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, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION item13 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	Trading Symbol	Name of the exchange on which registered
Common Stock, $0.0001 par value	**RMED**	**NYSE American**

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

Large accelerated filer	☐	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of a share of common stock on June 30, 2020 as reported by the New York Stock Exchange on such date was approximately $18.5 million. Shares of the registrant's common stock held by each executive officer, director and other persons who may be deemed an affiliate of the registrant have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 10, 2021, the registrant has 3,259,340 shares of common stock, par value $0.0001, outstanding.

RA MEDICAL SYSTEMS, INC.

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PART I

Special Note Regarding Forward-Looking Statements

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

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

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including, but not limited to, those described in "Risk Factors." These forward-looking statements reflect our beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report on Form 10-K and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled "Risk Factors" included in Part I, Item 1A and elsewhere in this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We qualify all of the forward-looking statements in this Annual Report on Form 10-K by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

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

ITEM 1. BUSINESS

Overview

Ra Medical Systems, Inc. is a commercial-stage medical device company leveraging our advanced excimer laser-based platform for use in the treatment of vascular and dermatological immune-mediated inflammatory diseases. We believe our products enhance patients' quality of life by restoring blood-flow in arteries and clearing chronic skin conditions.

The DABRA laser and single-use catheter, together referred to as DABRA, is used as a tool in the treatment of peripheral artery disease, or PAD, which commonly occurs in the legs. 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 was also granted CE mark approval in Europe in September 2016 for the endovascular treatment of infrainguinal arteries via atherectomy and for crossing total occlusions.

Our vascular business strategy is focused on multiple engineering efforts to improve our catheter offering as well as conducting a clinical study to obtain an atherectomy "indication for use" in the United States. Key catheter engineering efforts currently underway include projects to:

- Extend our catheter's shelf life. During 2020, we identified the factors limiting our shelf life, including the introduction of unwanted elements in the catheter's fluid core and the degradation of the coating on the inner diameter, and are currently implementing multiple remediations to address these issues. Our initial internal accelerated aging test data supports shelf life for our catheter of at least six months;
- Increase the robustness of our catheter via a braided overjacket, or a similar design, to make the catheter more kink-resistant when navigating tortuous anatomy. We expect to complete the engineering work for this catheter in the second half of 2021 and subsequently submit to the FDA for clearance; and
- Develop a version of the DABRA catheter that is compatible with a standard guidewire. We completed several guidewire-compatible catheter prototypes in the fourth quarter of 2020 and then conducted in vitro evaluations with several physicians. We expect to finalize the design for this catheter at the end of 2021.

As stated, we are currently pursuing an atherectomy indication for use, which the FDA defines to include a prespecified improvement in luminal patency. To satisfy the FDA's data requirements to support an atherectomy indication, we are performing a pivotal study designed to allow the FDA to evaluate the use of DABRA in atherectomy procedures. We received an Investigational Device Exemption, or IDE, approval in January 2020 and the study is approved for up to 10 clinical sites and 100 subjects.

We enrolled the first subject in February 2020. Throughout much of 2020, the COVID-19 pandemic substantially impacted our ability to activate new sites and enroll additional subjects. Many sites or potential sites have been or are currently operating at a reduced capacity, and some have been closed from time to time. In addition, potential study subjects may voluntarily opt to postpone their procedures due to COVID-19 concerns. As of March 11, 2021, we have enrolled 30 subjects and five sites have been cleared to enroll subjects. Due to the unpredictable impact the COVID-19 pandemic has had and will continue to have on enrollment in this study, we currently cannot estimate when enrollment will be completed.

We have paused shipments of catheters to commercial sites while we conduct further studies on the stability of our shelf life. We submitted additional test data in March 2021, which will need to be cleared by the FDA prior to resuming commercial shipments of catheters. We are continuing to supply catheters to those sites involved in our atherectomy clinical study. We do not anticipate rebuilding our vascular sales team until most of our engineering projects are complete and we have a more definitive timeline for obtaining an atherectomy indication.

Our Pharos laser is a medical device that we have marketed since October 2004 as a toolfor the treatment of proliferative skin conditions including psoriasis, vitiligo, atopic dermatitis, and leukoderma. The COVID-19 pandemic is negatively impacting the dermatology business as many customers delay the acquisition or purchase of capital equipment such as our Pharos laser. Because this business does not have a disposables component and we augment our capital equipment sales with recurring revenue derived from service and/or rental or lease agreements, we are experiencing less of an impact than business models that rely solely on capital equipment and/or disposables sales. We believe there could be an opportunity to grow the Pharos business in a capital-efficient after the business disruptions caused by the COVID-19 pandemic have subsided.

Recent Developments

COVID-19

The global spread of the novel coronavirus (COVID-19) has created significant volatility, uncertainty and economic disruption. The ultimate effects of the COVID-19 on our business, operations and financial condition are unknown at this time. In the near term, we expect that our revenue will continue to be adversely impacted and enrollment in our atherectomy clinical trial will continue to be delayed or slowed, as patients elect to postpone voluntary treatments and physicians' offices are either closed or operating at a reduced capacity. In addition, some customers are requesting more flexible payment terms on a temporary basis. We also may not be able to secure additional financing in a timely manner or on favorable terms, if at all. Our manufacturing facility located in Carlsbad, California is currently operational. Employee travel is limited to essential travel only and many employees are working from home when feasible. We have experienced minor delays in receiving shipments of parts, which has affected the timing of our key engineering efforts. To date, the shipment delays have not had a material impact on our ability to support our atherectomy indication trial. However, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain it or treat its impact, among others.

Department of Justice Civil Settlement and Corporate Integrity Agreement

On December 28, 2020, we entered into a Settlement Agreement with the United States of America, acting through the United States Department of Justice (the "DOJ") and on behalf of the Inspector General of the United States Department of Health and Human Services ("OIG"), to resolve the pending DOJ investigation and a related civil action concerning our marketing of the DABRA laser system and DABRA-related remuneration to certain physicians. In connection with the Settlement Agreement, we also have reached tentative agreements that, if executed by participating states, resolve previously disclosed related investigations conducted by certain state attorneys general.

The Settlement Agreement recites that a complaint filed by a former employee on behalf of the federal government in the United States District Court for the Eastern District of Michigan, and subsequently amended to assert claims on behalf of certain states, alleged, among other things, that we violated the False Claims Act, 31 U.S.C. § 3729, and certain state false claims acts by paying kickbacks to certain physicians in order to induce them to use the DABRA laser system, promoting off-label use of the DABRA laser system, failing to report adverse events to the United States Food and Drug Administration, marketing a device that does not work as advertised, and failing to adhere to Current Good Manufacturing Practices. The complaint, which was settled in connection with the Settlement Agreement, also alleged that we unlawfully retaliated against the former employee. Separate from the former employee's allegations in the civil action, the United States and the participating states contend that from May 1, 2017 through October 31, 2019, we (a) paid illegal remuneration to certain physicians to induce them to use the DABRA laser system in violation of the federal anti-kickback statute and (b) marketed the DABRA laser system for off-label use in atherectomy procedures despite product performance issues causing calibration and overheating problems, which posed a risk to physicians and patients (the "Covered Conduct"). We deny the allegations in the civil action and those asserted by the United States and the participating states, and the settlement does not constitute an admission of liability or wrongdoing by us.

Under the Settlement Agreement, and the tentative agreements with the participating states, we are required to make an initial payment of $2.5 million, of which we paid $2.4 million in December 2020 and will pay the remaining $0.1 million when the agreements with the participating states are finalized. Pursuant to the terms of the

Settlement Agreement, (a) if our revenue exceeds $10 million in any of the next four fiscal years (2021-2024), we also are required to pay an additional amount in settlement for the corresponding year: $500,000 for 2021, $750,000 for 2022, $1 million for 2023, and $1.25 million for 2024; (b) if we are acquired or are otherwise involved in a change in control transaction in the years 2020 through 2024, we are required to pay an additional settlement amount of $5 million, plus 4% of the value attributed to us in the transaction, so long as the attributed value is in excess of $100 million, with the total change in control payment never to exceed $28 million; and (c) if our obligations under the Settlement Agreement are avoided by bankruptcy, the United States may rescind the releases and bring an action against us in which we agree is not subject to an automatic stay, is not subject to any statute of limitations, estoppel or laches defense, and is a valid claim in the amount of $56 million, minus any prior change in control payments. Under the Settlement Agreement, we also paid the former employee's reasonable expenses, costs and attorneys' fees, which amount to $0.2 million.

The OIG has agreed, conditioned upon our full payment of amounts owed in the Settlement Agreement, and in consideration of our obligations under a Corporate Integrity Agreement, to release our permissive exclusion rights and refrain from instituting any administrative action seeking to exclude us from participating in Medicare, Medicaid, or other federal health care programs as a result of the Covered Conduct. The Corporate Integrity Agreement has a five-year term and imposes monitoring, reporting, certification, documentation, oversight, screening, and training obligations on us, including the hiring of a compliance officer and independent review organization.

Pursuant to the terms of the Settlement Agreement, the United States and the former employee have dismissed the complaint against us with prejudice and have released us from any civil or administrative monetary liability arising under the Covered Conduct. The Settlement Agreement does not include a release for any conduct other than the Covered Conduct or any criminal liability related to the Covered Conduct. The Settlement Agreement does not release any claims under investigation by the U.S. Securities and Exchange Commission, or SEC.

DABRA. DABRA (Destruction of Arteriosclerotic Blockages by laser Radiation Ablation) is our minimally-invasive excimer laser and single-use catheter system that is used by physicians as a tool in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease, a form of PAD, both above- and below-the-knee, by breaking down plaque to its fundamental chemistry, such as proteins, lipids and other chemical compounds, to eliminate blockages by essentially dissolving them without generating potentially harmful particulates. The accumulation of plaque in arteries, which is a result of lower extremity vascular disease, most commonly occurs in the pelvis and legs. Plaque accumulation, known as atherosclerosis, causes the narrowing of arteries, thereby reducing the flow of oxygenated blood to tissue and organs. If vascular blockages are left untreated, they can increase the risk of heart attack, stroke, amputation or death. Major risk factors for PAD include age, smoking, diabetes and obesity. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including coronary artery disease, or 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. PAD affects approximately 17 million people in the U.S. However, only 20-30% of PAD patients are actively being treated.

Current treatments for vascular blockages associated with PAD are largely endovascular and include angioplasty, stenting and atherectomy. Bypass surgery, which was frequently used in the past, is costly and often results in complications, including post-surgery pain, 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.

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 potential benefits over competing treatments and therapies. DABRA is easy to use with proper physician training and can cross and debulk, or reduce or remove, a broad range of plaque types. DABRA is predominantly used as an adjunct therapy with angioplasty balloons, drug-coated balloons, stents, and other endovascular treatments. DABRA employs photoablation, or the removal of body tissue by using photons, to remove blockages by breaking the bonds of the obstructing plaque directly. 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 DABRA's mechanism of action, photoablation, may result in less mechanical and thermal trauma to the vessel compared to other devices. 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. Our initial commercial strategy will focus on placing DABRA in office-based laboratories, or OBLs, and subsequently we intend to expand into the hospital catheterization market. Reimbursement claims for DABRA procedures are typically submitted by the provider to Medicare or another third-party payor using established Current Procedural Terminology, or CPT, codes. DABRA was also granted CE mark approval in Europe in September 2016 for the endovascular treatment of infrainguinal arteries via atherectomy and for crossing total occlusions. As noted above, we are currently pursuing an atherectomy indication in the U.S.

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

Psoriasis is a chronic autoimmune disorder that causes cells to build up rapidly and affects the surface of the skin. The National Psoriasis Foundation reports that psoriasis affects more than 8 million people in the U.S. Psoriasis often develops between the ages of 15 to 35, but can develop at any age. Vitiligo is an autoimmune condition in which the skin turns white due to the loss of melanocytes, cells that produce the pigment melanin, which gives skin color. Vitiligo affects approximately 1% of the population globally. Atopic dermatitis, more commonly known as eczema, is a chronic eczematous skin disease. There are approximately 16.5 million adults in the U.S. suffering from atopic dermatitis, according to the National Eczema Association. Leukoderma is the localized loss of pigment in the skin due to several causes including vitiligo.

Vascular Disease

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

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

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

Market Overview

PAD affects approximately 17 million people in the U.S. However, only 20-30% of PAD patients are actively being treated. Despite its prevalence and poor outcomes, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including CAD, in part because up to half of the PAD population is asymptomatic and many dismiss symptoms as normal signs of aging.

