL Cath Lab) Reimbursement Amount	Facility (Hospital Outpatient) Reimbursement Amount	Facility (Physician) Reimbursement Amount	Procedure
96920	$ 167.22	$ 176.46	$ 74.81	Laser tx skin < 250 sq cm
96921	$ 183.44	$ 176.46	$ 84.26	Laser tx skin 250-500 sq cm
96922	$ 249.03	$ 314.08	$ 135.05	Laser tx skin > 500 sq cm

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's 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.

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 Pharos treatment of psoriasis is reimbursable by Medicare and nearly all major insurance companies under three CPT codes that 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.

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 $2.8 million and $4.5 million of research and development expenses in the years ended December 31, 2018 and 2017, 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 December 31, 2018, we own four 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. A U.S. divisional application has also been filed in this patent family and remains pending. In the patent family titled "Methods and Devices for Treatment of Stenosis of Arteriovenous Fistula Shunts," we own one issued U.S. patent and three divisional applications remain pending in the U.S. A U.S. patent application titled "Laser Ablation Catheters Having Expanded Distal Tip Windows for Efficient Tissue Ablation" is currently pending in addition to a U.S. patent application titled "Catheter Grip Device and Method." A pending U.S. patent application titled "Liquid Filled Ablation Catheter with Overjacket" has been converted to a pending Japanese national stage application with plans to further convert this application into the national stage in the U.S., China and Europe. Our issued U.S. patents expire between 2035 and 2036, 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 FDA before they are marketed.

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

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 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, 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.

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 FDA to classify a low- to moderate-risk device not previously classified into Class I or II.

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 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 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 via an 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 FDA to evaluate the overall benefit-risk relationship of the device and to provide adequate information for the labeling of the device. 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 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.

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 regulation (which requires 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 the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA). In addition, we are subject to medical device reporting regulations that require us to report to the FDA, EMA, 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. 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. 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 sanctions and penalties, including warning letters and recalls.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in or are inconsistent with the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet.

The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products, and if we promote our products beyond their approved indications, we may be subject to enforcement actions or prosecution arising from that off-label promotion. 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 device, 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 product recalls if a company fails to comply with regulatory requirements. The FDA has the authority to conduct mandatory recalls, but that authority is rarely used.

The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions, and civil penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing requests for 510(k) clearance or PMA approval of new products;
- withdrawing 510(k) clearance or PMA approvals already granted; and
- criminal prosecution.

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.

Radiation Emitting Products

For all radiation emitting devices, additional requirements apply under the Electronic Product Radiation Control Provisions of the FDCA. Electronic product radiation means (i) any ionizing, or non-ionizing electromagnetic or particulate radiation, or (ii) any sonic, infrasonic, or ultrasonic wave emitted from an electronic product as the result of the operation of an electronic circuit in the product. The additional regulations on these products are intended to protect the public from hazardous or unnecessary radiation exposure emitted by these products. These requirements include compliance with applicable radiation safety performance standards and additional reporting to the FDA. The performance standards for lasers include specific user labeling requirements, radiation limitations, and technological requirements for certain safety features.

Non U.S. Regulatory

We have additional clearances from China, from both the CFDA and State Food and Drug Administration, or sFDA, and Korea, from the MDFS. In addition, we also received CE mark for the Pharos dermatological and DABRA vascular system in the third quarter of 2016, enabling our product launch in Europe. The FDA clearances and the CE mark also allow us to sell these products in other large markets.

Other Healthcare Laws

Our business operations and current and future arrangements with healthcare professionals, consultants, customers and patients, expose us to broadly applicable state and federal 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:

- 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.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities may conclude that some of our business practices, including our promotional activities and interactions with our customers do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, additional integrity reporting and oversight obligations, contractual damages, reputational harm, diminished profits and future earnings, and 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 occur, it could adversely affect our ability to operate our business and our results of operations.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits U.S. 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.

International Laws

In Europe, and throughout the world, other countries have enacted anti-bribery laws and/or regulations similar to the FCPA. Violations of any of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

There are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

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, in the U.S., in March 2010, the Patient Protection and Affordable Care Act, or ACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers. Among the ACA's provisions of importance to our business are the following:

- implementation of a 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices, which, due to subsequent legislation will not go into effect until January 1, 2020;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA and we expect such challenges and amendments to continue. For example, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices, the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, and the annual fee imposed on certain health insurance providers based on market share.

In addition, other legislative changes have 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. 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, 2018, we had 118 full-time employees. Our ability to manage growth effectively will require us to continue to implement and improve our management systems, recruit and train new employees and select qualified independent contractors. 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 13 – Segment Information" in the notes to the financial statements included elsewhere in this Annual Report on Form 10-K.

Geographic Information

During 2018 and 2017, substantially all of our long-lived assets were located within the United States. Approximately 7% of our revenue for 2018 and 10% of our 2017 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 may be unable to achieve revenue growth.

Our ability to grow our revenue in future periods will depend on our ability to successfully 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 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 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 market and sell DABRA. The commercial success of DABRA will depend on a number of factors, including the following:

- 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 under our new sales leadership;
- 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 and sell DABRA, we will not be able to achieve or maintain profitability, which will have a material adverse effect on our business, financial condition, and results of operations.

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 at the entry of the artery, a problem known as kinking. In addition, the DABRA laser needs to be calibrated correctly for each use. 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. Market acceptance of DABRA could be delayed by lack of physician or staff 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 physicians, catheterization laboratory owners and operators, patients, and others in the medical community consider our products safe, effective, and cost-effective treatment methods;
- 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;
- 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 PAD and the existence and proper use of our products, DABRA may not gain market acceptance, as many physicians do not routinely screen for PAD while screening for 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 U.S. Department of Justice, or DOJ for improper relationships with physicians. 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 have a material adverse effect on our business, financial condition, and results of operations.

We may experience development or manufacturing problems or delays that could limit the potential growth of our revenue or increase our losses.

We have only recently begun manufacturing at scale, and may encounter unforeseen situations in the manufacturing and assembly of our products that would result in delays or shortfalls in our production. For example, in the fourth quarter of 2018, we experienced production limitations as we were scaling up our catheter production, which had an adverse impact on our revenue. In response, we made changes in our production flow and we are now in the final stages of validating our manufacturing process. In addition, our production processes and assembly methods may have to change to accommodate any significant future expansion of our manufacturing capacity, which may increase our manufacturing costs, delay production of our products, reduce our product margin, 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 all of our products are manufactured at our 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, or if we are otherwise unable to keep up with demand for our products by successfully manufacturing, assembling, testing, and shipping our products in a timely manner, 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 have incurred losses in recent periods and may be unable to achieve profitability in the future.

We incurred net losses of $30.8 million and $17.8 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $60.2 million. We expect to continue to incur significant sales and marketing, product development, regulatory and other expenses as we continue to expand our marketing efforts to increase adoption of our products and expand existing relationships with our customers, 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 to increase 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 any substantial 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.

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 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.

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.

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. Any such 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 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.

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. Insurance coverage is increasingly expensive. 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, 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., or Philips, including Volcano Corporation and Spectranetics Corporation, including products from the C.R. Bard acquisition, and Abbott Laboratories. These companies are manufacturers of products used in competing therapies within the peripheral and coronary atherectomy markets such as:

- atherectomy, using mechanical methods to remove vascular blockages;
- balloon angioplasty and stents;
- specialty balloon angioplasty, such as scoring balloons, pillowing balloons, cutting balloons and drug-coated balloons;
- bypass surgery; 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 Daavlin, National Biological, STRATA Skin Sciences and large pharmaceutical companies producing biologicals 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 as of December 31, 2018. We cannot assure you that we will be able to successfully obtain approval for any of these additional product indications through the application process.

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.

We may require additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. As a result, we may not be able to continue our marketing efforts to increase the adoption of our products.

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development and marketing efforts. We expect our sales and marketing expenses to increase substantially in connection with our plan to continue our commercialization efforts of the DABRA system in the U.S. and internationally. These expenditures will also include costs associated with manufacturing and supply, sales and marketing costs, and general operations. In addition, other unanticipated costs may arise.

As of December 31, 2018, we had cash and cash equivalents of $64.3 million. On October 1, 2018, we completed our initial public offering, selling 4,485,000 shares of our common stock at $17.00 per share. Proceeds from our initial public offering, net of underwriting discounts and commissions and offering expenses, were $67.3 million. We believe that our existing cash and cash equivalents, will fund our projected operating expenses and capital expenditure requirements for at least the next 12 months.

The amount and timing of any expenditures needed to implement our sales and marketing programs will depend on numerous factors, including:

- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and 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;
- 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; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems, as a public company.

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.

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 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. 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. 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. 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. 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. 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 health care 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 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 health care 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 these domestic health care fraud and abuse laws could result in government or internal investigations, significant diversion of resources, exclusion from government health care reimbursement 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 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 health care 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 may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA, other applicable anti-bribery, anti-corruption 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; 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. including the Netherlands, China, Thailand, United Arab Emirates, Italy, United Kingdom, Japan and Saudi Arabia. For fiscal year 2018, approximately 7% 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.

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 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.

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. 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, with the exception of the "key man" insurance policy for our Chief Executive Officer, Dean Irwin. 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, 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.

Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that we maintain internal control over financial reporting that meets applicable standards. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no assurance that all control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction and a decrease in our stock price.

We will be required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. Such report will not be required until our annual report filed on Form 10-K for the year ended December 31, 2019. We will need to disclose any material weaknesses identified by our management in our internal control over financial reporting. 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 prior periods we identified certain material weaknesses in our internal controls related to revenue recognition and lack of staffing in the accounting and finance organization. In connection with these prior material weaknesses we implemented remediation measures including training of accounting personnel as well as hiring additional personnel with experience in the ongoing identification, design and implementation of internal control over financial reporting. In connection with our 2017 audit, as part of the restatement to the 2016 financial statements, we identified a material weakness in the design of our internal controls related to the administration of capital stock transactions, including stock issuances and a reverse stock split which were not effected in accordance with the requirements of applicable law and the communication of stock option awards which were not validly authorized.

Efforts to remediate the control deficiencies that led to the material weakness discussed above have been completed as of December 31, 2018. 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. We may not be successful in implementing these remediation efforts or in developing other internal controls, which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. 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 new 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.

We could be subject to claims based on defects with respect to certain corporate transactions that were not authorized in accordance with applicable law.

We have determined that due to the material weakness in our internal controls related to the administration of capital stock transactions, there have been defects with respect to certain corporate transactions, including (i) stock issuances that were not or may not have been properly approved by our board of directors and/or adequately documented, (ii) a reverse stock split for which we failed to file the amendment to our articles of incorporation, and (iii) the communication of option awards that were not validly authorized by our board of directors as a result of non-existent or defective board approvals, in each case in accordance with applicable law.

To remediate these defects, we have taken a number of actions. Our board of directors has ratified the defective stock issuances; we obtained agreements from holders of the vast majority of our common stock which include a confirmation of the securities each stockholder holds, a release of potential claims with respect to issuance of securities to such stockholders, and a surrender specifically of any claims to the equity of the Delaware corporation except for the shares of the Delaware corporation that such stockholder has received in the reincorporation merger pursuant to the merger agreement; we confirmed with the vast majority of the applicable stockholders that the appropriate number of shares of common stock outstanding immediately prior to the time of the intended reverse stock split were contributed to the capital of the Company effective as of the intended time of, and to give effect to, the intended reverse stock split; and we have approved compensation to and obtained releases from our impacted employees and other service providers to resolve potential claims, if any, related to the communicated grants of option awards and to promote retention and align their interests with the long-term interests of our stockholders. While we have attempted to narrow potential future claims by taking certain remedial corporate actions, the scope of liability with respect to such defects is uncertain and we cannot assure that these actions will entirely remediate these defects or that we will not receive claims in the future from other persons asserting rights to shares of our capital stock or to stock options or other equity. To the extent any such claims are successful, they could have a material adverse effect on our business, financial condition and results of operations.

Under certain authority, common law ratification by our board of directors of prior stock issuances may have caused such issuances to be valid stock issuances by us at the time of the respective issuances. However, there is uncertainty under applicable law as to whether such common law ratification may be effective under all circumstances. There can be no assurance that stockholders will not assert claims that a defective corporate act or putative stock issuance ratified by us is void or voidable due to the identified failure of proper authorization by our board of directors, as well as other claims related thereto, and, if asserted, that any such claims will not be successful. If such ratification is deemed not to be effective, then the issuances of certain shares of our stock and other attempted corporate actions would be invalid and we could have liability to grantees of our common stock, which may have a material adverse effect on our business and results of operations.

We have also confirmed that the vast majority of the applicable stockholders as of the time of the intended reverse stock split contributed a number of shares of common stock sufficient to give effect to the recapitalization intended by the reverse stock split. However, a holder of our common stock could argue that this process does not represent an adequate remedy for a potential failure to properly implement the reverse stock split. If the contribution of shares to the capital of the Company was not effective, then we could have liability to certain holders of our common stock, which may have a material adverse effect on our business and results of operations.

Additionally, we may have potential liability to certain of our employees, directors, consultants, and other service providers for communicated grants of option awards that were not authorized in compliance with applicable law. With respect to the communicated grants of option awards that were not validly authorized, we approved compensation and obtained a release of potential claims from such persons. We approved compensation to our impacted employees, directors, consultants, and other service providers to mitigate potential claims related to the communicated grants of option awards, if any. However, an impacted individual could argue that such compensation is not an adequate remedy for prior invalid option awards and, if a court were to impose a greater remedy, our financial exposure could be greater and have a material adverse effect on our business and results of operations. The foregoing could also result in tax withholding, employment taxes or other tax liabilities, including penalties and interest, all of which could have a material adverse effect on our business, financial condition and results of operations.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

At December 31, 2018, we had 118 full-time employees. As our sales and marketing strategies develop, we 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;
- 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, 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.

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. 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 Department of Justice, 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, many physicians use our products for off-label purposes and are allowed to do so. 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 recalls 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 require 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. Any future recalls of our products could divert managerial and financial resources, harm our reputation and adversely affect our business.

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. 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. 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, 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.

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 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 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 the fourth quarter of 2018, we submitted one report to the FDA for an event that involved a patient who experienced clinically non-significant vessel perforation. 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 increased costs of health care 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. 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 United States, in March 2010, the Patient Protection and Affordable Care Act, or ACA, was passed. The ACA has made significant changes to the way healthcare is financed by both federal and state governments and private insurers, and has directly impacted the medical device industry. Among other provisions that may affect our business, including provisions that are meant to contain healthcare costs, improve quality and/or expand access, the ACA implemented, with limited exceptions, a deductible excise tax of 2.3% on sales of medical devices by entities, including us, which manufacture or import certain medical devices offered for sale in the U.S., including many of our products. The tax was to become effective January 1, 2013, but is currently suspended until January 1, 2020. Revenue from many of our products will be subject to that excise tax.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA and we expect such challenges and amendments to continue. For example, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices, the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, and the annual fee imposed on certain health insurance providers based on market share. Congress may consider additional legislation to repeal or repeal and replace all or certain elements of the ACA, including the medical device excise tax. We continue to evaluate the impact of the ACA and its possible repeal or replacement on our business.

In addition, other legislative changes have been proposed and adopted in the United States 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 United States 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. 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 willing to pay to us.

Reimbursement varies based on country, 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 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 recognize these 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 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 health care spending including a campaign promise to repeal the ACA. If enacted and implemented, any measures to restrict health care spending could result in decreased revenue from 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.

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

Modifications to our products may require new 510(k) clearances or PMAs or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplemental approval or clearance; however, the FDA will review and can disagree with 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 require a new 510(k) clearance or possibly a PMA. We may not be able to obtain additional 510(k) clearances or PMAs for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We may make 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 marketing our products as modified, which could harm our operating results and require us to redesign our products. In these circumstances, we may be subject to significant enforcement actions.

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 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, 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 any such actions are instituted against us 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 expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our cleared devices.

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, 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 making false statements relating to healthcare matters. Similar to the 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;
- 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.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will 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.

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. For example, in 2018, we received letters from a competitor concerning one of their former employees who is currently working for us. The letters allege, among other things, that the employee is in violation of the employee's continuing obligations to the employee's prior employer. While we dispute the validity of the claims and would vigorously defend against them and assert appropriate defenses, litigation may be necessary to defend against these claims. 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 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 Thyratron 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

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:

- 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 as determined by our board of directors, 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.

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 New York Stock Exchange ("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:

- our failure to increase the sales of our products, specifically DABRA;
- 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;

- 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 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 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 management's attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations.

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, 2018, we had net operating loss, or NOL, carryforwards of approximately $27.7 million for federal income tax purposes, and $23.6 million for state income tax purposes. These federal and state NOL carryforwards 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 not determined if we have experienced Section 382 ownership changes in the past and if a portion of our NOLs is 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, 2018, our executive officers, directors, and 5% stockholders beneficially owned approximately 39% of the outstanding shares of our common stock. In addition, as of December 31, 2018, our officers, directors, 5% stockholders, and their affiliates held (i) options to purchase an aggregate of 1,221,000 shares of our common stock at exercise prices of $28.94 per share; and (ii) 927,742 restricted stock units, which would give our officers, directors, and 5% stockholders ownership of approximately 44% 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, or other major corporate transaction. 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 increased 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, 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 after the lock-up and other legal restrictions on resale discussed in our prospectus relating to our initial public offering lapse, the trading price of our common stock could decline. As of December 31, 2018 we had outstanding 12,689,251shares of our common stock. Of these shares, the 4,485,000 shares sold in our initial public offering may be sold in the public market without restriction, unless purchased by our affiliates. Of the remaining shares, 316,431 restricted shares are eligible for sale in the public market beginning 90 days after the date of the prospectus relating to our initial public offering under Rule 144 and 7,887,820 shares will become eligible for sale upon expiration of the lock-ups in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, Rule 144 and Rule 701 under the Securities Act, and our insider trading policy. The lock-up agreements pertaining to our initial public offering will expire on March 26, 2019. The underwriters, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, subject to certain limitations, shares issued or issuable upon the exercise of options vested as of the expiration of the lock-up period will be eligible for sale at that time, as well as shares to be issued upon settlement of outstanding restricted stock units that vest in the future. Moreover, pursuant to our 2018 Equity Incentive Plan, or 2018 Plan, equity incentive awards representing up to an aggregate of 1,522,354 shares of our common stock were available for issuance to our employees, directors and consultants as of December 31, 2018. 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 296,752 shares were available for sale under our ESPP as of December 31, 2018. 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 believe this property will accommodate our anticipated production growth for the foreseeable future.