Without treatment, the disease can result in severe complications including amputation or death. The most common reason for amputation today is PAD. Despite the relative under diagnosis and treatment of PAD, the 2021 U.S. atherectomy market is projected to be over $750 million. 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***. 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. Recent data supports that there are approximately 1 million annual endovascular procedures for the treatment of PAD in the U.S. Angioplasty and stenting are the most commonly performed minimally-invasive interventional treatments.

- ***Angioplasty***. In an angioplasty procedure, a long, thin tube, or catheter, with a balloon tip is inserted into the blocked or narrowed part of the artery over a previously positioned guidewire that directs the catheter to the affected area. The balloon is then inflated, compressing the plaque and stretching the arterial wall. While angioplasty catheters are relatively easy to use, they stretch the arterial wall, sometimes leading to dissections of, and damage to, the arterial walls. Angioplasty does not remove the plaque, which remains in the artery. In addition, traditional 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.
- ***Drug Coated Balloon***. Drug coated balloons (DCBs) are often used in conjunction with atherectomy. Drug coated balloon angioplasty is similar to a regular angioplasty procedure, but in this case the balloon catheter used has an anti-restenotic drug coating on the surface of balloon. When the balloon is inflated the drug is delivered to the vessel wall which may help prevent restenosis. Unlike regular

angioplasty, low pressures are generally used to inflate DCBs thereby reduced arterial wall stretch, dissections and damage to the arterial wall. However, the long-term safety and durability of DCB angioplasty remains uncertain, in particular in treating lesions below the knee.

- ***Cutting Balloon***. A cutting balloon is a special balloon catheter which has small blades bonded along the length of the balloon. These devices were developed to overcome some of the limitations of regular angioplasty, namely the risk for dissection and vessel wall damage due to the dilating forces used with regular angioplasty balloons. When the balloon is inflated the dilating force is concentrated along the blades creating small, longitudinal incisions along the length of the vessel wall. Cutting balloons are commonly used as a vessel preparation tool in conjunction with a DCB or stenting, particularly in calcified lesions or for in-stent restenosis.
- ***Intravascular Lithotripsy***. Intravascular Lithotripsy is a calcium modification PTA balloon, designed for the treatment of moderately to severely calcified PAD lesions. The catheter delivers sonic pressure waves to target and disrupt calcium within the vessel. Once the calcium is cracked the balloon is inflated at low pressures to achieve lumen gain.
- ***Stenting***. Stenting is generally performed in tandem with angioplasty. A stent is a wire-mesh tube that acts as a scaffold inside the artery to keep it open. Stents are currently available in a wide range of varieties, including drug-coated stents. Despite their widespread use, stents may cause injury and inflammation to the arterial wall during placement and continued trauma post-procedure. 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.
- ***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. Approximately 200,000 amputations occur annually in the U.S. as a result of PAD.

Our Solution

Strengths of Our Approach

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

- ***Safety***. DABRA is designed to track the patient's true lumen, or the center of the artery, and not to penetrate between the layers of arterial structure known as the subintimal space. Damage or stretching of the arterial walls, which can lead to dissection or perforation, may be reduced.
- ***Efficacy***. Unlike many treatments for PAD that do not remove plaque, DABRA employs photoablation to disintegrate plaque by breaking its chemical bonds, thereby reducing the plaque to the components of its fundamental chemistry without generating potentially harmful particulates.
- ***Utility***. DABRA enables physicians to remove plaque from long and calcified lesions in arteries located in the lower extremities both above- and below-the-knee. DABRA is able to cross and debulk a wide variety of plaque, removing vascular blockages. For example, in patients with a CTO, the physician may use DABRA to cross the CTO prior to alternative treatments consisting of balloon angioplasty and possibly stenting.
- ***Ease of Use***. DABRA employs techniques similar to those used in angioplasty, which are familiar to the approximately 10,000 interventional cardiologists, vascular surgeons and interventional radiologists in the U.S. who are generally trained in endovascular techniques. In order to further the ease of use for physicians, we are working towards increasing the robustness of our catheter via a braided overjacket, or a similar design, to make the catheter more kink-resistant when navigating tortuous anatomy. We are also working on developing a version of the DABRA catheter that is compatible with a standard guidewire.
- ***Cost and Time Efficient***. When we relaunch DABRA, we intend to price our single-use catheters competitively and provide the DABRA laser system for a nominal periodic fee without requiring the purchase of capital equipment, which we believe will make DABRA a cost-effective solution for providers. The average lasing time in our pivotal study was approximately two and a half minutes per procedure.

Our Strategy

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

- ***Increasing the shelf life and improving the consistency of the DABRA catheter.*** In the third quarter of 2019, we engaged in a voluntary recall of the catheters with a 12-month shelf life to replace them with catheters with a two-month shelf life. We have identified current limitations on shelf life relating to aspects of the fluid core and coating and are currently implementing multiple remediations to address these issues. Our initial internal accelerated aging test data supports shelf life for our catheter of at least six months.
- ***Product enhancements***. We are working on two important design changes to the DABRA catheter. First, we are increasing the robustness of our catheter via a braided overjacket, or a similar design, to make the catheter more kink-resistant when navigating tortuous anatomy. Second, we are developing a version of the DABRA catheter that is compatible with a standard guidewire. Following these two enhancements, we intend to develop a larger diameter catheter to target atherectomy procedures in the larger vessels more commonly seen in above-the-knee procedures.
- ***Atherectomy indication for use***. We are currently pursuing an atherectomy indication for use, which the FDA defines to include a prespecified improvement in luminal patency. To satisfy the FDA's data requirements to support an atherectomy indication, we are performing a pivotal study designed to allow the FDA to evaluate the use of DABRA in atherectomy procedures. We received an IDE approval in January 2020 and the study is approved for up to 10 clinical sites and 100 subjects. We enrolled the first

subject in February 2020. Throughout much of 2020, the COVID-19 pandemic substantially impacted our ability to activate new sites and enroll additional subjects. Many sites or potential sites have been or are currently operating at a reduced capacity, and some have been closed from time to time. In addition, potential study subjects may voluntarily opt to postpone their procedures due to COVID-19 concerns. As of March 11, 2021, five sites have been cleared to enroll subjects and 30 subjects have been enrolled in the trial. Due to the unpredictable impact the COVID-19 pandemic has had and will continue to have on enrollment in this study, we currently cannot estimate when enrollment will be completed.

- ***Expanding DABRA sales.*** We do not anticipate rebuilding our vascular sales team until most of our engineering projects are complete and we have a more definitive timeline for obtaining an atherectomy indication.

Products

The DABRA Product

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

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

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

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

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

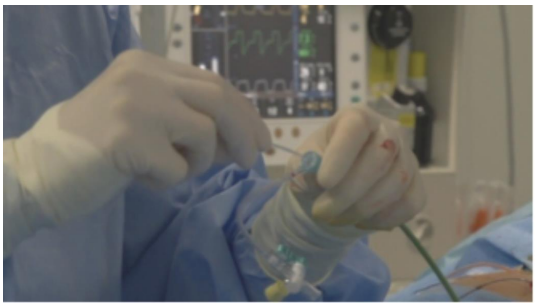
The DABRA Laser

The DABRA Catheter

The DABRA Procedure

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

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



Clinical Studies and Patient Data

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

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

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

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

The Pharos Product

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

The Pharos Laser

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

We believe that the principal benefits of Pharos are:

- ***Wavelength.*** Studies have shown that the action spectrum, or the rate of a physiological activity plotted against wavelength of light, for immunologically modulated skin disorders is centered at about 308 nanometers. Pharos is a 308 nanometer laser, making it ideally suited for use as a tool in the treatment of these disorders.

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

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

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

Dermatological Disease

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

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

Market Overview

Psoriasis, atopic dermatitis and vitiligo are common skin disorders throughout the world. The National Psoriasis Foundation reports that psoriasis affects over 8 million people in the U.S. Globally, this skin condition is estimated to affect over 125 million people, 2-3% of the total population. A study on the economic costs of psoriasis, including direct costs (medical expenses), indirect costs (work productivity), quality of life costs, and comorbidity costs, showed an estimated $135 billion annual expense for everyone with psoriasis in the United

States. The study found that the majority of psoriasis patients miss an average of 26 days of work a year due to their disease. Currently, more than 18 million adults suffer from atopic dermatitis in the U.S., making it one of the most common inflammatory skin diseases. Vitiligo is a pigmentation disorder that affects approximately 1% of the population globally.

Customers

No single customer represented more than 10% of our total revenue for 2020 or 2019.

Sales and Marketing

We market and sell Pharos primarily through our direct sales force in the U.S. and we partner with distributors in select geographies outside of the U.S. We are supplying DABRA catheters to those sites involved in our atherectomy clinical study. We have paused shipments of catheters to commercial sites while we conduct further studies on the stability of our shelf life. We submitted additional test data in March 2021, which will need to be cleared by the FDA prior to resuming commercial shipments of catheters. We do not anticipate rebuilding our vascular sales and marketing team until most of our engineering projects are complete and we have a more definitive timeline for obtaining an atherectomy indication.

Our Pharos marketing program focuses on:

- educating physicians regarding the proper use and application of our products;
- 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 our products.

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 the foreseeable future.

Competition

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

Vascular blockages are currently treated with angioplasty balloons, stents, and atherectomy devices that include excimer laser ablation. Our major competitors for our vascular solutions include Medtronic plc, Cardiovascular Systems Inc., Boston Scientific Corp., Avinger, Inc., Koninklijke Philips N.V., including Volcano Corporation and Spectranetics Corporation, Becton Dickinson and Company, including products from the C.R. Bard

acquisition, AngioDynamics and Abbott Laboratories. We believe that DABRA competes favorably with our competitors' products in terms of safety, ease of use, utility and cost.

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

Reimbursement

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

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

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

Research and Development

The major focus of our research and development team is to leverage our existing technology platform for new applications and improvements to our existing applications, including multiple engineering efforts to improve our current catheter. 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 commercial team 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 $9.0 million and $4.5 million of research and development expenses in the years ended December 31, 2020 and 2019, respectively.

Resources Material to Our Business

Patents and Proprietary Technology

Patents

In order to remain competitive, we must develop and maintain protection on the proprietary aspects of our technologies. We rely on a combination of patent, copyright, trademark and trade secret laws, and confidentiality and invention assignment agreements to protect our intellectual property rights. The protection of intellectual property has been and remains a priority for us. As of March 8, 2021, we own six issued U.S. patents and continue to pursue patent protection in five different patent families. In the patent family titled "Small Flexible Liquid Core Catheter for Laser Ablation in Body Lumens and Methods for Use," we own one issued U.S. patent, one issued Chinese patent and one granted European patent which has been validated in Switzerland, Germany, Denmark, France, United Kingdom, Italy, Netherlands and Sweden. A U.S. divisional application and three U.S. continuation applications have also been filed in this patent family and remain pending. In the patent family titled "Methods and Devices for Treatment of Stenosis of Arteriovenous Fistula Shunts," we own four issued U.S. patents and one continuation application remains pending in the U.S. In the patent family titled "Laser Ablation Catheters Having Expanded Distal Tip Windows for Efficient Tissue Ablation" we own one issued U.S. patent with one continuation application in this family still pending. The patent family titled "Liquid Filled Ablation Catheter with Overjacket" includes pending applications in the U.S. and China. An additional international PCT patent application titled "Liquid Filled Laser Ablation Catheter with Full Length Outer Jacket Support" is also pending in another patent family. Our issued U.S. patents expire between 2035 and 2037, subject to payment of required maintenance fees, annuities, and other charges.

Trademarks

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

Trade Secrets

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

Government Regulation and Product Approval

United States

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

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

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

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

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

Pre-market Authorization and Notification

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

510(k) Notification

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

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

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

We have received 510(k) premarket clearances from the FDA to market our excimer laser and catheter systems for treatment of psoriasis, vitiligo, atopic dermatitis, leukoderma, and for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease and with an intended use for ablating a channel in occlusive peripheral vascular disease.

De Novo Classification

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

PMA Approval

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

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

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

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

Clinical Trials

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

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

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

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

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

Postmarket Requirements

After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, the medical device reporting regulations (which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and reports of corrections and removals regulations (which require manufacturers to report recalls or removals and field corrections to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA). After a May 2018 inspection, the FDA issued to us a Form 483 that included observations for failure to properly evaluate whether certain complaints related to Pharos and DABRA that we have received rose to a level required to be reported to the FDA. In response, we informed the FDA that we have modified our complaint review procedures and we completed a retrospective evaluation and have not found any complaints which require a submission to the FDA. In connection with our Audit Committee investigation, the Audit Committee also found failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to FDA's satisfaction. In addition, the FDA conducted an unannounced facility inspection in December 2019. The FDA issued to us a Form 483 that included observations that schedules for the adjustment, cleaning, and other maintenance of equipment have not been adequately established, a device master record index was not current, and document control procedures have not been fully established. All actions are complete and the final Form 483 report was sent to the FDA on September 25, 2020. Failure to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to FDA's satisfaction, can subject us to warning letters, recalls, or other sanctions and penalties.