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.

ITEM 3. LEGAL PROCEEDINGS

Strata Litigation

On August 30, 2018, Strata Skin Sciences, Inc. and Uri Geiger, a member of the board of directors of Strata Skin Sciences, Inc. (collectively "Strata") filed an action against us in Pennsylvania State Court, Montgomery County (Civil Action No. 18-21421), requesting declaratory relief that: (1) Strata is 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 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 does not request any monetary damages. We believe that the action by Strata 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 we responded with preliminary objections to the action on September 19, 2018. A hearing on our objections was scheduled for February 21, 2019 but has been delayed due to the unavailability of Strata's lawyers on that date. We are awaiting a new date for the hearing to be scheduled. We believe that Strata's action lacks merit, and plan to vigorously oppose the action on procedural and substantive grounds within the prescribed time limits.

Other Matters

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business, financial condition, and results of 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

Our common stock has been listed on the New York Stock Exchange under the symbol "RMED" since September 27, 2018. Prior to that date, there was no public trading market for our common stock.

On March 13, 2019, the last reported sales price of our common stock was $6.55 and, according to our transfer agent, as of March 13, 2019, there were 179 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

Since January 1, 2018 we have issued and sold the following unregistered securities:

Common Stock Issuances

From January 2018 to May 2018, we sold 316,080 shares of our common stock, at a purchase price of $25.00 per share, to investors in connection with our 2017 financing for aggregate cash consideration of $7.9 million.

The offers, sales, and issuances of the securities described above were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. With respect to the offers, sales, and issuances of the securities described above, all purchasers were "accredited investors" as that term is defined under Item 501 of Regulation D. In each case, the issuances were made, without any general solicitation or advertising, to a limited number of sophisticated purchasers with knowledge and experience of financial and business matters related to an investment in the company's securities. The purchasers of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof. Each of the purchasers of securities had adequate access, through employment, business or other relationships, to information about the Registrant.

Option and Restricted Stock Unit Issuances—Non-Executive Employees

Pursuant to the terms of our 2018 Stock Compensation Plan, we granted to our non-executive employees, consultants and other service providers (i) options to purchase an aggregate of 680,900 shares of our common stock at exercise prices of $28.94 per share on June 4, 2018; and (ii) 481,906 restricted stock units effective June 8, 2018.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. We believe the offers, sales, and issuances of the above securities were exempt from registration under the Securities Act by virtue of Section 4(a)(2) of the Securities Act because the issuance of securities to the recipients did not involve a public offering or in reliance on Rule 701 because the transactions were pursuant to compensatory benefit plans or contracts relating to compensation as provided under such rule. The sales of these securities were made without any general solicitation or advertising.

Option and Restricted Stock Unit Issuances—Executive Officers and Directors

Pursuant to the terms of our 2018 Stock Compensation Plan, we granted to certain of our officers and directors (i) options to purchase an aggregate of 1,221,000 shares of our common stock at exercise prices of $28.94 per share on June 4, 2018; and (ii) 858,926 restricted stock units effective June 8, 2018.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. We believe the offers, sales, and issuances of the above securities were exempt from registration under the Securities Act by virtue of Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder because the issuance of securities to the recipients did not involve a public offering. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof. All recipients had adequate access, through their relationships with the Registrant, to information about the Registrant. The sales of these securities were made without any general solicitation or advertising.

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 Jaffray & Co. 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.

There has been no material change in the expected use of the net proceeds from our IPO, as described in our final prospectus filed with the SEC on September 27, 2018 pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

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. Following the temporary placement period for DABRA and once our customers decide to continue using DABRA in their facilities, we typically enter into DABRA laser commercial usage agreements or DABRA laser placement acknowledgements with each customer, which we refer to collectively as Usage Agreements. The terms of the Usage Agreements vary by customer, but each Usage Agreement provides for the specific terms of continued use of DABRA, including periodic maintenance fees and do not provide for a minimum purchase obligation. As of December 31, 2018, we had 53 lasers at customer sites under signed Usage Agreements with varying volumes of purchases. 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. These procedures are typically referred to in the medical community as atherectomy procedures, which the medical community commonly defines as any removal by surgery or specialized catheterization of an atheroma, or blockage, in an artery. Even though the medical community refers to it as atherectomy, DABRA is not currently cleared by the FDA for atherectomy. Nevertheless, third-party health payers can reimburse a procedure performed by a device which is not cleared or approved for a specific indication or procedure, if the physician determines the device and procedure are medically appropriate for a particular patient. Payers and the medical community can take a broader view than FDA in recognizing the scope of appropriate device use. In order to address this perceived uncertainty regarding reimbursement, we currently are pursuing expanded indications for use for DABRA to include 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, and an indication for use for the treatment of in-stent restenosis. To satisfy the FDA's data requirements to support an atherectomy indication, we plan to perform a new study designed to allow the FDA to evaluate the DABRA atherectomy procedure. The first subject is projected to be enrolled and treated in the second quarter of 2019, and we expect to have final results of the trial in the first quarter of 2020. We believe the incremental cost of obtaining the atherectomy indication will not be material.

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 a longer time frame (two years) than our pivotal trial, which had a 180 day follow up. We have case reports of patients with extended freedom from restenosis even out to over four years, which prompted us to study longer-term outcomes more closely. We intend to provide updates on a periodic basis throughout the study.

In addition, we intend to 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 venous and arterial occlusions, or blockages in the veins or arteries. 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 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, and South Korea Ministry of Drug Safety (now called the Ministry of Food and Drug Safety, or MDFS), in the applicable jurisdictions. Pharos was commercialized in 2004 and we have shipped over 1,000 systems to customers globally through December 31, 2018. Pharos is in use in nearly every U.S. state and in over 20 markets including several non-U.S. countries. 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 $30.8 million and $17.8 million for the years ended December 31, 2018 and December 31, 2017, respectively, and had an accumulated deficit of $60.2 million as of December 31, 2018. As of December 31, 2018, we had available cash and cash equivalents of approximately $64.3 million and had current liabilities of approximately $6.0 million and long-term liabilities of approximately $1.4 million. As of December 31, 2018, our liabilities included equipment financings of $0.9 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.

Recent Developments

We experienced issues that had an impact on our fourth quarter revenue and into the first quarter of 2019. In particular, the hiring and training of qualified sales personnel was dependent on the onboarding of our Chief Commercial Officer, who joined in December 2018, and we also found that we needed a more robust training program for our newly hired sales personnel. In addition, we experienced production limitations in our manufacturing process as we scaled up catheter production. These production limitations affected the number of evaluation cases performed during the fourth quarter of 2018 and into the first quarter of 2019. We made changes in our production flow and we are now in the final stages of validating our manufacturing process. In addition, our Chief Commercial Officer implemented a new training program during the first quarter of 2019.

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 internal sales force to target 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 margin

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

Cost of revenue for service and other includes the cost of maintaining and servicing the warranties on our products.

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

We calculate gross margin as gross profit divided by total net revenue. Our gross margin 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 margin to increase 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 and increase our gross margin. While we expect gross margin to increase 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, consulting, materials and clinical trial expenses. R&D expenses include:

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

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, allocated facilities-related expenses and shipping and handling costs. We expect to continue to grow our sales force and increase marketing efforts as we continue commercializing DABRA in both domestic and international markets. We also expect increased costs due to the additional legal, accounting, insurance and other expenses associated with becoming a public company.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

The following table shows our results of operations for the years ended December 31, 2018, and 2017 (in thousands):

	For the Years Ended		
	2018	**2017**	**Change $**
Statements of operations data:			
Net revenue			
Product sales	$ 3,159	$ 3,067	$ 92
Service and other	3,098	2,803	295
Total net revenue	6,257	5,870	387
Cost of revenue			
Product	2,652	2,854	(202)
Service and other	1,554	1,311	243
Total cost of revenue	4,206	4,165	41
Gross profit	2,051	1,705	346
Operating expenses:			
Selling, general and administrative	30,435	14,947	15,488
Research and development	2,776	4,518	(1,742)
Total operating expenses	33,211	19,465	13,746
Operating loss	(31,160)	(17,760)	(13,400)
Other income, net	338	(4)	342
Loss before income taxes	(30,822)	(17,764)	(13,058)
Income tax expense	10	1	9
Net loss	$ (30,832)	$ (17,765)	$ (13,067)

Comparison of years ended December 31, 2018, and 2017—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 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 13 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 for the years ended December 31, 2018, and 2017 (in thousands):

	For the Years Ended		
	2018	2017	Change $
Vascular	$ 1,552	$ 259	$ 1,293
Dermatology	4,705	5,611	(906)
Total net revenue	$ 6,257	$ 5,870	$ 387

Vascular

Net revenue was $1.6 million and $0.3 million for the years ended December 31, 2018 and 2017, respectively. The increase of approximately $1.3 million was primarily due to increased catheter sales following the completion of our initial 12-month commercial launch in June 2018. There were nominal sales during our initial commercial launch following FDA clearance of our DABRA system in May 2017 in the prior year. We expect our vascular revenue to increase over time as our growing sales force and marketing efforts establish a larger base of customers who regularly use the DABRA system.

Dermatology

Net revenue was $4.7 million and $5.6 million for the years ended December 31, 2018 and 2017, respectively. The decrease of approximately $0.9 million was due primarily to a decrease in direct unit product sales as a result of diverting some of our sales resources in 2018 to commercializing the DABRA system, aggregated in our vascular segment, partially offset by an increase of $0.3 million in revenue from service contracts on our dermatology lasers.