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

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

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

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

Radiation Emitting Products

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

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

Non U.S. Regulatory

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

Other Healthcare Laws

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

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

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

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

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

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

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

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

Foreign Corrupt Practices Act

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

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

Privacy and Data Protection Laws

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

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

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

U.S. Healthcare Reform

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

Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, the Patient Protection and Affordable Care Act of 2010, or PPACA, and the Medicare Access and CHIP Reauthorization Act of 2015 substantially changed the way healthcare is delivered and financed by both governmental and private insurers. These changes included the creation of demonstration programs and other value-based purchasing initiatives that provide financial incentives for physicians and hospitals to reduce costs, including incentives for furnishing low cost therapies. Under the Trump Administration, there were ongoing efforts to modify or repeal all or part of PPACA or take executive action that affects its implementation. Tax reform legislation was passed that includes provisions that impact healthcare insurance coverage and payment such as the elimination of the tax penalty for individuals who do not maintain health insurance coverage (the so-called “individual mandate”). Such actions or similar actions could have a negative effect on the utilization of our products. We are uncertain as to the extent such efforts will continue under the Biden administration and to what extent there will be additional reform proposals at federal and state levels. On December 18, 2019, the United States Court of Appeals for the Fifth Circuit upheld a lower court’s determination in Texas v. Azar, 4:18-cv-00167, that the individual mandate was unconstitutional and remanded the case to the lower court for further analysis as to whether PPACA as a whole is unconstitutional because the individual mandate is not severable from other provisions of the law. In November 2020, the United States Supreme Court held oral arguments on the Fifth Circuit United States Court of Appeals decision that held that the individual mandate is unconstitutional. It is uncertain how the United States Supreme Court will rule on this case or how healthcare measures of the Biden administration will impact the PPACA and our business. Litigation and legislation over the PPACA are likely to continue, with unpredictable and uncertain results. We cannot predict the ultimate results of the Texas case or whether additional legislative reform proposals will be adopted, when they will be adopted, or what impact they may have on us, but any such proposals could have a negative impact on our business and provide incentives for hospitals and physicians to not use our products.

General legislative action may also affect our business. For example, the Budget Control Act of 2011 included provisions to reduce the federal deficit. The Budget Control Act, as amended, resulted in the imposition of reductions of up to 2% in Medicare payments to providers which began in April 2013, which, due to subsequent legislative amendments, will stay in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2021, unless additional congressional action is taken. These or other similar reductions in government healthcare spending could result in reduced demand for our products or additional pricing pressure.

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

Employees and Human Capital

As of December 31, 2020, we had 85 full-time employees. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

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 16 – Segment Information” in the notes to the financial statements included elsewhere in this Annual Report on Form 10-K.

Geographic Information

During 2020 and 2019, substantially all of our long-lived assets were located within the United States. Approximately 5% of our revenue for 2020 and 9% of our 2019 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.

Risk Factor Summary

Risks Related to Our Business and Products

- We have determined that there is substantial doubt about our ability to continue as a going concern, and we will need additional financings to execute our business plan and to fund our operations.
- We may be unable to successfully remedy the performance, shelf life and calibration issues associated with our DABRA catheters, achieve market acceptance of DABRA, or achieve revenue growth.
- Our success depends in large part on DABRA. If we are unable to successfully manufacture, market and sell DABRA, our business prospects will be significantly harmed.
- Our ability to successfully complete our atherectomy trial may be hindered or delayed by the COVID-19 pandemic and DABRA catheter performance limitations that are currently being addressed by various engineering efforts.
- We anticipate requiring additional capital to finance our operations, which may not be available to us on acceptable terms or at all.
- We are required to devote significant resources to complying with the terms and conditions of our Settlement Agreement and Corporate Integrity Agreement and, if we fail to comply, we could be subject to penalties or, under certain circumstances, excluded from government healthcare programs, which would materially adversely affect our business.
- Physicians and staff may not commit enough time to sufficiently learn how to use our products.

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.
- Our medical device operations are subject to pervasive and continuing FDA regulatory requirements.
- Product clearances and approvals can often be denied or significantly delayed.
- 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.

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.
- 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.
- 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.
- We may not be able to protect our intellectual property and proprietary rights throughout the world.
- Changes in patent law in the U.S. or abroad could diminish the value of patents in general, thereby impairing our ability to protect our products.
- 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.

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 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.
- 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.

Risks Related to Ownership of Our Common Stock

- 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.
- 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.
- If we fail to comply with the continued listing standards of the NYSE American, our common stock could be delisted. If it is delisted, the market value and the liquidity of our common stock would be impacted.

Risks Related to Our Business and Products

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

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

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

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

Our ability to grow our revenue in future periods will depend on our ability to successfully remedy the inconsistencies in our DABRA catheter performance, penetrate our target markets and increase sales of our products and any new product indications that we introduce, which will, in turn, depend in part on our success in growing our installed unit base and driving continued use of our systems, including long-term adoption by physicians. During the fourth quarter of 2018 and into 2019, we saw an increase in calibration issues experienced by physicians. In addition, in reviewing the performance inconsistencies, we found that our catheters occasionally overheated, which could cause a risk of injury to patients and physicians. These higher than anticipated rates of non-calibration resulted in customer dissatisfaction with the product, resulting in what we believe to be fewer purchases by our customers. In the third quarter of 2019, we determined that catheters that were more than two months from sterilization had a significantly higher rate of non-calibration than catheters that were within two months of sterilization. As a result, in September 2019, we initiated a voluntary recall of our catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters. Accordingly, we reduced the number of sales and marketing personnel in

order to conserve cash and focus our efforts on key territories and accounts. We also initiated a voluntary recall of our DABRA catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters, and have paused commercial sales not related to our atherectomy clinical trial These actions will likely make it more difficult in the near term to achieve significant revenue growth. In addition, new product indications will also need to be approved or cleared by the FDA and comparable non-U.S. regulatory agencies to help drive revenue growth. If we cannot achieve revenue growth, it would have a material adverse effect on our business, financial condition, and results of operations.

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

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

- our ability to timely remedy the current inconsistencies in our DABRA catheter performance, including extended shelf life and reduce non-calibrations, reduced kinking, and identify future issues;
- our ability to further enhance our DABRA catheter performance with an improved design to make the catheter more kink-resistant when navigating tortuous anatomy;
- our ability to develop a guidewire-compatible version of our DABRA catheter designed to allow physicians to navigate the vasculature more easily;
- our ability to develop a larger diameter catheter to facilitate treatment of larger vessels more commonly seen in above-the-knee procedures;
- our ability to continue commercializing DABRA for its cleared indications for use with a smaller sales force;
- our ability to complete our atherectomy trial in a timely manner or at all, which may be affected by reductions in voluntary medical procedures during the ongoing COVID-19 pandemic as well as by limitations in our DABRA catheter performance, as described above;
- our ability to receive FDA clearance for an atherectomy indication for use;
- our ability to successfully conduct the voluntary recall of our DABRA catheters and subsequently achieve market acceptance following the change in our labeling from a 12-month to two-month shelf life;
- our ability to improve and extend the shelf life of our DABRA catheters and obtain FDA clearance for the extended shelf life;
- any agreements or punitive actions that arise out of any adverse judgment or settlement of the active and ongoing investigations by governmental agencies;
- our ability to receive regulatory clearance or approval for, and timely introduce, enhancements to the DABRA catheter design;
- the effectiveness of our and our distributors' marketing and sales efforts in the U.S. and abroad, including our efforts to build out and properly train our sales team;
- our ability to attract, motivate, train and retain experienced and qualified sales personnel;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competing treatments, including the time and expertise needed for training to effectively use the DABRA system as compared to competing treatments;
- our ability to properly support DABRA usage with our own qualified personnel or our ability to properly train and support our customers to use the DABRA system effectively on their own;
- the availability of coverage and adequate levels of reimbursement under private and governmental health insurance plans for DABRA-based procedures;
- our ability to obtain, maintain, and enforce our intellectual property rights in and to DABRA;
- our ability to achieve and maintain compliance with regulatory requirements applicable to DABRA;

- our ability to continue to develop, validate and maintain a commercially viable manufacturing process that is compliant with current Good Manufacturing Practices, or cGMP; and
- whether we are required by the FDA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for future or current indications.

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

Our ability to successfully complete our atherectomy trial may be hindered or delayed by the COVID-19 pandemic and DABRA catheter performance limitations that are currently being addressed by various engineering efforts.

The current COVID-19 pandemic and the DABRA catheter performance limitations may impact our ability to complete our atherectomy study in a timely manner. For example, enrollment in our atherectomy clinical trial may be further delayed or slowed by continuing increases in COVID-19 cases, as patients elect, or are asked,to postpone voluntary treatments and physicians' offices are either closed or only performing procedures on patients with a more advanced disease state that may not meet the enrollment criteria for our atherectomy clinical trial. In addition, inconsistencies or limitations in our DABRA catheter performance, including a current two-month shelf life and a history of non-calibrations, may deter some clinical sites from participating in our atherectomy study. Other limitations in our DABRA catheter performance, such as the potential for kinking during certain clinical scenarios or the lack of a guidewire-compatible version of our DABRA catheter, may limit the number of cases in which the DABRA catheter will be used during the trial. We have recently experienced delays in our efforts to develop these design enhancements to the DABRA catheter as a result of delays in obtaining materials from a key supplier. Accordingly, we cannot predict whether or when we will be able to successfully complete our atherectomy indication trial. Any inability to complete our atherectomy indication trial could have an adverse impact on our ability to successfully manufacture, market and sell DABRA, which in turn could adversely impact our business, financial condition and results of operations.

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

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development and commercialization efforts. As of December 31, 2020, we had cash and cash equivalents of $23.9 million and an accumulated deficit of $153.2 million. For the years ended December 31, 2020 and 2019, we used $28.3 million and $33.2 million in cash for operating activities, respectively. We have experienced recurring net losses from operations, negative cash flows from operating activities, and a significant accumulated deficit and expect to continue to incur net losses into the foreseeable future. As a result, our financial statements include explanatory disclosures expressing substantial doubt about our ability to continue as a going concern.

In the near term, we expect our recurring operational costs to decrease as a result of our cost savings initiatives. In the third quarter of 2019, we began implementing certain operational efficiency and cost savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives included targeted workforce reductions of our sales and marketing teams. We reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to five clinical specialists as of December 31, 2020, and have suspended sales of DABRA catheters not related to our atherectomy clinical trial. In addition, we have paused shipments of catheters to commercial sites while we conduct further studies on the stability of our shelf life. We submitted additional test data in March 2021, which will need to be cleared by the FDA prior to resuming commercial shipments of catheters. Further such actions may be required on an ongoing basis to optimize our organization. For example, we may need to decrease or defer capital expenditures and development activities or implement further operating expense reduction measures. Such measures may impair our ability to invest in developing, marketing and selling new and existing products. Until we are able to generate additional revenue to support our level of operating expenses, we will continue to incur operating and net losses and negative cash flow from operations. Additionally, we anticipate additional legal and other costs related to our completed Audit Committee investigation, including the pending securities class action and derivative lawsuits, a pending SEC investigation and a pending DOJ criminal investigation as well as compliance with, and payments under, the terms of our Settlement Agreement and Corporate Integrity Agreement associated with our settlement of a DOJ civil investigation. Because of the numerous risks and uncertainties associated with our commercialization

efforts and future product development and these lawsuits and ongoing government investigations, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase our profitability.

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

- whether we are able to successfully and timely remedy the inconsistencies in our DABRA catheter performance, including extended shelf life and reduced non-calibrations;
- whether we are able to further enhance our DABRA catheter performance with an improved design to reduce kinking and develop a guidewire-compatible version of our DABRA catheter designed to allow physicians to navigate the vasculature more easily;
- our ability to develop a larger diameter catheter to facilitate treatment of larger vessels more commonly seen in above-the-knee procedures;
- the timing of enrollment in our clinical trial for an atherectomy indication for use;
- our ability to achieve sufficient market acceptance, the ability for our customers to get coverage and adequate reimbursement from third-party payors and our ability to achieve acceptable market share for DABRA and Pharos;
- our ability to improve and extend the shelf life of our DABRA catheters and obtain FDA clearance for the extended shelf life;
- 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 use for which we receive regulatory clearance or approval, including the cost and timing of expanding our manufacturing capabilities, as well as establishing our sales and marketing capabilities;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the timing, receipt, and amount of license fees and sales of, or royalties on, our future products or future improvements on our existing products, if any; and
- the time and cost necessary to complete post-marketing studies that could be required by regulatory authorities or other studies required to obtain clearance for additional indications.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our products, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. If we are unable to obtain adequate financing on commercially reasonable terms when needed, we may have to delay, reduce the scope of or suspend our sales and marketing efforts, which would have a material adverse effect on our business, financial condition, and results of operations. We also expect the economic uncertainty due to the COVID-19 pandemic to have a negative impact on our ability to secure additional financing in a timely manner or on favorable terms, if at all.

We are required to devote significant resources to complyingwith the terms and conditions of our Corporate Integrity Agreement and, if we fail to comply, we could be subject to penalties or, under certain circumstances, excluded from government healthcare programs, which would materially adversely affect our business.

On December 28, 2020, we entered into a five-year Corporate Integrity Agreement with the OIG. The Corporate Integrity Agreement requires that we maintain our existing compliance programs, as well as expanding compliance-related requirements during the term of the Corporate Integrity Agreement. The Corporate Integrity Agreement requires us to establish specific procedures and requirements regarding consulting activities, marketing activities and other interactions with healthcare professionals and healthcare institutions and the sale and marketing of our products; ongoing monitoring, reporting, certification and training obligations; and the engagement of an independent review organization to perform certain auditing and reviews and prepare certain reports regarding our compliance with federal health care programs. Developing and maintaining these processes, policies and procedures necessary to comply with the Corporate Integrity Agreement will require a significant portion of management's attention and the application of significant resources. In addition, while we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws, all potentially applicable foreign regulations and/or laws and/or all requirements of the Corporate Integrity Agreement. If we breach the Corporate Integrity Agreement, we could become liable for payment of certain stipulated penalties or could be excluded from participation in federal health care programs. The costs associated with compliance with the Corporate Integrity Agreement, or any liability or consequences associated with its breach, could have an adverse effect on our business.

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

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

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

- whether we are able to successfully and timely remedy the inconsistencies in our DABRA catheter performance, including extending shelf life and reducing non-calibrations;
- whether physicians, catheterization laboratory owners and operators, patients, and others in the medical community consider our products to be safe, effective, and cost-effective treatment methods;
- our ability to improve and extend the shelf life of our DABRA catheters and obtain FDA clearance for the extended shelf life;
- our ability to further enhance our DABRA catheter performance with an improved design to reduce kinking when navigating tortuous anatomy;
- our ability to develop a guidewire-compatible version of our DABRA catheter designed to allow physicians to navigate the vasculature more easily;

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

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

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

The research, development, marketing and sale of our current products and any potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. At the same time, companies in the medical device industry are under continued scrutiny by the OIG and the DOJ, for improper relationships with physicians. For example, on December 28, 2020, we entered into a Settlement Agreement and a related Corporate Integrity Agreement related to a resolution of a DOJ civil investigation concerning, among other things, whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. Our failure to comply with the Corporate Integrity Agreement or 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 the reputational harm or negative publicity resulting from the settlement or pending government investigations could impact physicians' willingness to conduct business with us, which would have a material adverse effect on our business, financial condition, and results of operations.

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

Beginning in the fourth quarter of 2018, we started experiencing inconsistencies in our DABRA catheter performance. We believed at the time that these inconsistencies were related to controlling the temperature of the oven used in the manufacturing process, which we had previously referred to as production limitations. These inconsistencies led to an increase in the number of catheters that failed to calibrate at customer sites, despite calibrating successfully during our quality assurance steps. During that same period, our sales team noted higher rates of non-calibration of catheters at customer physician offices. The higher than anticipated rates of non-calibration resulted in customer dissatisfaction with the product, resulting in what we believe to be fewer purchases by our customers and therefore lower revenue during the fourth quarter of 2018 and into 2019, however, the decrease in purchases and the impact of such decrease on our revenues is not determinable. In response, we upgraded our temperature control regulator and made certain changes in our production flow and validated the changes that we believed corrected the production limitations. After manufacturing several well-performing lots with this upgraded process, the percentage of catheters that failed to calibrate at customer sites began to increase after decreasing during April and May 2019. After collecting field data and performing internal testing, we observed that while catheters can perform satisfactorily up to one year, catheters that were more than two months from sterilization had a significantly higher rate of non-calibration than catheters that were within two months from sterilization. As a result, in September 2019, we initiated a voluntary recall of our catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters. At the FDA's request, we engaged in additional shelf life testing as part of a special 510(k) and suspended commercial sales of catheters in order to remedy the shelf life issues. The FDA subsequently decided not to clear the special 510(k) and requested to see additional test data to confirm the stability of the shelf life before permitting us to resume commercial shipments. We submitted this additional test data in March 2021.

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

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

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

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

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

In the third quarter of 2019 we initiated a voluntary recall of our DABRA catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters, as we observed through field data and internal testing that catheters more than two months from sterilization have a significantly higher rate of non-calibration. While the newly labeled DABRA catheters showed a significant decrease in non-calibrations, we have paused commercial sales of DABRA catheters not being used for the atherectomy clinical trial while we continue our engineering efforts to improve the shelf-life of our catheters.

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

We incurred net losses of $36.0 million and $57.0 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $153.2 million. We expect to continue to incur significant manufacturing, product development, regulatory and other expenses as we continue to remedy the inconsistencies in our DABRA catheter performance,to obtain regulatory clearances or approvals for our products in additional jurisdictions and for additional indications, to develop new products or add new features to our existing products, and to defend, cooperate and resolve pending lawsuits and government investigations, as applicable. In addition, our general and administrative expenses have increased following our initial public offering and we expect these costs to continue due to the additional costs associated with being a public company. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenue in order to achieve and sustain profitability and, even if we achieve profitability, we cannot be sure that we will remain profitable for an extended period of time. Our failure to achieve or maintain profitability would have a material adverse effect on our business, financial condition, and results of operations and could negatively impact the value of our common stock.

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

As previously disclosed in our public filings, the Audit Committee completed its internal investigation. In connection with the Audit Committee investigation, we voluntarily contacted the Enforcement Division of the SEC in August 2019 to advise them of the investigation and on November 13, 2019, the SEC notified us that it was conducting an investigation. On March 11, 2020, the SEC served us with document subpoenas. We have been, and intend to continue, cooperating with the SEC's investigation. In November 2019, we learned that the DOJ opened a criminal investigation relating to us.We have been, and intend to continue, cooperating in the DOJ's investigation.

As disclosed above, on December 28, 2020, we entered into a Settlement Agreement with the DOJ to resolve a civil False Claims Act investigation and a related civil action, and in connection with the Settlement Agreement, reached tentative agreements that, if executed by participating states, resolve previously disclosed related civil investigations conducted by certain state attorneys general. Under the Settlement Agreement, and the tentative agreements with the participating states, we are required to make an initial payment of $2.5 million, of which we paid $2.4 million in December 2020 and will pay the remaining $0.1 million when the agreements with the participating states are finalized. In addition, if our revenue exceeds $10 million in any of the next four fiscal years, we also are required to pay an additional amount in settlement for the corresponding year: $500,000 for 2021, $750,000 for 2022, $1 million for 2023, and $1.25 million for 2024. If we are acquired or are otherwise involved in a change-in-control transaction prior to December 31, 2024, we also are required to pay an additional settlement amount of $5 million, plus 4% of the value of the transaction if the value of the transaction is in excess of $100 million, with the total change-in-control payment not to exceed $28 million. Under the Settlement Agreement, we also paid the former employee's reasonable expenses, costs and attorneys' fees, which amounted to $0.2 million. We also have additional obligations under a related Corporate Integrity Agreement, which has a five-year term and imposes monitoring, reporting, certification, documentation, oversight, screening, and training obligations on us, including the hiring of a compliance officer and independent review organization.

If one or more government agencies, including those conducting the pending investigations identified above, commences legal action and we are found to have violated state or federal laws or regulations, we may be subject to civil or criminal damages, penalties, fines, disgorgement, injunctions, cease and desist orders, other equitable remedies, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which would have a material adverse effect on our business, financial condition, and results of operations for

years. Regardless of whether actions are commenced, if we were to settle with one or more government agencies or state governments, including those conducting the ongoing investigations identified above, such settlements could include an agreement to pay civil or criminal damages, deferred prosecution agreements, or other equitable remedies, exclusion form governmental health care programs, and the curtailment or restructuring of our operations, any of which would have a material adverse effect on our business, financial condition and results of operations for years after any settlement is reached. In light of the ongoing nature of the investigations, whether actions will be commenced, whether these investigations can be settled before or after actions are commenced, and the terms on which these investigations can be resolved is not certain.

We have incurred, and may continue to incur, significant expenses related to legal, accounting, and other professional services in connection with the completed Audit Committee investigation and related legal matters, including the securities class action, shareholder derivative lawsuit, and government investigations, as well as costs related to compliance under, and payments made pursuant to, the Settlement Agreement and Corporate Integrity Agreement. These expenses and the diversion of the attention of the management team that has occurred, and is expected to continue, has adversely affected, and could continue to adversely affect, our business, financial condition, and results of operations.

As a result of the matters reported above, we are exposed to greater risks associated with litigation, regulatory proceedings and government enforcement actions. Any future investigations or additional lawsuits could have a material adverse effect on our business, financial condition, and results of operations.

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

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

The emergence and effects related to a pandemic, epidemic or outbreak of an infectious disease, including the current COVID-19 pandemic could adversely affect our operations.

If a disaster such as a pandemic, epidemic, outbreak of an infectious disease or other public health crisis were to occur in an area in which we operate, our operations could be adversely affected. For example, COVID-19 has now been characterized as a global pandemic and how long and how extensive the economic effects will last, has not been determined. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain it or treat its impact, among others. A further spread of the pandemic could cause include the temporary closure of our manufacturing facilities and those used in our supply chain processes, restrictions on the export or shipment of our products, business closures in impacted areas, and further restrictions on our employees' and consultants' ability to travel and to meet with customers. The pandemic has, and will likely continue, to cause delays in enrollment in our atherectomy indication trial. In addition, we have experienced minor delays in receiving shipments of parts, which has not had a material impact on the timing of our

key engineering efforts, nor our ability to support our atherectomy indication clinical trial.The pandemic could also adversely affect our ability to secure additional financing in a timely manner or on favorable terms, if at all.

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

In June 2019, we became the subject of a lawsuit alleging securities law violations based on alleged misstatements or omissions in the Registration Statement for our IPO and in subsequent public statements. This type of litigation can be expensive and disruptive to normal business operations, and the outcome can be difficult to predict regardless of the facts involved. An unfavorable outcome with respect to this lawsuit could have a material adverse effect on our business, financial condition, results of operations or cash flows. For additional information regarding this lawsuit, see Note 15, "Commitments and Contingencies," in the notes to the financial statements included elsewhere in this Annual Report on Form 10-K.

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

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

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

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

- decreased demand for our products;
- harm to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- inability to market and sell our products; and
- a resulting decline in the price of our common stock.

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

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

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

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

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

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

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

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

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

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

Our primary competitors for Pharos are The Daavlin Company, National Biological Corp., STRATA Skin Sciences and large pharmaceutical companies producing 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.

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 cleared or 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 uncleared or unapproved indications, manufacturers may promote their products only for the cleared or approved indications and in accordance with the provisions of the cleared or 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, 2020. We cannot assure you that we will be able to successfully obtain clearance or approval for any of these additional product indications through the application process or that a premarket FDA submission may not be necessary.

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

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

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

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

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

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

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

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

Our promotional materials and training methods must comply with FDA regulations and other applicable laws, including restraints and prohibitions on the promotion of off-label, or uncleared use, of our products. Physicians may use our products for off-label use without regard to these prohibitions, as FDA regulations do not restrict or regulate a physician's choice of treatment within the practice of medicine. Although our policy is to follow published FDA guidance in order to avoid promoting our products improperly, the FDA or other regulatory agencies or third parties could disagree and conclude that we have engaged in off-label promotion. For example, our DABRA Laser System has been cleared by the FDA for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease and has an intended use for ablating a channel in occlusive peripheral vascular disease. We have not received FDA clearance or approval to market DABRA for an atherectomy indication, and we may not promote DABRA for an atherectomy indication. As previously disclosed, the DOJ served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning, among other things, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs. Without admitting any liability or wrongdoing, on December 28, 2020 we entered into a Settlement Agreement and related Corporate Integrity Agreement that resolved this civil investigation. Our pivotal clinical study of the DABRA Laser System completed in 2017 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 cannot predict the extent to which our competitors may be successful in dissuading physicians from using the DABRA system out of concerns regarding reimbursement. Furthermore, we may incur additional liability from

claims initiated under the Lanham Act or other federal and state unfair competition laws with respect to how our products have been marketed and promoted.