Cost of revenue

The following table shows our cost of revenue from our two segments for the years ended December 31, 2018 and 2017, (in thousands):

	For the Years Ended		
	2018	2017	Change $
Vascular	$ 1,521	$ 193	$ 1,328
Dermatology	2,685	3,972	(1,287)
Total cost of revenue	$ 4,206	$ 4,165	$ 41

Vascular

Cost of revenue was $1.5 million and $0.2 million for the years ended December 31, 2018 and 2017. The $1.3 million increase was primarily due to increased labor, material and overhead costs to support the increased sales efforts of our vascular products, which increased following the completion of our initial 12-month commercial launch in June 2018.

Dermatology

Cost of revenue was $2.7 million and $4.0 million for the years ended December 31, 2018 and 2017, respectively. The decrease of $1.3 million was primarily due to fewer units manufactured as a result of lower sales and lower costs of the units that were manufactured due to efficiencies derived from the increase in total lasers manufactured, which included lasers manufactured to support the vascular segment.

Gross profit

The following table shows our gross profit from our two segments for the years ended December 31, 2018, and 2017 (in thousands):

	For the Years Ended		
	2018	2017	Change $
Vascular	$ 31	$ 66	$ (35)
Dermatology	2,020	1,639	381
Total gross profit	$ 2,051	$ 1,705	$ 346

Vascular

Gross profit was $31,000 for the year ended December 31, 2018 and $66,000 for the year ended December 31, 2017, respectively. Compared to the year ended December 31, 2017, the year ended December 31, 2018 included increased costs to scale up our manufacturing capacity following the completion of our initial 12-month commercial launch period in June 2018 compared to nominal catheter sales during our initial commercial launch in the same period in the prior year. We expect our gross profit to improve over time as our growing sales force and marketing efforts establish a larger customer base and our manufacturing volume increases.

Dermatology

Gross profit was $2.0 million and $1.6 million for the years ended December 31, 2018 and 2017, respectively. The increase of $0.4 million was primarily due to efficiencies derived from the increase in total lasers manufactured, which included lasers manufactured to support the vascular segment.

Comparison of years ended December 31, 2018, and 2017—General

Selling, general and administrative expenses. SG&A expenses were $30.4 million and $14.9 million for the years ended December 31, 2018 and 2017, respectively. The $15.5 million increase was related to increases of (i) $6.2 million in salary, benefits, recruiting expenses and other personnel-related costs due to expanding our sales force and hiring administrative staff to operate as a public company, (ii) $3.2 million in stock-based compensation expense primarily due to the modification accounting treatment of replacement awards and new grants, (iii) $2.1 million in legal and consulting fees to operate as a public company, (iv) $1.5 million in travel and trade shows, (v) $0.7 million in marketing and advertising costs, (vi) $0.6 million in sales training related costs (vii) $0.6 million in insurance due to being publicly traded, (viii) $0.3 million in shipping costs due to increased volume from the vascular product offering and (ix) $0.3 million in various other administrative costs. Notes 2 and 10 to the financial statements appearing elsewhere in this Annual Report on Form 10-K more fully describe the accounting treatment for stock-based compensation awards.

Research and development expenses. R&D expenses were $2.8 million and $4.5 million for the years ended December 31, 2018 and 2017, respectively. The $1.7 million decrease was primarily due to a decrease of $1.3 million in stock-based compensation expense, primarily due to the impact of larger stock price increases in the prior year on share-based awards that were revalued at each reporting period, $0.4 million less in resources devoted to catheter research and development in 2018 as a result of the completion of our initial commercial product development in 2017. Notes 2 and 10 to the financial statements appearing elsewhere in this Annual Report on Form 10-K more fully describe the accounting treatment for stock-based compensation awards.

Other income (expense), net. Other income, net was $0.3 million for the year ended December 31, 2018 and other expense was $4,000 for the year ended December 31, 2017. In 2018, other income was primarily comprised of interest income on the net proceeds from the IPO that were received in October 2018. In 2017, other expense related to interest expense on equipment financing.

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.

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 of fixed assets, although these are non-cash charges, the assets being depreciated 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, 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,	
	2018	2017
	(in thousands)	
Statement of Operations Data:		
Net loss	$ (30,832)	$ (17,765)
Depreciation	624	218
Interest income	(352)	—
Interest expense	14	4
Income tax expense	10	1
EBITDA	(30,536)	(17,542)
Stock-based compensation	14,728	12,706
Adjusted EBITDA	$ (15,808)	$ (4,836)

Adjusted EBITDA was negative $15.8 million compared to negative $4.8 million for the years ended December 31, 2018 and 2017, 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, and the costs of preparing for and operating as a public company.

Liquidity and Capital Resources

As of December 31, 2018, we had cash and cash equivalents of $64.3 million and an accumulated deficit of $60.2 million. Our primary sources of capital have been from the sale of our products and services, the net proceeds from our initial public offering, and, to a lesser extent, private placements of common stock and debt financing arrangements. In the year ended December 31, 2018, we raised an aggregate of $7.9 million in proceeds from private placements of our common stock.

On October 1, 2018, we completed our initial public offering, including the underwriters full exercise of their over-allotment option, selling 4,485,000 shares of our common stock at $17.00 per share. Net proceeds from our

initial public offering were $67.3 million, after deducting underwriting discounts and commissions and offering expenses.

We believe that our cash and cash equivalents as of December 31, 2018 will be sufficient to fund our operations for at least the next 12 months. As we continue to commercialize DABRA, we expect our costs to increase in the future as we continue the development of a direct sales force, the expansion of our manufacturing facilities, and as we continue to make substantial expenditures on research and development, including the costs of any current and future clinical studies. Additionally, we are incurring additional costs as a result of operating as a public company. 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 may be approved in the U.S. and select non-U.S. markets;
- the costs of expanding our U.S. and international sales and marketing infrastructure and our manufacturing operations;
- 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 cost, timing and outcomes of any litigation involving our company, products, and business activities;
- 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.

Cash Flows

	For the Years Ended		
	Actual		Change
	2018	2017	$
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (18,508)	$ (5,523)	$ (12,985)
Investing activities	(582)	(547)	(35)
Financing activities	75,168	10,386	64,782
Net increase in cash and cash equivalents	$ 56,078	$ 4,316	$ 51,762

Net cash used in operating activities

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.

During the year ended December 31, 2017, net cash used in operating activities was $5.5 million, consisting primarily of a net loss of $17.8 million and an increase in net operating assets of $0.8 million, primarily related to decreases in accounts receivable, inventory and deferred revenue. These items were partially offset by non-

cash charges of $13.1 million, consisting of depreciation, stock-based compensation expense, common stock issued in exchange for services and a loss on disposal of property and equipment.

Net cash used in investing activities

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.

During the year ended December 31, 2017, net cash used in investing activities was $0.5 million consisting primarily of purchases of manufacturing equipment.

Net cash provided by financing activities

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.

During the year ended December 31, 2017, net cash provided by financing activities was $10.4 million from the issuance of common stock related to a private placement financing.

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, 2018, our contractual obligations due by period:

	Payments due by period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations(1)	$ 4,337	$ 500	$ 1,042	$ 877	$ 1,918
Equipment Financing(2)	850	293	557	—	—
Total	$ 5,187	$ 793	$ 1,599	$ 877	$ 1,918

(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 a material weakness in our internal control over financial reporting. For additional information, see the risk factor in Item 1A entitled "*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."

Revenue recognition

Product Sales

We recognize revenue from product sales when the following four criteria have been met: (i) the product has been shipped or services have been performed and we have no significant remaining obligations; (ii) persuasive evidence of an arrangement exists; (iii) the price to the buyer is fixed or determinable; and (iv) collection is reasonably assured. Revenues from product sales are recorded net of cash discounts. None of our sales contain right-of-return provisions and we have historically only experienced nominal returns.

We also offer certain cash discounts associated with the sales of our products. These discounts are negotiated on a transaction by transaction basis and therefore do not include any estimate at the time of sale. The discounts are recorded as a reduction to accounts receivable and product sales.

For shipment of our products, we take into account the time at which to recognize revenue, generally this is when title and risk of loss is transferred.

Multiple Element Arrangements

We regularly enter into contracts where revenue is derived from multiple deliverables, including products or services. These contracts typically include a device and extended service contracts. Revenue recognition for contracts with multiple deliverables is based on the individual units of accounting determined to exist in the contract. A delivered item is considered a separate unit of accounting when the delivered item has value to the customer on a stand-alone basis. Items are considered to have stand-alone value when they are sold separately by any vendor or when the customer could resell the item on a stand-alone basis.

Arrangement consideration is then allocated to those separate units of account based on their relative selling price. When applying the relative selling price method, the selling price for each deliverable is determined using the following hierarchy: (i) vendor-specific objective evidence, or VSOE, of the selling price; (ii) third-party evidence of selling price; or (iii) best estimated selling price. We record revenue related to these multiple deliverables as products are delivered and services are performed. In order to establish VSOE of selling price, we must regularly sell the product or service on a standalone basis with a substantial majority priced within a relatively narrow range. In cases where there are not a sufficient number of standalone sales and VSOE of selling price cannot be determined, then we utilize third-party evidence of selling price, if available, or best estimated selling price, or BESP.

We determine BESP for an individual element based on our average selling price of that discrete element during the annual period, excluding transactions that are not representative of standalone sales. We regularly review and maintain our BESP and update these estimates at least annually.

Billable Service Arrangements

Revenue from billable services, including repair activity, is recognized when the service is provided.

Extended Warranty Arrangements

Revenues received with respect to extended warranties on products are recognized over the duration of the extended warranty period on a straight-line basis.

Lease Arrangements

We also derive revenue pursuant to product lease agreements. These leases are classified as operating leases in accordance with the relevant accounting guidelines, and the related revenue is recognized on a straight-line basis.

Distributor Transactions

In certain markets, we sell products and provide services to customers through distributors that specialize in medical device products. In cases where the product is delivered to a distributor, revenue recognition generally occurs when title transfers to the distributor. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers. These transactions are accounted for in accordance with our revenue recognition policy described herein.

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 is 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, 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:

	Employees	Nonemployees
Service condition only	Straight-line	Re-value through the performance commitment date
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	Re-value the award once the performance criterion is considered probable of occurrence and recognize expense for the then fair value of the award
Service criterion is not complete	Straight-line	Straight-line, except the award is re-valued through the performance commitment date
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 of December 31, 2017, all stock-based compensation awards were classified as liabilities in the financial statements which were revalued at each reporting period with the change in fair value recorded to compensation expense. 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*—Our shares were not traded in any public market. 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, our share valuation was estimated using both the income and market approaches, which were weighted 50% each. A discount of 35% was then applied for lack of marketability for our common stock. As of the reporting date for each period presented, the dates at which the stock-based compensation liability was remeasured at fair value, the common stock price was based on the recent equity issuances with new third party investors who were not previous shareholders of Ra Medical.

- *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.

As described in Note 10 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, our board of directors determined the fair value of each share of underlying common stock 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.

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.

Jobs Act Accounting Election

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that 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 and cash equivalents of $64.3 million as of December 31, 2018, 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, 2018, 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 Executive Officer and Chief Financial 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, 2018. 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 connection with our 2017 audit, we identified a material weakness in our internal control over financial reporting in the design of our internal controls related to the administration of capital stock transactions, including stock issuances and a reverse stock split which were not effected in accordance with the requirements of applicable law and the communication of stock option awards which were not validly authorized.

As discussed below, we took actions to remediate this material weakness in internal control over financial reporting.

Based upon our evaluation and the remediation efforts described below, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

We previously disclosed a material weakness in our internal control over financial reporting related to the administration of capital stock transactions, including stock issuances and a reverse stock split which were not effected in accordance with the requirements of applicable law and the communication of stock option awards which were not validly authorized.

We took actions to remediate the material weakness relating to our internal controls over financial reporting, as described below. The controls and processes we implemented to remediate the identified material weakness included:

- hiring qualified personnel with expertise to perform specific functions, including our Chief Financial Officer, General Counsel and Corporate Controller;
- the engagement of third-party legal counsel to assist in the administration of capital stock transactions; and
- designing and implementing improved processes and internal controls, including ongoing senior management review and audit committee oversight.

As a result of the remediation activities and controls in place as of December 31, 2018 described above, we have remediated the previously disclosed material weakness. 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

This Annual Report on Form 10-K does not include management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies. Further, our independent public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting as long as we are an "emerging growth company" pursuant to the provisions of 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

Director Resignation

On March 11, 2019, Melissa Burstein resigned from the Company's board of directors, effective immediately. The resignation was due to time constraints and did not result from any disagreement with the Company on any matter related to the Company's operations, policies or practices. Ms. Burstein remains employed by the Company as Executive Vice President. In light of this change and reduced levels of responsibility, the Company has determined that Ms. Burstein is no longer an executive officer or Section 16 officer. Following the resignation of Ms. Burstein from the Board, the Board reduced the size of the Board to six members in accordance with the provisions of the Company's Certificate of Incorporation and bylaws.

Executive Compensation

On March 11, 2019, following the recommendation made by the compensation committee of our board of directors, the independent members of our board of directors approved an approximately 3% increase in the annual base salaries for our principal executive officer, principal finance officer, and certain named executive officers. Effective as of March 1, 2019, the annual base salary for Dean Irwin increased to $430,540, Andrew Jackson increased to $358,440, and Jeffrey Kraws increased to $347,110.

Annual Meeting of Stockholders

Our annual meeting of stockholders will be held at 9:00 a.m. Pacific Time on June 6, 2019, at 1926 Kellogg Avenue, Suite 100, Carlsbad, California 92008. Holders of record at the close of business on April 10, 2019 will be entitled to vote at the meeting.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Proxy Statement relating to our 2019 Meeting of Stockholders. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year ended December 31, 2018.

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.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement relating to our 2019 Meeting of Stockholders. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year ended December 31, 2018.

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

The information required by this item is incorporated by reference to our Proxy Statement relating to our 2019 Meeting of Stockholders. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year ended December 31, 2018.

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

The information required by this item is incorporated by reference to our Proxy Statement relating to our 2019 Meeting of Stockholders. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year ended December 31, 2018.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement relating to our 2019 Meeting of Stockholders. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year ended December 31, 2018.

PART IV — FINANCIAL INFORMATION

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report.

(1) Financial Statements.

(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
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 Dean Irwin, dated as of July 13, 2018.	S-1	333-226191	10.8	7/16/2018
10.9+	Change in Control and Severance Agreement, by and between the Registrant and Melissa Burstein, dated as of July 13, 2018.	S-1	333-226191	10.9	7/16/2018

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.10+	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
10.11+	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
10.12+	Confirmatory Employment Letter, by and between the Registrant and Dean Irwin, dated as of July 13, 2018.	S-1	333-226191	10.12	7/16/2018
10.13+	Confirmatory Employment Letter, by and between the Registrant and Melissa Burstein, dated as of July 13, 2018.	S-1	333-226191	10.13	7/16/2018
10.14+	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
10.15+	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
10.16+	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
10.17+	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
10.18+*	Employment Letter by and between the Registrant and Thomas Fogarty, dated as of December 12, 2018				
23.1*	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (contained on signature page).				

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
31.1*	Certification of Chief Executive 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.				
31.2*	Certification of Chief 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.				
32.1*^	Certifications 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.				
32.2*^	Certifications of Chief 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.				
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 14, 2019

By: /s/ Dean Irwin
Dean Irwin
Chief Executive Officer, Chairman of the Board, Co-President, and Chief Technology Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dean Irwin and Andrew Jackson, 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:

Signature	Title	Date
/s/ Dean Irwin Dean Irwin	Chief Executive Officer, Chairman of the Board, Co-President, and Chief Technology Officer (Principal Executive Officer)	March 14, 2019
/s/ Andrew Jackson Andrew Jackson	Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2019
/s/ Maurice Buchbinder, M.D. Maurice Buchbinder, M.D.	Director	March 14, 2019
/s/ Martin Colombatto Martin Colombatto	Director	March 14, 2019
/s/ Richard Mejia, Jr. Richard Mejia, Jr.	Director	March 14, 2019
/s/ Mark E. Saad Mark E. Saad	Director	March 14, 2019
/s/ William R. Enquist, Jr. William R. Enquist, Jr.	Director	March 14, 2019

INDEX TO FINANCIAL STATEMENTS

RA MEDICAL SYSTEMS, INC.

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, 2018 and 2017, the related statements of operations, stockholder's equity (deficit) and cash flows for each of the two years in the period ended December 31, 2018 and the related notes to the financial statements (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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

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 14, 2019

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, 2018	December 31, 2017
ASSETS		
Current Assets		
Cash and cash equivalents	$ 64,315	$ 8,237
Accounts receivable, net	1,320	517
Inventories	2,097	1,196
Prepaid expenses and other current assets	1,501	92
Total current assets	69,233	10,042
Property and equipment, net	4,757	1,159
Other non-current assets	45	68
TOTAL ASSETS	$ 74,035	$ 11,269
LIABILITIES AND STOCKHOLDERS' EQUITY(DEFICIT)		
Current Liabilities		
Accounts payable	$ 1,125	$ 426
Accrued expenses	2,809	324
Current portion of deferred revenue	1,723	1,714
Current portion of equipment financing	293	44
Other current liabilities	—	125
Total current liabilities	5,950	2,633
Deferred revenue	767	775
Equipment financing	557	19
Stock-based compensation liability	—	15,376
Other liabilities	56	81
Total liabilities	7,330	18,884
Commitments and contingencies (Note 12)		
Stockholders' Equity (Deficit)		
Preferred stock, $0.0001 par value, 10,000,000 and 0 shares authorized at December 31, 2018 and 2017, respectively; none issued	—	—
Common stock, $0.0001 par value, 300,000,000 shares and 25,000,000 authorized at December 31, 2018 and 2017, respectively; 12,689,251 and 7,888,170 issued and outstanding at December 31, 2018 and 2017, respectively	1	1
Additional paid-in capital	126,925	21,773
Accumulated deficit	(60,221)	(29,389)
Total stockholders' equity (deficit)	66,705	(7,615)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 74,035	$ 11,269

See notes to financial statements.

Ra Medical Systems, Inc.