In addition, we operate in an industry characterized by extensive litigation. However, the scope of potential liability with respect to any such claims, enforcement actions, or lawsuits is uncertain, and we cannot assure you that we will not receive claims from competitors or other third parties or be subject to enforcement actions in the future from regulatory agencies. For example, the FDA, FTC, the Office of the Inspector General of the Department of Health and Human Services, or HHS, the DOJ and various state Attorneys General actively enforce laws and regulations that prohibit the promotion of off-label uses. As disclosed above, on December 28, 2020, we entered into a Settlement Agreement and the related Corporate Integrity Agreement to resolve a DOJ civil investigation into, among other things, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and in connection with the Settlement Agreement, we also have reached tentative agreements that, if executed by participating states, resolve previously disclosed related investigations conducted by certain state attorneys general. The Settlement Agreement does not include a release for any conduct other than the Covered Conduct or any criminal liability related to the Covered Conduct. We have been, and intend to continue, cooperating with the DOJ's ongoing criminal investigation.

The False Claims Act, prohibits, among other things, making a fraudulent claim for payment of federal funds, causing such a fraudulent claim to be made, or making a false statement to get a false claim paid. The government may assert that a claim resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim under the False Claims Act. Many companies have faced government investigations or lawsuits by whistleblowers who bring a *qui tam* action under the False Claims Act on behalf of themselves and the government for a variety of alleged improper marketing activities, including providing free product to customers expecting that the customers would bill federal programs for the product, providing consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company's products, and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs. In addition, the government and private whistleblowers have pursued False Claims Act cases against medical device companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses. Medical device and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs. If we are found to have improperly promoted off-label uses, we may be subject to significant liability, including civil fines, criminal fines and penalties, civil damages, exclusion from federal funded healthcare programs and potential liability under the federal False Claims Act and any applicable state false claims act. Due to the Settlement Agreement and the Corporate Integrity Agreement, and ongoing SEC civil and DOJ criminal investigations, we have incurred, and will continue to incur, substantial legal costs, including settlement costs, costs of compliance with such agreements, and payments made pursuant to such agreements, and business disruption, including from ongoing and future compliance with such agreements. In the future, if we are found to have violated the False Claims Act, it may result in significant financial penalties, on a per claim or statement basis, treble damages and exclusion from participation in federal health care programs. In addition, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials, which could negatively impact our marketing and decrease demand for our products. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers, competitors, or other persons claiming to be harmed by such conduct.

The FDA, HHS, DOJ, and/or state Attorneys General, competitors, and other third parties may take the position that we have violated or are not in compliance with such guidelines, 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, threatened or actual government enforcement actions or lawsuits by third parties have and could continue to 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.

Regardless of whether actions are commenced, if we were to settle with one or more government agencies, including those conducting the ongoing and unresolved investigations identified above, such settlements could include an agreement to pay civil or criminal damages, injunctions, cease and desist orders, deferred prosecution agreements, or other equitable remedies, exclusion from governmental health care programs, and the curtailment or

restructuring of our operations, any of which would have a material adverse effect on our business, financial condition and results of operations for years after any settlement is reached. In light of the ongoing nature of the investigations, whether actions will be commenced, whether these investigations can be settled before or after actions are commenced, and the terms on which these investigations can be resolved is not certain.

Litigation and other legal proceedings may adversely affect our business.

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

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

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

In the United States, we are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our products. The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Any allegation, investigation, or violation of domestic healthcare fraud and abuse laws could result in government or internal investigations, significant diversion of resources, exclusion from government healthcare programs and the curtailment or restructuring of our operations, significant fines, penalties, or other financial consequences, any of which may ultimately have a material adverse effect on our business, financial condition, and results of operations. For example, our Audit Committee identified potential healthcare compliance risk areas relating to the previous sales, marketing and education programs for our products. In particular, the Audit Committee found that we lacked documentation of sufficient detail and specificity regarding certain payments to physicians, ostensibly for training and consulting services, and did not accurately reflect the purpose and nature of approximately $300,000 of payments to three physicians, which could be perceived as an improper attempt to obtain business or to gain special advantage. The Audit Committee also found that our salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes.

As disclosed above, we believe as many as 13 states are participating in the DOJ's False Claims Act investigation. In November 2019, we learned that the DOJ opened a criminal investigation relating to us. We have been, and intend to continue, cooperating with the DOJ in its ongoing investigations described above. On December 28, 2020, we entered into a Settlement Agreement and a related Corporate Integrity Agreement that resolved a DOJ civil investigation and related lawsuit that concerned, among other things whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. As also

disclosed above, the DOJ is conducting a criminal investigation and the SEC a civil investigation. We have been, and intend to continue, cooperating with these pending investigations.

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

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

Responding to any enforcement action or related investigation, such as the currently ongoing DOJ and SEC investigations, 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, healthcare laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, financial condition, and results of operations for years after these investigations are resolved.

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

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

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

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

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

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

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

We have partnered with distributors for DABRA and Pharos in select geographies outside of the U.S. For the year ended December 31, 2020, approximately 5% of our sales were outside of the U.S. We are not currently distributing DABRA outside the U.S., and will likely not be able to do so until we extend the shelf life of the DABRA catheter. We may not be able to collect all of the funds owed to us by our foreign distributors. Some foreign distributors may experience financial difficulties, including bankruptcy, which may hinder our collection of accounts receivable. Where we extend credit terms to distributors, we periodically review the collectability and creditworthiness when determining the payment terms for such distributors. If our uncollectible accounts exceed our expectations, this could adversely impact our operating results. In addition, failure by our foreign distributors to comply with the Foreign Corrupt Practices Act or similar laws, insurance requirements, or other contract terms could have a negative impact on our business. Failure to manage the risks related to our foreign distributors would have a material adverse effect on our business, financial condition, and results of operations.

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

The U.S. has imposed or proposed new or higher tariffs on certain products exported by a number of U.S. trading partners, including China, Europe, Canada, and Mexico. In response, many of those trading partners, including China, have imposed or proposed new or higher tariffs on American products. Continuing changes in government trade policies create a heightened risk of further increased tariffs that impose barriers to international

trade. During the year ended December 31, 2020, approximately 5% of our revenue came from international markets.

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

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

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

We face intense competition for executive-level talent from a variety of sources, including from current and potential competitors in the medical device and healthcare industries. Our continued success is dependent, in part, upon our ability to attract and retain superior executive officers.

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

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

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

Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition, and results of operations.

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

We were required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report filed on Form 10-K for the year ended December 31, 2019. As an "emerging growth company," we will avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an "emerging growth company" unless at that time we are still a "smaller reporting 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 SEC or other regulatory authorities, which would require additional financial and management resources.

In reviewing the allegations and findings from an Audit Committee investigation related to an initially anonymous complaint in 2019, as well as additional matters discovered during the course of the investigation, we identified material weaknesses in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to the aggregation of control deficiencies in our control environment, in particular an inappropriate "tone at the top" set by certain members of senior management, a failure to promote adherence to our Code of Ethics and Conduct, and the lack of sufficient competent resources in key roles at the organization.

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

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

reputation, financial condition or divert financial and management resources from our core business, and would have a material adverse effect on our business, financial condition and results of operations.

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

At December 31, 2020, we had 85 full-time employees. In the third quarter of 2019, we began implementing certain operational efficiency and cost savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives include targeted workforce reductions of our sales and marketing teams. We reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to five clinical specialists as of December 31, 2020.

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

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

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

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

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

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

Risks Related to Regulatory Approval and our Industry

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

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

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

Our current products are subject to extensive regulation by the FDA and non-U.S. regulatory agencies. Further, all of our potential products and improvements of our current products will be subject to extensive regulation and will likely require permission from regulatory agencies and ethics boards to conduct clinical trials, and clearance or approval from the FDA and non-U.S. regulatory agencies prior to commercial sale and distribution. Failure to comply with applicable U.S. requirements 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 recalls and certain device field removals and corrections to the FDA;
- and obtaining premarket notification 510(k) clearance for devices prior to marketing.

As previously disclosed, the Audit Committee found, among other things, that we, out of a concern for the DABRA catheters' performance, engaged in efforts to replace product held by customers, which constituted product recalls, but were not documented as such. As disclosed above, we have entered to a Settlement Agreement, and the tentative agreements with the participating states, resolving a DOJ civil investigation concerning certain Covered Conduct, and the OIG has agreed, conditioned upon our full payment of amounts owed in the Settlement Agreement, and in consideration of our obligations under a Corporate Integrity Agreement, to release our permissive

exclusion rights and refrain from instituting any administrative action seeking to exclude us from participating in Medicare, Medicaid, or other federal health care programs as a result of the Covered Conduct. The Corporate Integrity Agreement has a five-year term and imposes monitoring, reporting, certification, documentation, oversight, screening, and training obligations on us, including the hiring of a compliance officer and independent review organization.

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. We do not believe any of our current products are Class III devices, but future products could be, which would subject them to the PMA process.

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

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

The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices, and product quality management. For example, as discussed above, on December 28, 2020, we entered into a Settlement Agreement with the DOJ to resolve a civil False Claims Act investigation and related civil action, and in connection with the Settlement Agreement, we also have reached tentative agreements that, if executed by participating states, resolve previously disclosed related investigations conducted by certain state attorneys general. Under the Settlement Agreement, and the tentative agreements with the participating states, we are required to make an initial payment of $2.5 million, of which we paid $2.4 million in December 2020 and will pay the remaining $0.1 million when the agreements with the participating states are finalized. We also may be required to make additional payments in the future upon the achievement of revenue targets or consummating a change-in-control transaction. We also entered into a 5-year Corporate Integrity Agreement with the OIG. The Settlement Agreement does not include a release for any conduct other than the Covered Conduct or any criminal liability related to the Covered Conduct. The Settlement Agreement does not release any claims under investigation by the U.S. Securities and Exchange Commission. The DOJ criminal investigation and SEC investigation are ongoing, and we are cooperating with those investigations. These 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; fines and penalties for violation of our Corporate Integrity Agreement, 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. As previously disclosed, the Audit Committee found that we lacked documentation of sufficient detail and specificity regarding certain payments to physicians, ostensibly for training and consulting services, and as to three physicians did not accurately reflect the purpose and nature of approximately $300,000 of payments, which that could be perceived as an improper attempt to obtain business or to gain special advantage, and we subsequently entered into the Settlement Agreement with the DOJ relating to claims under the civil False Claims Act investigation concerning, among other things, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute. 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 for years after any resolution of these investigations and any resulting claims are resolved

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. Our ability to enroll patients in clinical trials, including our atherectomy indication trial, could be impacted by the COVID-19 outbreak, as many patients are electing or being asked to delay procedures at this time.

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 device 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 premarket 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. For example, the COVID-19 outbreak could affect the FDA's ability to review applications or supplements. Such delays or refusals could have a material adverse effect on our business, financial condition, and results of operations.

The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under

development or impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

Any regulatory clearances or approvals that we have received for our products will be subject to limitations on the cleared or approved indicated uses for which the product may be marketed and promoted or to the conditions of approval, or contain requirements for potentially costly post-marketing testing. We are required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing product safety issues could result in increased costs to assure compliance. The FDA and other agencies, including the DOJ, closely regulate and monitor the post-clearance or approval marketing and promotion of products to ensure that they are marketed and distributed only for the cleared or approved indications and in accordance with the provisions of the cleared or approved labeling. For example, the DOJ served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b.

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

If a regulatory agency discovers previously unknown problems with our products, 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 our products, such regulatory agency or enforcement authority may impose restrictions on that product or us, including requiring withdrawal of the product from the market. In addition to this type of penalty for failing 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. As disclosed previously, we settled a DOJ civil False Claims Act investigation concerning, among other things, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs.

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

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

The FDA and similar foreign governmental authorities have the authority to order the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions, or other adverse events, such as serious injuries or deaths, or quality-related issues such as manufacturing errors or design or labeling defects.