Statements of Operations
(in thousands, except per share data)

	Year Ended December 31,	
	2018	**2017**
Net revenue		
Product sales	$ 3,159	$ 3,067
Service and other	3,098	2,803
Total net revenue	6,257	5,870
Cost of revenue		
Product sales	2,652	2,854
Service and other	1,554	1,311
Total cost of revenue	4,206	4,165
Gross profit	2,051	1,705
Operating expenses		
Selling, general and administrative	30,435	14,947
Research and development	2,776	4,518
Total operating expenses	33,211	19,465
Operating loss	(31,160)	(17,760)
Other income (expense)		
Interest income	352	—
Interest expense	(14)	(4)
Total other income (expense)	338	(4)
Loss before income tax expense	(30,822)	(17,764)
Income tax expense	10	1
Net loss	(30,832)	(17,765)
Basic and diluted net loss per share	$ (3.34)	$ (2.35)
Basic and diluted weighted average common shares outstanding	9,230	7,545

See notes to financial statements.

Ra Medical Systems, Inc.

Statements of Stockholders' Equity (Deficit)
(in thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid- in- Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balances at December 31, 2016	7,463	$ 1	$ 11,243	$ (11,624)	$ (380)
Common stock issued	421	—	10,430	—	10,430
Common stock issued for services	4	—	100	—	100
Net loss	—	—	—	(17,765)	(17,765)
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	12,689	$ 1	$ 126,925	$ (60,221)	$ 66,705

See notes to financial statements.

Ra Medical Systems, Inc.

Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (30,832)	$ (17,765)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	624	218
Provision for doubtful accounts	255	—
Stock-based compensation	14,728	12,706
Common stock issued in exchange for services	—	100
Loss on disposal of property and equipment	—	53
Changes in operating assets and liabilities:		
Accounts receivable	(1,058)	(124)
Inventories	(3,874)	(644)
Prepaid expenses and other assets	(1,386)	(8)
Accounts payable	699	(47)
Accrued expenses	2,485	(95)
Deferred revenue	1	(91)
Other liabilities	(150)	174
Net cash used in operating activities	(18,508)	(5,523)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(582)	(547)
Net cash used in investing activities	(582)	(547)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of underwriters' discount of $5,338	78,806	10,430
Initial public offering costs	(3,556)	—
Payments on equipment financing	(82)	(44)
Net cash provided by financing activities	75,168	10,386
NET CHANGE IN CASH AND CASH EQUIVALENTS	56,078	4,316
CASH AND CASH EQUIVALENTS, beginning of year	8,237	3,921
CASH AND CASH EQUIVALENTS, end of year	$ 64,315	$ 8,237
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 demonstration lasers and lasers placed with customers	$ 2,848	$ 377
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for interest	$ 11	$ 4
Cash payments for taxes	$ 5	$ 1

See 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 dermatological and vascular 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 psoriasis, vitiligo, atopic dermatitis, leukoderma and peripheral artery disease ("PAD").

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.

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, inventory reserves, reserves for warranty costs, fair value of stock option awards granted and revenue recognition for multiple element arrangements.

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 and other credits.

The Company sells or leases its lasers to distributors or physicians directly with various forms of financing options. The Company does business and 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,	
	2018	2017
Balance at beginning of period	$ 12	$ 12
Provision for doubtful accounts	255	—
Deductions	(53)	—
Balance at end of period	$ 214	$ 12

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.

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 years
Furniture and fixtures	5 years
Machinery and equipment	10 years
Demonstration lasers and lasers placed with customers	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. There were no impairment charges for the years ended December 31, 2018 or 2017.

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.

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's only assets or liabilities measured at fair value are its money market account, stock-based compensation liability and its abandoned operating lease. Note 10 and Note 12 discuss the valuation techniques for the stock-based compensation liability and abandoned operating lease, respectively.

Product warranty—The Company records estimated product warranty costs at the time of sale. Products are warrantied against defects in material and workmanship when properly used for their intended purpose and appropriately maintained. Product warranties are included for the first year after the sale. 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, and in certain instances, estimated property damage. 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 deferred 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 sales in the accompanying statements of operations. Changes in estimates to previously established warranty accruals result from current period updates to assumptions regarding repair costs and are included in current period warranty expense.

Revenue recognition

Product Sales

The Company recognizes revenues from the product sales when the following four criteria have been met: (i) the product has been shipped or services have been performed and the Company has no significant remaining obligations; (ii) persuasive evidence of an arrangement exists; (iii) the price to the buyer is fixed or determinable; and (iv) collection is reasonably assured. Revenues from product sales are recorded net of cash discounts. None of the Company's sales contain right-of-return provisions.

The Company also offers certain cash discounts associated with the sales of its products. These discounts are negotiated on a transaction by transaction basis and therefore do not include any estimate at the time of sale. The discounts are recorded as a reduction to accounts receivable and product sales.

For shipment of its products, the Company takes into account the time at which to recognize revenue, generally this is when title and risk of loss is transferred.

Multiple Element Arrangements

The Company regularly enters into contracts where revenue is derived from multiple deliverables, including products or services. These contracts typically include a device and extended service contracts. Revenue recognition for contracts with multiple deliverables is based on the individual units of accounting determined to exist in the contract. A delivered item is considered a separate unit of accounting when the delivered item has value to the customer on a stand-alone basis. Items are considered to have stand-alone value when they are sold separately by any vendor or when the customer could resell the item on a stand-alone basis.

Arrangement consideration is then allocated to those separate units of account based on their relative selling price. When applying the relative selling price method, the selling price for each deliverable is determined using the following hierarchy: (i) vendor-specific objective evidence ("VSOE") of the selling price; (ii) third-party evidence of selling price; or (iii) best estimated selling price. The Company records revenue related to these multiple deliverables as products are delivered and services are performed. In order to establish VSOE of selling price, the Company must regularly sell the product or service on a standalone basis with a substantial majority priced within a relatively narrow range. In cases where there is not a sufficient number of standalone sales and VSOE of selling price cannot be determined, then the Company utilizes third-party evidence of selling price, if available, or best estimated selling price ("BESP").

The Company determines BESP for an individual element based on the average selling price of such discrete element during the annual period, excluding transactions that are not representative of standalone sales. The Company regularly reviews and maintains its BESP and updates these estimates at least annually.

Billable Service Arrangements

Revenue from billable services, including repair activity, is recognized when the service is provided.

Extended Warranty Arrangements

Revenues received with respect to extended warranties on products are recognized over the duration of the extended warranty period on a straight-line basis.

Lease Arrangements

The Company also derives revenue pursuant to product lease agreements. These leases are classified as operating leases in accordance with the relevant accounting guidelines, and the related revenue is recognized on a straight-line basis.

Distributor Transactions

In certain markets, the Company sells products and provides services to customers through distributors that specialize in medical device products. In cases where the product is delivered to a distributor, revenue recognition generally occurs when title transfers to the distributor. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers. These transactions are accounted for in accordance with the Company's revenue recognition policy described herein.

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 $0.6 million and $0.3 million for the years ended December 31, 2018 and 2017, respectively.

Advertising expense—The Company charges advertising costs to expense as incurred. Advertising expense for the years ended December 31, 2018 and 2017, amounted to $40,000 and $23,000, 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 is 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, 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 stock-based compensation expense as follows:

	Employees	Nonemployees
Service condition only	Straight-line	Re-value through the performance commitment date
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	Re-value the award once the performance criterion is considered probable of occurrence and recognize expense for the then fair value of the award
Service criterion is not complete	Straight-line	Straight-line, except the award is re-valued through the performance commitment date
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.

Comprehensive loss—Comprehensive loss is equal to net loss for all periods presented.

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 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, 2018. As of December 31, 2017, accounts receivable due from four of the Company's customers was 57% of accounts receivable.

No individual customer represented greater than 10% of total net revenue for the years ended December 31, 2018 or 2017.

Recent accounting pronouncements—On April 5, 2012, President Obama signed the Jump-Start Our Business Startups Act (the "JOBS Act") into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. 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. ASU 2014-09 defines a five-step process to achieve this core principle, and in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than are required under existing US GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation, among others. The new standard also requires an entity to recognize as an asset the incremental costs of obtaining a contract with a customer if the entity expects to recover those costs. ASU 2014-09 is effective for the Company beginning January 1, 2019, with (i) retrospective application of ASU 2014-09 to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09 (the full retrospective method) or (ii) retrospective application of ASU 2014-09 with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09 (the modified retrospective method). The Company will adopt this accounting standard in the first quarter of fiscal year 2019 using the modified retrospective method. Based on the analysis performed, the Company expects to record 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. The Company will capitalize these contract acquisition costs and

amortize them over the contract service period and (iii) recognition of 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 will recognize the significant financing component over the contract service period. Based on its analysis to date, the Company expects the adoption of the new standard to result in a net impact of less than $0.1 million to accumulated deficit.

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 will adopt the standard using the optional transition method provided by ASC Update No. 2018-11*, Leases (Topic 842): Targeted Improvements*. Under this method, the Company will initially apply the new leasing rules on January 1, 2019, and recognize the cumulative effect of initially applying the standard as an adjustment to our opening balance of accumulated deficit, rather than at the earliest comparative period presented in the financial statements. As part of the adoption, the Company is electing the package of practical expedients permitted under the new lease standard, which among other things, allows the Company to carry forward the historical lease classification. The Company also is electing the practical expedient to combine lease and non-lease components. Based on information currently available, the Company estimates that the adoption will result in the recognition of right-of-use assets and lease liabilities of approximately $3.0 million to $3.5 million for operating leases in which the Company is the lessee. The new lease standard will not change the Company's accounting for leases in which the Company is the lessor.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. The amendments in this update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. Under the ASU, an entity will account for the effects of a modification unless (i) the fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified, (ii) the vesting conditions of the modified award are the same vesting conditions as the original award immediately before the original award is modified and (iii) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The Company adopted ASU 2017-09 on January 1, 2018 and the adoption did not have a material impact on the Company's financial statements or related financial statement disclosure.

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 is evaluating the effect that this guidance will have on the financial statements and related disclosures.

Note 3—Inventories

Inventories consisted of the following (in thousands):

	December 31,	
	2018	2017
Raw materials	$ 1,333	$ 705
Work in process	88	110
Finished goods	676	381
Inventories	$ 2,097	$ 1,196

Note 4—Property and Equipment, net

Property and equipment consisted of the following (in thousands):

	December 31,	
	2018	2017
Demonstration lasers and lasers placed with customers	$ 3,254	$ 483
Machinery and equipment	1,135	745
Automobiles	1,115	154
Computer hardware and software	366	301
Leasehold improvements	104	13
Furniture and fixtures	82	60
Construction in progress	14	178
Property and equipment, gross	6,070	1,934
Accumulated depreciation	(1,313)	(775)
Property and equipment, net	$ 4,757	$ 1,159

Depreciation expense was $0.6 million and $0.2 million for the years ended December 31, 2018 and 2017, respectively.

Note 5—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2018	2017
Compensation and related benefits	$ 1,734	$ 236
Accrued warranty (Note 6)	112	87
Accrued services	963	1
Accrued expenses	$ 2,809	$ 324

Note 6—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,	
	2018	2017
Balanced at beginning of period	$ 87	$ 97
Increase in warranty accrual	287	198
Claims satisfied	(262)	(208)
Accrued warranty	$ 112	$ 87

Warranty expense was $0.3 million and $0.2 million for the years ended December 31, 2018 and 2017, respectively, and is included in cost of revenue in the accompanying statements of operations.

Note 7—Line of Credit and Equipment Financing

The Company had a line of credit with a bank allowing for borrowing up to $0.3 million, collateralized by personal property of the Company and guaranteed by a shareholder of the Company, with interest at 4.5% per year. The line of credit expired on September 1, 2017.

During 2016, the Company entered into two loan agreements to finance equipment placed in physician's offices under monthly rental contracts. The loans bear interest at 8%. One loan expired in February 2019 and the other loan expires in August 2019. Interest expense for the years ended December 31, 2018 and 2017 associated with these transactions was $2,000 and $4,000, respectively. The outstanding balance at December 31, 2018 was $19,000 and included in 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 year ended December 31, 2018 was $8,000. The outstanding balance at December 31, 2018 was $0.8 million and included in equipment financing.

Future maturities are as follows (in thousands):

Years ending December 31,		
2019	$	293
2020		292
2021		265
Total	$	850

Note 8—Stockholders' Equity (Deficit)

Common stock—The Company has one class of stock outstanding: common shares. The Company issued 316,080 and 421,450 shares of stock in exchange for $7.9 million and $10.4 million that related to the private placements which took place in 2018 and 2017, respectively.

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.

Common stock issued for services—During 2017, the Company paid certain consulting services with Company stock. In 2017, the Company issued 4,000 shares as payment for $0.1 million of consulting services performed and included as a component of selling, general and administrative on the statement of operations.

The number of shares issued was based on the fair value of the common stock at the date of the performance of the consulting services and the associated to amount owed by the Company in exchange for such services. See Note 10 for further discussion on the valuation techniques used for the Company's common stock.

Preferred stock— At December 31, 2018 and 2017, the Company has no shares of preferred stock outstanding.

Note 9—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. For the years ended December 31, 2018 and 2017, basic and diluted loss per share were the same.

Note 10—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.

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 believes 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.

As of December 31, 2017, the liabilities for stock-based compensation awards were classified as a component of noncurrent liabilities on the balance sheet as the Company did not expect that such amounts would be settled through the use of current assets or through the creation of current liabilities.

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. 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.

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, 2018, 1,522,354 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.

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 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.

A summary of the activity and related information of the Communicated Option Awards 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, 2016	654,500	$ 2.22	5.05	$ 3,781
Granted	394,000	7.35	6.02	
Forfeited	(115,000)	6.00	—	
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 during the year ended December 31, 2018 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	9.43	
Forfeited	(25,800)	19.27	—	
Outstanding at December 31, 2018	1,920,100	$ 28.59	9.43	$ —
Exercisable at December 31, 2018	80,499	$ 28.94	9.42	$ —
Vested and expected to vest at December 31, 2018	1,920,100	$ 28.94	9.43	$ —

A summary of the activity and related information of the restricted stock units issued during the year ended December 31, 2018 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	1,494,111	$ 26.91

Stock-based compensation expense recorded in operating expenses was as follows (in thousands):

	Year ended December 31,	
	2018	2017
Selling, general and administrative	$ 11,936	$ 8,744
Research and development	1,951	3,258
Stock-based compensation in operating expenses	$ 13,887	$ 12,002

Stock-based compensation amounts of $0.6 million and $0.7 million were capitalized to property and equipment and inventory during the years ended December 31, 2018 and 2017, respectively.

Unrecognized compensation expense for stock options issued as of December 31, 2018 was $14.2 million and is expected to be recognized over a weighted-average period of 2.4 years. Unrecognized compensation expense for the restricted stock units as of December 31, 2018 was $22.5 million and is expected to be recognized over a weighted-average period of 0.9 years.

The Communicated Option Awards were presented as a stock-based compensation liability which was revalued at each reporting period with the change in fair value recorded to compensation expense. As of December 31, 2018 and 2017, the stock-based compensation liability was $0 and $15.4 million, respectively. As of the date of the modification of the Communicated Option Awards, the stock-based compensation liability was $18.2 million.

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:

	Year ended December 31,	
	2018	2017
Risk-free interest rate	2.49%	1.96%
Volatility	34.13%	43.70%
Expected dividend yield	0.00%	0.00%
Expected life	2.9	2.6

The weighted-average fair value for Communicated Option Awards granted during 2018 and 2017 was $12.91 and $21.52, respectively. 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 December 31, 2017, the date at which the stock-based compensation liability was remeasured at fair value, the common stock price was based on the recent equity issuances with third party investors, who were not previous shareholders of the Company. 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:

	Year ended December 31, 2018
Risk-free interest rate	2.89 %
Volatility	42.64 %
Expected dividend yield	0.00 %
Expected life	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 296,752 shares of common stock were available for sale under our ESPP as of December 31, 2018. 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 11—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 statement of operations is as follows:

	Year ended December 31,	
	2018	2017
Tax computed at the federal statutory rate	21.0 %	34.0 %
State income taxes, net of federal benefits	2.7	5.8
Tax reform—tax rate change	—	(18.6)
Nondeductible expenses	(2.0)	—
Other	(2.2)	—
Change in valuation allowance	(19.5)	(21.2)
	—	—

The federal and state income tax provision is summarized as follows (in thousands):

	Year ended December 31,	
	2018	2017
Current		
Federal	$ —	$ —
State	10	1
	10	1
Deferred		
Federal	—	—
State	—	—
	—	—
Income tax expense	$ 10	$ 1

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,	
	2018	2017
Deferred Tax Assets:		
Net operating loss carryforwards	$ 6,990	$ 1,994
Other accruals	88	79
Reserves	203	142
Deferred revenue	661	697
Intangible assets	353	618
Stock-based compensation	6,464	4,314
	$ 14,759	$ 7,844
Deferred Tax Liabilities:		
Property and equipment	(888)	(5)
Valuation allowance	$ (13,871)	$ (7,839)
Total deferred taxes	$ —	$ —

At December 31, 2018, the Company had available federal and state net operating loss carryforwards of approximately $27.7 million and $23.6 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 not completed an IRC Section 382 analysis regarding the limitation of net operating losses.

As of December 31, 2018, the Company does not have any unrecognized tax benefits. The Company does not anticipate that the amount of unrecognized tax benefits will significantly increase or decrease in the next 12 months. There were no interest and penalties accrued as of December 31, 2018. 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.

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, 2018 and 2017.

The difference between the statutory federal income tax rate and the effecti ve income tax rate reported in the statements of operations is primarily due to the Tax Act (as defined below), state income taxes and the change in the valuation allowance.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. The Company is no longer subject to audit by U.S. federal, state and local tax authorities for years before 2014. The Company is not currently under examination by any taxing jurisdiction. As of December 31, 2018 and 2017, there is no accrued interest or penalties recorded in the financial statements. However, the net operating loss carryover may be adjusted three years from the date the loss is utilized on an income tax return.

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act significantly changes U.S. tax law by, among other things, lowering corporate income tax rates, eliminating certain deductions, allowing full expensing of capital spending, implementing a territorial tax system, and imposing a repatriation tax on deemed repatriated earnings of foreign subsidiaries. The Company has completed its analysis of the Tax Act. The Tax Act permanently reduces the U.S. corporate income tax rate from a maximum of 34% to a flat 21% rate, effective January 1, 2018. As a result of the reduction in the U.S. corporate income tax rate from 34% to 21% under the Tax Act, the Company revalued its ending net deferred tax assets at December 31, 2017. The impact of this revaluation was offset by a reduction in the valuation allowance, thus having no impact on the income tax expense recognized in the statement of operations for the year ended December 31, 2017.

Note 12—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.