For example, we have conducted four recent recalls related to our DABRA and Pharos products. In August 2018 , we initiated a voluntary recall of our Pharos laser due to the potential for the laser to calibrate with the iris closed. This recall was classified as a Class II recall by FDA (a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote). The four affected lasers were corrected and a request for termination was submitted to the FDA in November 2018. In August 2019 , we initiated a voluntary recall of a limited number of Pharos lasers due to a software error that caused the device to fail at low doses. This recall was classified as a Class II recall by the FDA. The software was revised, and the affected lasers were corrected. A request for termination was submitted to the FDA in March 2020. In September 2019, we initiated a voluntary recall of our DABRA catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters, which we believe will significantly reduce the number of catheters that fail to calibrate. We submitted a request for termination to the FDA in February 2020, and as of July 2020, 98% of the affected product has been returned to us. Finally, a voluntary recall of DABRA lasers was initiated in January 2020 to correct a software issue that could result in user

or patient injury or may adversely impact laser performance. This recall was classified as a Class II recall by the FDA. This field correction is ongoing and is expected to complete in August 2020. In addition, in July 2020 we initiated a voluntary recall of our DABRA lasers to replace the wheels with lower profile wheels that were cleared by the FDA in the DABRA 510(k). We formally notified the FDA of this recall in accordance with applicable lawand expect it will be classified by the FDAin due course. This field correction is ongoing and is expected to be completed in the first quarter of 2021. Any government-mandated recall or additional voluntary recall by us could occur as a result of component failures, manufacturing errors, design or labeling defects or other issues. These voluntary recalls and any future recalls of our products could divert managerial and financial resources, harm our reputation and adversely affect our business.

In addition, the FDA conducted an unannounced facility inspection in December 2019. The FDA issued to us a Form 483 that included observations that schedules for the adjustment, cleaning, and other maintenance of equipment have not been adequately established, a device master record index was not current, and document control procedures have not been fully established. We responded to the FDA with the corrective measures we are taking and to address the issued identified in the Form 483 and, based on this information, the FDA issued to us an Establishment Inspection Report, or EIR, closing out the inspection. All actions are complete and the final Form 483 report was sent to the FDA on September 25, 2020.

Also, we have been engaged in additional shelf life testing at the FDA's request as part of a special 510(k). Due to recent variations noted in the shelf life of the catheter during our testing procedures, we have paused commercial sales of DABRA catheters not being used for the atherectomy clinical trial. We submitted additional test data in March 2021, which will need to be cleared by the FDA prior to resuming commercial shipments of catheters.

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

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

In addition, we are subject to medical device reporting regulations that require us to report to the FDA or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would be likely to cause or contribute to a death or serious injury if the malfunction recurred. After a May 2018 inspection, the FDA issued to us a Form 483 that included observations for failure to properly evaluate whether certain complaints related to Pharos and DABRA that we have received rose to a level required to be reported to the FDA. At that time, in response, we informed the FDA that we have modified our complaint review procedures and we completed a retrospective evaluation and have not found any complaints which require a submission to the FDA. We have not requested, and the FDA has not issued, an EIR related to this inspection. In connection with our Audit Committee investigation, the Audit Committee also found failures to properly identify reportable events or to file timely reports, as well as failure to address each of the May 2018 observations to FDA's satisfaction. Although we have since identified and made the appropriate reports to the FDA, these prior failures can subject us to sanctions and penalties, including warning letters and recalls.

Physicians, hospitals and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

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

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

If we or our suppliers 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 and our suppliers 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 or manufacturing processes or our suppliers' facilities or manufacturing processes are found to be in non-compliance or fail to take satisfactory corrective action in response to adverse QSR inspectional findings, FDA could take legal or regulatory enforcement actions against us and/or our products, including but not limited to the cessation of sales or the initiation of a recall of distributed products, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

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

approved products or necessitate the recall of distributed products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

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

Various claims, design features or performance characteristics of our medical devices, that we regarded as permitted by the FDA without new 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 clinical studies and marketing clearances or approvals, which could be lengthy, costly and possibly unobtainable.

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

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

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

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

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

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

In addition, the PPACA and the Medicare Access and CHIP Reauthorization Act of 2015 substantially changed the way healthcare is delivered and financed by both governmental and private insurers. These changes included the creation of demonstration programs and other value-based purchasing initiatives that provide financial incentives for physicians and hospitals to reduce costs, including incentives for furnishing low cost therapies for chronic wounds even if those therapies are less effective than our products. Under the Trump Administration, there were ongoing efforts to modify or repeal all or part of PPACA or take executive action that affects its implementation. Tax reform legislation was passed that includes provisions that impact healthcare insurance coverage and payment such as the elimination of the tax penalty for individuals who do not maintain health insurance coverage (the so-called "individual mandate"). Such actions or similar actions could have a negative effect on the utilization of our products. We are uncertain as to the extent such efforts will continue under the Biden administration and to what extent there will be additional reform proposals at federal and state levels. On December 18, 2019, the United States Court of Appeals for the Fifth Circuit upheld a lower court's determination in *Texas v. Azar*, 4:18-cv-00167, that the individual mandate was unconstitutional and remanded the case to the lower court for further analysis as to whether PPACA as a whole is unconstitutional because the individual mandate is not severable from other provisions of the law. In November 2020, the United States Supreme Court held oral arguments on the Fifth Circuit United States Court of Appeals decision that held that the individual mandate is unconstitutional. It is uncertain how the United States Supreme Court will rule on this case or how healthcare measures of the Biden administration will impact the PPACA and our business. Litigation and legislation over the PPACA are likely to continue, with unpredictable and uncertain results. We cannot predict the ultimate results of the *Texas* case or whether additional legislative reform proposals will be adopted, when they will be adopted, or what impact they may have on us, but any such proposals could have a negative impact on our business and provide incentives for hospitals and physicians to not use our products.

Other healthcare reform legislative changes have also been proposed and adopted in the U.S. since the PPACA 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, which, due to subsequent legislative amendments, will stay in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2021, unless additional congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue, attain profitability.

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

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

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

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

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

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

Demand for our products or new approved indications for our existing products may fluctuate over time if federal or state legislative or administrative policy changes affect coverage or reimbursement levels for our products or the services related to our products. In the U.S., there have been and we expect there will continue to be legislative and regulatory proposals to change the healthcare system, such as the potential repeal of the PPACA,

some of which could significantly affect our business. It is uncertain what impact the current U.S. presidential administration will have on healthcare spending. If enacted and implemented, any measures to restrict healthcare spending could result in decreased revenue from the sale of our products and decreased potential returns from our research and development initiatives. Other legislative or administrative reforms to the U.S. or international reimbursement systems in a manner that significantly reduces reimbursement for procedures performed using our products or denies coverage for those procedures could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

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

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

We have adopted a code of ethics and business conduct, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. For example, the Audit Committee investigation identified certain behavior inconsistent with the Company's Code of Ethics and Conduct and related policies. In addition, as discussed above, we entered into to a Settlement Agreement with the DOJ to resolve a civil investigation and related civil action, and in connection with the Settlement Agreement, entered into a 5-year Corporate Integrity Agreement with the OIG. We have, and will

continue to incur, costs related to compliance under, and payments made pursuant to, the Settlement Agreement and Corporate Integrity Agreement. These expenses and the diversion of the attention of the management team that has occurred, and is expected to continue, has adversely affected, and could continue to adversely affect, our business, financial condition, and results of operations. In the future. In addition, as disclosed above, there is an ongoing DOJ criminal investigation and an SEC investigation. If such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result ingovernment investigations, civil and criminal proceedings, 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. In the future, whether or not we are successful in defending against such further actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- federal false claims laws, including the federal False Claims Act, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, established new statutes imposing criminal healthcare fraud liability and increased civil monetary penalties for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the healthcare fraud statutes HIPAA established or specific intent to violate them in order to have a liability;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health, or HITECH, Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We believe we are not a covered entity for purposes of HIPAA, and we believe that we generally do not conduct our business in a manner that would cause us to be a business associate under HIPAA;
- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members. Effective January 2022, we will also be required to collect and report information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

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

Our Audit Committee identified certain conduct that may implicate healthcare laws and FDA regulatory requirements, including a failure to timely make at least two MDRs to the FDA, replacement of product held by customers, which constituted product recalls, but were not documented as such, a lack of sufficient documentation to support certain payments to physicians, and as to three physicians did not accurately reflect the purpose and nature of the payments, instructions to salespeople to characterize DABRA as performing atherectomy and encouragement to doctors to seek reimbursement using atherectomy codes, and direction of potentially valuable benefits and opportunities to doctors that were informed in part by sales prospects. As disclosed above, we entered into a Settlement Agreement with the DOJ to resolve a civil investigation and related civil complaint concerning Covered Conduct. Also as disclosed above, the DOJ is conducting a criminal investigation and the SEC a civil investigation. We are cooperating with both investigations.

We have undertaken efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations. Such efforts may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment,

exclusion of product candidates from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occurs, it could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Intellectual property rights do not necessarily address all potential threats.

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

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

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

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

Risks Related to Our Reliance on Third Parties

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

We are currently experiencing inconsistencies in our DABRA catheter performance as more fully described in the risk factor entitled "—We are experiencing inconsistencies in our DABRA catheter performance, including shelf life and non-calibrations. This and any other development or manufacturing problems or delays that could limit the potential growth of our revenue or increase our losses." In addition to the inconsistencies and risks described in the foregoing risk factor, we may encounter unforeseen situations that would result in delays or shortfalls in manufacturing. Key components and sub-assemblies of DABRA and Pharos are currently provided by a limited number of suppliers, and we do not maintain large inventory levels of these components and sub-assemblies. For example, we rely on a limited number of suppliers for the 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

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

Prior to our listing on the NYSE in September 2018, there was no public market for shares of our common stock. Although our common stock is listed on the NYSE American, 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 report, these factors include:

- increased expenses from remedying the performance issues of our catheters;
- our failure to increase the sales of our products, specifically DABRA and remedy the performance issues associated with our DABRA catheters;
- the failure by our customers to obtain adequate reimbursements or reimbursement levels that would be sufficient to support product sales to our customers and pricing of our products to support revenue projections;
- unanticipated serious safety concerns related to the use of our products;
- changes in our organization;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our future growth;
- the size and growth of our target markets;
- actual or anticipated variations in quarterly operating results;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including stockholder litigation, government actions or litigation related to intellectual property;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- any delay in any regulatory filings for our future products and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such products;
- adverse regulatory decisions, including failure to receive regulatory approval of our future products, failure to maintain regulatory approval for our existing products or failure to obtain regulatory approval for additional indications for our existing products;
- changes in laws or regulations applicable to our products;
- adverse developments concerning our suppliers or distributors;

- our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices;
- our inability to establish and maintain collaborations if needed;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of large blocks of our common stock including sales by our executive officers and directors;
- trading volume of our common stock;
- limited "public float" in the hands of a small number of persons whose sales or lack of sales of our common stock could result in positive or negative pricing pressure on the market price for our common stock;
- additions or departures of key scientific or management personnel;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

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

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

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

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

- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- changes in FDA regulations and comparable foreign regulations;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

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

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

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

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

As of December 31, 2020, we had net operating loss carryforwards, or NOLs, of approximately $14.3 million for federal income tax purposes, and $13.4 million for state income tax purposes. The federal net operating loss can be carried forward indefinitely and the state net operating losses begin expiring in 2032. 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 completed an IRC Section 382 analysis regarding the limitation of net operating losses through December 31, 2020 and determined that an ownership change occurred in May 2020. The effect of the ownership change is reflected in the NOL balances as of December 31, 2020. The Company calculated the limitation on net operating losses and other tax attributes and reduced the value of the deferred tax assets resulting in a tax expense impact of $20.8M. The tax expense was offset by tax benefit recorded on the reduction in valuation allowance recorded for the deferred tax assets for the year ended December 31, 2020. 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. Ownership changes that materially limit our use of our historical NOLs could harm our future operating results by effectively increasing our future tax obligations. In addition, as a result of the Tax Cuts and Jobs Act of 2017, as modified by the recently enacted Coronavirus Aid, Relief, and Economic Security Act of 2020, or CARES Act, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely and deductibility of federal NOLs generally may be limited in future years.

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 their own legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

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

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

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

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

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

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

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

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of December 31, 2020, we had outstanding 3,188,679 shares of our common stock.

In connection with our May 2020 and August 2020 equity offerings, we issued warrants to investors and our placement agent, and an aggregate of 2,345,033 warrants are outstanding as of December 31, 2020. In addition, pursuant to our 2018 Equity Incentive Plan, or 2018 Plan, equity incentive awards representing up to an aggregate of 110,329 shares of our common stock were available for issuance to our employees, directors and consultants as of December 31, 2020. 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 19,463 shares were available for sale under our ESPP as of December 31, 2020. 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. In addition to the increase in shares available to grant in 2020 due to the "evergreen" provisions contained in the 2018 Plan and the ESPP, in the first quarter of 2020 we adopted the 2020 Inducement Equity Incentive Plan (or, the 2020 Plan) for the purpose of attracting, retaining and incentivizing employees in furtherance of our success. On adoption, 32,000 shares of common stock were reserved solely for the granting of inducement stock options, restricted stock, restricted stock units and other awards and 9,000 shares were available for issuance as of December 31, 2020. 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 certificate of incorporation and 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 certificate of incorporation relating to the issuance of preferred stock and management of our business or our 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 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 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 certificate of incorporation and 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 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 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 certificate of incorporation or our bylaws; any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our 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. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

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 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.