On August 30, 2018, Strata Skin Sciences, Inc. and Uri Geiger, a member of the board of directors of Strata Skin Sciences, Inc. (collectively "Strata") filed an action against the Company in Pennsylvania State Court, Montgomery County (Civil Action No. 18-21421), requesting declaratory relief that: (1) Strata is 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 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 does not request any monetary damages. The Company believes that the action by Strata 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. A hearing on the Company's objections was scheduled for February 21, 2019 but has been delayed due to the unavailability of Strata's lawyers on that date. We are awaiting a new date for the hearing to be scheduled. The Company believes that Strata's action lacks merit, and plans to vigorously oppose the action on procedural and substantive grounds within the prescribed time limits.

Lease commitments—The Company has various noncancelable operating leases related to office spaces and manufacturing facilities in Carlsbad, California. In 2017, the Company entered into an operating lease for office space and manufacturing facilities and abandoned an existing lease. The Company recorded an expense and a corresponding liability of $0.2 million as a result of the lease abandonment. The expense was included in selling, general and administrative expenses in the statement of operations. In 2018, the Company re-occupied the abandoned facility. There was no liability outstanding at December 31, 2018.

Some of these agreements have escalating rent payment provisions. Rent expense under such agreements is recognized on a straight-line basis. Total rent expense for the years ended December 31, 2018 and 2017, was $0.4 million and $0.3 million, respectively.

Future minimum rental payments due are as follows (in thousands):

Years Ending December 31,	
2019	$ 500
2020	514
2021	528
2022	432
2023	445
Thereafter	1,918
Total	$ 4,337

Note 13—Segment Information

The Company has organized its business into two operating segments based on the product specialties: the dermatology segment and the vascular 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 for the years ended December 31, 2018 and 2017 (in thousands):

	For the Year Ended December 31,	
	2018	2017
Vascular	$ 1,552	$ 259
Dermatology	4,705	5,611
Net revenue	$ 6,257	$ 5,870
Vascular	$ 1,521	$ 193
Dermatology	2,685	3,972
Cost of revenue	$ 4,206	$ 4,165
Vascular	$ 31	$ 66
Dermatology	2,020	1,639
Gross profit	$ 2,051	$ 1,705

Generally, all assets are common assets, except for demonstration lasers and lasers placed with customers, which are a subset of property and equipment. The net book value of the demonstration lasers and lasers placed with customers aggregated in the vascular segment was $2.2 million and $0.2 million as of December 31, 2018 and 2017, respectively. The net book value of the demonstration lasers and lasers placed with customers aggregated in the dermatology segment was $0.7 million and $0.3 million as of December 31, 2018 and 2017, respectively.

Net revenue, classified by the major geographic areas in which our customers are located, was as follows (in thousands):

	For the Year Ended December 31,	
	2018	2017
United States	$ 5,835	$ 5,273
All other countries	422	597
Net revenue	$ 6,257	$ 5,870

Note 14—Subsequent Events

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.

In January 2019, the Company entered into a master lease agreement to finance up to 10 automobiles for $0.3 million, of which, seven have been financed for $0.2 million. The lease expires in January 2021 and bear interest at 6.4%.

Exhibit 10.18

December 8, 2018

Via Email
Thomas Fogarty

Re: Offer Letter

Dear Tom:

I am pleased to offer you a position with Ra Medical Systems, Inc. (the "**Company**"), as its Chief Commercial Officer. If you decide to join us, you will receive an annual salary of $308,000, which will be paid in accordance with the Company's normal payroll procedures, and subject to applicable tax withholdings. You will also be eligible to earn bonuses based on individualized and company-wide targets, subject to the terms and conditions of the Company's bonus plan for similarly situated employees (the "**Plan**"), which will be approved and distributed following your start date with the Company. Your aggregate annual bonus opportunity will be equal to up to 50% of your base salary ("**Annual Bonus Target**"). Please note that any incentive compensation, or any portion thereof, is subject to your continued employment with the Company through the date the bonus is earned and will be paid to you in accordance with the Company's applicable bonus plan and the Company's normal payroll procedures for incentive compensation, provided that no bonus will be paid later than March 15 of the calendar year following the calendar year in which the bonus was earned. For all bonuses, you must remain employed through the date the bonus is actually paid to you in order to earn the bonus.

As an employee, you will also be eligible to participate in certain employee benefit programs generally made available to similarly situated Company employees, including, but not limited to, group health insurance and paid time off, subject to the satisfaction of any eligibility requirements and subject to the terms of such benefit programs. Information on currently available benefit programs will be provided to you shortly after your start date. You should note that the Company may modify job titles and salaries, and may modify or terminate benefits from time to time as it deems necessary or appropriate.

In addition, if you decide to join the Company, it will be recommended to the Company's Board of Directors or an applicable committee thereof following your start date that the Company grant you an award of restricted stock units (the "**RSUs**") with respect to shares of the Company's common stock having an approximate grant date value equal to $150,000. The number of shares of the Company's common stock subject to the RSU's shall be calculated on

the closing price per share as of the date of grant with the result rounded down to the nearest whole share. The RSU's shall vest in accordance with the Company's standard vesting schedule for RSUs as in effect on the date of grant, subject to your continuing to be a service provider to the Company through each vesting date. The RSU's will be subject to the terms and conditions of the Company's 2018 Equity Incentive Plan and forms of RSU award agreement thereunder (collectively, the "**Stock Agreements**"), in each case, which will be made available to you following the date your RSUs are granted. No right to any stock is earned or accrued until such time that vesting occurs, nor does the grant confer any right to continue vesting or employment.

The Company is excited about your joining and looks forward to a beneficial and productive relationship. Nevertheless, you should be aware that your employment with the Company is for no specified period and constitutes at-will employment. As a result, you are free to resign at any time, for any reason or for no reason. Similarly, the Company is free to conclude its employment relationship with you at any time, with or without cause, and with or without notice. We request that, in the event of resignation, you give the Company at least two weeks' notice.

The Company reserves the right to conduct background investigations and/or reference checks on all of its potential employees. Your job offer, therefore, is contingent upon a clearance of such a background investigation and/or reference check, if any.

For purposes of federal immigration law, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated.

We also ask that, if you have not already done so, you disclose to the Company any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed. It is the Company's understanding that any such agreements will not prevent you from performing the duties of your position and you represent that such is the case. Moreover, you agree that, during the term of your employment with the Company, you will not engage in any other employment, occupation, consulting or other business activity directly related to the business in which the Company is now involved or becomes involved during the term of your employment, nor will you engage in any other activities that conflict with your obligations to the Company. Similarly, you agree not to bring any third party confidential information to the Company, including that of your former employer, and that in performing your duties for the Company you will not in any way utilize any such information.

As a Company employee, you will be expected to abide by the Company's rules and standards. Specifically, you will be required to sign an acknowledgment that you have read and that you understand the Company's policies and the rules of conduct which are included in the Company's employee handbook.

As a condition of your employment, you are also required to sign and comply with an At-Will Employment, Confidential Information, Invention Assignment and ArbitrationAgreement which requires, among other provisions, the assignment of patent and other intellectual property rights to any invention made during your employment at the Company, and non-disclosure of Company proprietary information. Please note that we must receive your signed At-Will Employment, Confidential Information, Invention Assignment and Arbitration Agreement before your first day of employment.

To accept the Company's offer, please sign and date this letter in the space provided below. A duplicate original is enclosed for your records. If you accept our offer, your first day of employment will be December 17, 2018. This letter, along with any agreements relating to proprietary rights between you and the Company, set forth the terms of your employment with the Company and supersede any prior representations or agreements including, but not limited to, any representations made during your recruitment, interviews or pre-employment negotiations, whether written or oral. This letter, including, but not limited to, its at-will employment provision, may not be modified or amended except by a written agreement signed by the CEO or CFO of the Company and you. This offer of employment will terminate if it is not accepted, signed and returned by December 12, 2018.

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We look forward to your favorable reply and to working with you atRa Medical Systems, Inc.

Sincerely,

/s/ Dean Irwin
Dean Irwin
Chief Executive Officer

Agreed to and accepted:

Signature: /s/ Thomas G. Fogarty

Printed Name: Thomas G. Fogarty

Date: December 12, 2018

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-227696 on Form S-8 of our report dated March 14, 2019, relating to the financial statements of Ra Medical Systems, Inc., appearing in this Annual Report on Form 10-K of Ra Medical Systems, Inc. for the year ended December 31, 2018.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
March 14, 2019

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dean Irwin, 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)) for the registrant andhave:

   (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) 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

   (c) 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 14, 2019

By: /s/ Dean Irwin

Dean Irwin
Chief Executive Officer,
Co-President,
Chief Technology Officer,
Chairman of the Board of Directors
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL 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)) for the registrant andhave:

   (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) 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

   (c) 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 14, 2019

By: /s/ Andrew Jackson
Andrew Jackson
Chief Financial Officer (Principal Financial Officer)

Exhibit 32.1

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, Dean Irwin, hereby certify that, to my knowledge:

(i) the Company's Annual Report on Form 10-K for the year ended December 31, 2018 to which this Certification is attached as Exhibit 32.1 (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 14, 2019

By: /s/ Dean Irwin
Dean Irwin
Chief Executive Officer, Co-President, Chief Technology Officer,
Chairman of the Board of Directors (Principal Executive 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.

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL 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, 2018 to which this Certification is attached as Exhibit 32.2 (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 14, 2019

By: /s/ Andrew Jackson
Andrew Jackson
Chief Financial Officer (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.