If we fail to comply with the continued listing standards of the NYSE American, our common stock could be delisted. If it is delisted, the market value and the liquidity of our common stock would be impacted.

We recently transferred the listing of our common stock from the NYSE to the NYSE American. The continued listing of our common stock on NYSE American is contingent on our continued compliance with a number of listing standards. In order to maintain this listing, we must maintain certain share prices, financial and share distribution targets, including maintaining a minimum amount of shareholders' equity and a minimum number of public shareholders. In addition to these objective standards, the NYSE American may delist the securities of any issuer: (i) if, in its opinion, the issuer's financial condition and/or operating results appear unsatisfactory; (ii) if it appears that the extent of public distribution or the aggregate market value of the security has become so reduced as to make continued listing on the NYSE American inadvisable; (iii) if the issuer sells or disposes of principal operating assets or ceases to be an operating company; (iv) if an issuer fails to comply with the NYSE American's listing requirements; (v) if an issuer's common stock sells at what the NYSE American considers a "low selling price" and the issuer fails to correct this via a reverse split of shares after notification by the NYSE American; or (vi) if any other event occurs or any condition exists which makes continued listing on the NYSE American, in its opinion, inadvisable. There is no assurance that we will remain in compliance with these standards.

Delisting from NYSE American would adversely affect our ability to raise additional financing through the public or private sale of equity securities, significantly affect the ability of investors to trade our securities and

negatively affect the value and liquidity of our common stock. Delisting also could limit our strategic alternatives and attractiveness to potential counterparties and have other negative results, including the potential loss of employee confidence, decreased analyst coverage of our securities, the loss of institutional investors or interest in business development opportunities. Moreover, we committed in connection with the sale of securities to use commercially reasonable efforts to maintain the listing of our common stock during such time that certain warrants are outstanding.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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

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

ITEM 3. LEGAL PROCEEDINGS

Securities Litigation

On June 7, 2019, a putative securities class action complaint captioned *Derr v. Ra Medical Systems, Inc., et. al.,* (Civil Action no. 19CV1079 LAB NLS) was filed in the United States District Court for the Southern District of California against us, certain current and former officers and directors, and certain underwriters of our IPO. Following the appointment of a lead plaintiff and the filing of a subsequent amended complaint, the lawsuit alleges that the defendants made material misstatements or omissions in our registration statement in violation of Sections 11 and 15 of the Securities Act of 1933 and between September 27, 2018 and November 27, 2019, inclusive, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. Management intends to vigorously defend against this lawsuit. On March 11, 2020, lead plaintiffs voluntarily dismissed the underwriter defendants without prejudice. On March 13, 2020, defendants filed a motion to dismiss the amended complaint. On July 14, 2020, the court informed the parties that the motion to dismiss is suitable for decision without oral argument. At this time, we cannot predict how a court or jury will rule on the merits of the claims and/or the scope of the potential loss in the event of an adverse outcome. Should we ultimately be found liable, the liability could have a material adverse effect on our financial condition and our results of operations for the period or periods in which it is incurred.

On October 1, 2019, a shareholder derivative complaint captioned *Noel Borg v. Dean Irwin, et. al* (Civil Action no. 1:99-cm-09999) was filed in the United States District Court for the District of Delaware against certain current and former officers and directors, purportedly on behalf of the Company, which is named as a nominal defendant in the action. The complaint alleges breaches of fiduciary duty, unjust enrichment, waste, and violations of Section 14(a) of the Securities Exchange Act of 1934. On October 21, 2019, pursuant to the parties' stipulation, the court stayed the derivative lawsuit until the related class action is resolved. While we have obligations to indemnify and/or advance the defendants' legal fees and costs in connection with this lawsuit, any monetary recovery from the defendants would be to the benefit of us.

Government Investigations

As previously announced in the Form 8-K filed on August 12, 2019, the Audit Committee of Ra Medical's Board of Directors (the "Audit Committee") conducted an investigation of certain allegations raised by a former employee. We announced the Audit Committee's findings in the Form 8-K filed on October 31, 2019. The primary investigative findings were: (i) the DABRA catheter frequently failed to calibrate and occasionally overheated,

posing a risk of injury to physicians and patients; (ii) our explanations regarding our fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because they did not explicitly reference inconsistent DABRA catheter performance and catheter failures; (iii) we failed to timely make at least two Medical Device Reports, or MDRs, to the FDA; (iv) we, out of a concern for the DABRA catheters' performance, engaged in systematic efforts to replace product held by customers, which constituted product recalls, but were not documented as such, (v) we lack documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, and as to three physicians did not accurately reflect the purpose and nature of approximately $300,000 of payments, which could be perceived as an improper attempt to obtain business or to gain special advantage, (vi) while the indication for use in the 510(k) clearance we obtained for the DABRA system is not for atherectomy, our salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes, (vii) our determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects, and (viii) we received complaints regarding regulatory or compliance concerns that, because they implicated executive officers, should have been brought to the attention of the Board or the Audit Committee, but were not. The Audit Committee, in reviewing the allegations, identified certain behavior inconsistent with our Code of Ethics and Conduct and related policies.

On December 28, 2020, we entered into a Settlement Agreement with the United States of America, acting through the DOJ and on behalf of the OIG, to resolve the pending DOJ investigation and a related civil action concerning our marketing of the DABRA laser system and DABRA-related remuneration to certain physicians. In connection with the Settlement Agreement, we also have reached tentative agreements that, if executed by participating states, resolve previously disclosed related investigations conducted by certain state attorneys general.

The Settlement Agreement recites that a complaint filed by a former employee on behalf of the federal government in the United States District Court for the Eastern District of Michigan, and subsequently amended to assert claims on behalf of certain states, alleged, among other things, that we violated the False Claims Act, 31 U.S.C. § 3729, and certain state false claims acts by paying kickbacks to certain physicians in order to induce them to use the DABRA laser system, promoting off-label use of the DABRA laser system, failing to report adverse events to the United States Food and Drug Administration, marketing a device that does not work as advertised, and failing to adhere to Current Good Manufacturing Practices. The complaint, which was settled in connection with the Settlement Agreement, also alleged that we unlawfully retaliated against the former employee. Separate from the former employee's allegations in the civil action, the United States and the participating states contend that from May 1, 2017 through October 31, 2019, we (a) paid illegal remuneration to certain physicians to induce them to use the DABRA laser system in violation of the federal anti-kickback statute and (b) marketed the DABRA laser system for off-label use in atherectomy procedures despite product performance issues causing calibration and overheating problems, which posed a risk to physicians and patients (the "Covered Conduct"). We deny the allegations in the civil action and those asserted by the United States and the participating states, and the settlement does not constitute an admission of liability or wrongdoing by us.

Under the Settlement Agreement, and the tentative agreements with the participating states, we are required to make an initial payment of $2.5 million, of which we paid $2.4 million in December 2020 and will pay the remaining $0.1 million when the agreements with the participating states are finalized. Pursuant to the terms of the Settlement Agreement, (a) if our revenue exceeds $10 million in any of the next four fiscal years (2021-2024), we also are required to pay an additional amount in settlement for the corresponding year: $500,000 for 2021, $750,000 for 2022, $1 million for 2023, and $1.25 million for 2024; (b) if we are acquired or are otherwise involved in a change in control transaction in the years 2020 through 2024, we are required to pay an additional settlement amount of $5 million, plus 4% of the value attributed to us in the transaction, so long as the attributed value is in excess of $100 million, with the total change in control payment never to exceed $28 million; and (c) if our obligations under the Settlement Agreement are avoided by bankruptcy, the United States may rescind the releases and bring an action against us in which we agree is not subject to an automatic stay, is not subject to any statute of limitations, estoppel or laches defense, and is a valid claim in the amount of $56 million, minus any prior change in control payments. Under the Settlement Agreement, we also paid the former employee's reasonable expenses, costs and attorneys' fees, which amount to $0.2 million.

The OIG has agreed, conditioned upon our full payment of amounts owed in the Settlement Agreement, and in consideration of our obligations under a Corporate Integrity Agreement, to release our permissive exclusion rights and refrain from instituting any administrative action seeking to exclude us from participating in Medicare, Medicaid, or other federal health care programs as a result of the Covered Conduct. The Corporate Integrity Agreement has a five-year term and imposes monitoring, reporting, certification, documentation, oversight, screening, and training obligations on us, including the hiring of a compliance officer and independent review organization.

Pursuant to the terms of the Settlement Agreement, the United States and the former employee have dismissed the complaint against us with prejudice, and have released us from any civil or administrative monetary liability arising under the Covered Conduct. The Settlement Agreement does not include a release for any conduct other than the Covered Conduct or any criminal liability related to the Covered Conduct. The Settlement Agreement does not release any claims under investigation by the SEC.

As also previously announced, we voluntarily contacted the SEC's Enforcement Division regarding the Audit Committee's investigation. On November 13, 2019, the SEC notified us that it is conducting an investigation. We have been, and intend to continue, cooperating with the SEC in its ongoing investigation. We are unable to predict the ultimate outcome, and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

On November 21, 2019, we became aware that the Criminal Division, Fraud Section of the U.S. Department of Justice has an open investigation related to us. At this time, it is unclear if we are a target in this investigation. We have been, and intend to continue, cooperating with the DOJ in its active and ongoing investigation. We are unable to predict the ultimate outcome, and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

Other Litigation

On August 30, 2018, Strata Skin Sciences, Inc. ("Strata") and Uri Geiger, a member of the board of directors of Strata Skin Sciences, Inc. (collectively "Strata") filed an action against us in Court of Common Pleas of Montgomery County, Pennsylvania (Civil Action No. 18-21421) (the "Pennsylvania Case"), requesting declaratory relief that: (1) Strata and Mr. Geiger are not liable for tortious interference, defamation, libel, or unfair competition based on an e-mail by Mr. Geiger to an investment bank (the "Geiger Email"); (2) Strata and Mr. Geiger made no actionable statements about us to such investment bank; (3) we cannot enforce the 2011 settlement and release agreement between us and PhotoMedex, Inc. ("Settlement Agreement") against Strata; and (4) that any dispute regarding the Geiger Email does not relate to the Settlement Agreement. The action filed by Strata and Mr. Geiger does not request any monetary damages.

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

On August 11, 2020, we and the Strata Parties executed a settlement agreement, dated as of August 6, 2020, that includes a mutual release of claims and an agreement to terminate the Pennsylvania Case and the California Case.

On February 12, 2020, Dean Irwin,our former Chief Executive Officer, filed a Demand for Arbitration, alleging thatwe attempted to coerce him into signing a non-standard separation agreement and release of claims, contrary to the terms of his Severance Agreement. Mr. Irwin claims that he was willing to sign our standard separation agreement and release of claims. Based on this allegation, Mr. Irwin is claiming nonpayment of wages, penalties for nonpayment of wages, failure to provide wage statements, breach of contract, and breach of implied covenant of good faith and fair dealing. On December 21, 2020, the arbitrator granted summary judgment in favor of the Company on four of the five issues raised by Mr. Irwin in the arbitration. The Company and Mr. Irwin executed a settlement agreement, effective as of January 19, 2021, whereby the Company paid Mr. Irwin $265,000 in exchange for a mutual release of claims and dismissal of the arbitration.

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II — FINANCIAL INFORMATION

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

Market Information and Holders

Our common stock is traded on the NYSE American under the symbol "RMED."

On March 10, 2021, the last reported sales price of our common stock was $5.95 and, according to our transfer agent, as of March 10, 2021, there were 68 record holders of our common stock. The actual number of stockholders is greater than the number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust or by other entities.

Dividend Policy

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On September 26, 2018, our Registration Statement on Form S-1 (File No. 333-226191) relating to our initial public offering was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 179,400 shares of our common stock, including 23,400 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a price of $425.00 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.

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

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

As discussed elsewhere in this Annual Report on Form 10-K, we are currently focusing onsupplying catheters to those sites involved in our atherectomy clinical study while we prioritize remedying the inconsistencies in our DABRA catheter performance. Accordingly, we intend to use the remainder of the net proceeds for these and other general corporate purposes, including atherectomy indication clinical trial.

Recent Repurchases of Equity Securities

None.

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

Ra Medical Systems, Inc. is a commercial-stage medical device company leveraging our advanced excimer laser-based platform for use in the treatment of vascular and dermatological immune-mediated inflammatory diseases. We believe our products enhance patients' quality of life by restoring blood-flow in arteries and clearing chronic skin conditions.

The DABRA laser and single-use catheter, together referred to as DABRA, is used as a tool in the treatment of peripheral artery disease, or PAD, which commonly occurs in the legs. 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 was also granted CE mark approval in Europe in September 2016 for the endovascular treatment of infrainguinal arteries via atherectomy and for crossing total occlusions.

Our vascular business strategy is focused on multiple engineering efforts to improve our catheter offering as well as conducting a clinical study to obtain an atherectomy "indication for use" in the United States. Key catheter engineering efforts currently underway include projects to:

- Extend our catheter's shelf life. During 2020, we identified the factors limiting our shelf life, including the introduction of unwanted elements in the catheter's fluid core and the degradation of the coating on the inner diameter, and are currently implementing multiple remediations to address these issues. Our initial internal accelerated aging test data supports shelf life for our catheter of at least six months;
- Increase the robustness of our catheter via a braided overjacket, or a similar design, to make the catheter more kink-resistant when navigating tortuous anatomy. We expect to complete the engineering work for this catheter in the second half of 2021 and subsequently submit to the FDA for clearance; and
- Develop a version of the DABRA catheter that is compatible with a standard guidewire. We completed several guidewire-compatible catheter prototypes in the fourth quarter of 2020 and then conducted in vitro evaluations with several physicians. We expect to finalize the design for this catheter at the end of 2021 and subsequently submit to the FDA for clearance.

As stated, we are currently pursuing an atherectomy indication for use, which the FDA defines to include a prespecified improvement in luminal patency. To satisfy the FDA's data requirements to support an atherectomy indication, we are performing a pivotal study designed to allow the FDA to evaluate the use of DABRA in atherectomy procedures. We received an Investigational Device Exemption, or IDE, approval in January 2020 and the study is approved for up to 10 clinical sites and 100 subjects.

We enrolled the first subject in February 2020. Throughout much of 2020, the COVID-19 pandemic substantially impacted our ability to activate new sites and enroll additional subjects. Many sites or potential sites have been or are currently operating at a reduced capacity, and some have been closed from time to time. In addition, potential study subjects may voluntarily opt to postpone their procedures due to COVID-19 concerns. As of December 31, 2020, we have enrolled 20 subjects and five sites have been cleared to enroll subjects. Due to the unpredictable impact the COVID-19 pandemic has had and will continue to have on enrollment in this study, we currently cannot estimate when enrollment will be completed.

We are continuing to supply catheters to those sites involved in our atherectomy clinical study. We have paused shipments of catheters to commercial sites while we conduct further studies on the stability of our shelf life.

We submitted additional test data in March 2021, which will need to be cleared by the FDA prior to resuming commercial shipments of catheters. We do not anticipate rebuilding our vascular sales team until most of our engineering projects are complete and we have a more definitive timeline for obtaining an atherectomy indication.

Our Pharos laser is a medical device that we have marketed since October 2004 as a tool for the treatment of proliferative skin conditions including psoriasis, vitiligo, atopic dermatitis, and leukoderma. The COVID-19 pandemic is negatively impacting the dermatology business as many customers delay the acquisition or purchase of capital equipment such as our PHAROS laser. Because this business does not have a disposables component and we augment our capital equipment sales with recurring revenue derived from service and/or rental or lease agreements, we are experiencing less of an impact than business models that rely solely on capital equipment and/or disposables sales. We continue to evaluate our overall strategy for the dermatology business and believe there could be an opportunity to grow revenues and increase its cash contribution in the future. Changes to our dermatology business strategy, as well as the timing of those potential changes, will be influenced by the continued impact of the COVID-19 pandemic.

Recent Developments

COVID-19

The global spread of the novel coronavirus (COVID-19) has created significant volatility, uncertainty and economic disruption. The ultimate effects of the COVID-19 on our business, operations and financial condition are unknown at this time. In the near term, we expect that our revenue will continue to be adversely impacted and enrollment in our atherectomy clinical trial will continue to be delayed or slowed, as patients elect to postpone voluntary treatments and physicians' offices are either closed or operating at a reduced capacity. In addition, some customers are requesting more flexible payment terms on a temporary basis. We also may not be able to secure additional financing in a timely manner or on favorable terms, if at all. Our manufacturing facility located in Carlsbad, California is currently operational. Employee travel is limited to essential travel only and many employees are working from home when feasible. We have experienced minor delays in receiving shipments of parts, which has affected the timing of our key engineering efforts. To date, the shipment delays have not had a material impact on our ability to support our atherectomy indication trial. However, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain it or treat its impact, among others.

Reverse Stock Split

On November 16, 2020, we filed a certificate of amendment to the Certificate of Incorporation with the Secretary of State of the State of Delaware to effect a reverse stock split of our Common Stock at a ratio of one-for-twenty-five, or the Reverse Stock Split. The Reverse Stock Split became effective as of 4:01 p.m. Eastern time on November 16, 2020, and our Common Stock began trading on the New York Stock Exchange on a post-split basis on November 17, 2020. Unless otherwise noted, all share and per share numbers contained in this annual report are reflected on a post-split basis for all periods presented.

NYSE American

On December 17, 2020, we received approval to list our Common Stock on the NYSE American and provided written notice to the New York Stock Exchange, or the NYSE, of our intention to list our Common Stock on NYSE American and to simultaneously delist such securities from the NYSE. Our final day trading on the NYSE was on December 21, 2020 and we commenced trading on NYSE American on December 22, 2020 under our current stock symbol "RMED."

Components of our Results of Operations

Net revenue

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

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

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

Cost of revenue and gross profit (loss)

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

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

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

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

Research and development expenses

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

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

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

Selling, general and administrative expenses

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

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

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

	Years Ended December 31,		
	2020	2019	Change $
Statements of operations data:			
Net revenue			
Product sales	$ 1,407	$ 3,859	$ (2,452)
Service and other	2,998	3,340	(342)
Total net revenue	4,405	7,199	(2,794)
Cost of revenue			
Product sales	2,890	5,856	(2,966)
Service and other	2,592	2,994	(402)
Total cost of revenue	5,482	8,850	(3,368)
Gross (loss) profit	(1,077)	(1,651)	574
Operating expenses:			
Selling, general and administrative	25,974	51,549	(25,575)
Research and development	9,008	4,530	4,478
Total operating expenses	34,982	56,079	(21,097)
Operating loss	(36,059)	(57,730)	21,671
Other income, net	21	788	(767)
Loss before income taxes	(36,038)	(56,942)	20,904
Income tax expense	7	15	(8)
Net loss	$ (36,045)	$ (56,957)	$ 20,912

Comparison of years ended December 31, 2020, and 2019—By reportable segments

We organize our business into two operating segments based on the product specialties: the vascular segment and the dermatology segment. In deciding how to allocate resources and assess performance, we regularly evaluate the net revenue and gross profit (loss) of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to us and not specific to a particular segment; therefore, these amounts are not evaluated by us on a segmented basis. Additional information on our reportable segments is contained in Note 16 to the financial statements appearing elsewhere in this Annual Report on Form 10-K.

Net revenue

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

	Years Ended December 31,		
	2020	2019	Change $
Vascular	$ 259	$ 1,275	$ (1,016)
Dermatology	4,146	5,924	(1,778)
Total net revenue	$ 4,405	$ 7,199	$ (2,794)

Vascular

Net revenue was $0.3 million and $1.3 million for the years ended December 31, 2020 and 2019, respectively. The decrease of approximately $1.0 million was due to decreased catheter unit sales.

We do not expect our net revenue to increase in the near term as we sell catheters only to support our atherectomy clinical study while we focus on remedying the inconsistencies in our DABRA catheter performance and obtaining an atherectomy indication. In addition, we expect net revenue to continue to be negatively impacted by the COVID-19 pandemic, as patients elect to postpone voluntary treatments and physicians' offices are either closed or operating at a reduced capacity. Over the longer term, if we are able to extend the shelf life, introduce design changes to the catheter and obtain an atherectomy indication, we believe we will be able to increase our vascular revenue.

Dermatology

Net revenue was $4.1 million and $5.9 million for the years ended December 31, 2020 and 2019, respectively. The decrease of approximately $1.8 million was due primarily to a decrease of $1.5 million in direct unit product sales and $0.3 million in service revenue due to less activity as a result of COVID-19.

Cost of revenue

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

	Years Ended December 31,		
	2020	2019	Change $
Vascular	$ 1,970	$ 4,036	$ (2,066)
Dermatology	3,512	4,814	(1,302)
Total cost of revenue	$ 5,482	$ 8,850	$ (3,368)

Vascular

Cost of revenue was $2.0 million and $4.0 million for the years ended December 31, 2020 and 2019. The $2.0 million decrease was due to (i) decreased unit sales, (ii) decrease in warranty costs of replacement units, (iii) decrease in stock-based compensation expense, partially offset by increased expenses related to quality enhancement initiatives.

Dermatology

Cost of revenue was $3.5 million and $4.8 million for the years ended December 31, 2020 and 2019, respectively. The decrease of $1.3 million was due to a decrease in direct unit product sales and decreased service costs due to less activity from COVID-19, decreased stock-based compensation expense, partially offset by increased expenses related to quality enhancement initiatives.

Gross (loss) profit

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

	Years Ended December 31,		
	2020	2019	Change $
Vascular	$ (1,711)	$ (2,761)	$ 1,050
Dermatology	634	1,110	(476)
Total gross (loss) profit	$ (1,077)	$ (1,651)	$ 574

Vascular

Gross loss was $1.7 million and $2.8 million for the year ended December 31, 2020 and 2019. The $1.1 million decrease in gross loss was primarily due to a decrease in warranty costs of replacement units and decreased stock-based compensation expense, partially offset by increased labor costs due to quality enhancement initiatives and increased overhead due to operating under capacity.

We expect our gross loss to be negatively impacted in the short term as we sell catheters only to support our atherectomy clinical study while we continue efforts to remedy the inconsistencies in our DABRA catheter performance and obtain an atherectomy indication. In addition, we expect the gross loss to continue to be negatively impacted by the COVID-19 pandemic, as patients elect to postpone voluntary treatments and physicians' offices are either closed or operating at a reduced capacity.

Dermatology

Gross profit was $0.6 million and $1.1 million for the years ended December 31, 2020 and 2019, respectively. The decrease of $0.5 million was primarily due to increased labor costs due to quality enhancement initiatives and increased overhead due to operating under capacity.

We expect the gross profit to continue to be negatively impacted by the COVID-19 pandemic, as patients elect to postpone voluntary treatments and physicians' offices are either closed or operating at a reduced capacity.

Comparison of years ended December 31, 2020, and 2019—General

Selling, general and administrative expenses. SG&A expenses were $26.0 million and $51.5 million for the years ended December 31, 2020 and 2019, respectively. The $25.5 million decrease was to primarily related to decreases of (i) $17.1 million in stock-based compensation expense, (ii) $4.9 million in salary, benefits, recruiting expenses and other personnel-related costs primarily due to reductions in our sales force, (iii) $3.9 million in travel and trade shows, sales related costs, and marketing, (iv) $0.4 million in legal expense, which represents accruals for loss contingencies, primarily due a $2.7 million settlement for the DOJ False Claims Act investigation, and other litigation matters, offset by decreases in legal services and (v) $0.2 million in other expenses, partially offset by increased insurance expense of $1.0 million.

Research and development expenses. R&D expenses were $9.0 million and $4.5 million for the years ended December 31, 2020 and 2019, respectively. The $4.5 million increase was primarily due to increases of $3.1 million in personnel and consulting expenses, $2.1 million in supplies and $0.4 million in other costs, including clinical study expenses, partially offset by decreases of $1.1 million primarily related to stock-based compensation expense. These increases are due to engineering efforts on our next-generation catheters, including increased shelf life and improved deliverability, and also progress on the atherectomy clinical study.

Other income (expense), net. Other income (expense), net was net other income of $21,000 and $0.8 million for the years ended December 31, 2020 and 2019, respectively. The decrease of $0.8 million is primarily due to a decrease of interest income due to a decrease in cash and cash equivalents during the comparable periods and a decrease in interest expense primarily related to the significant financing component for multi-year warranty service contracts.

Non-GAAP Measures

EBITDA and Adjusted EBITDA are performance measures that provide supplemental information we believe is useful to analysts and investors to evaluate our ongoing results of operations, when considered alongside other GAAP measures. These Non-GAAP Measures exclude the financial impact of items management does not consider in assessing our ongoing operating performance, and thereby facilitate review of our operating performance on a period-to-period basis.

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

- EBITDA excludes certain recurring, non-cash charges such as depreciation and amortization of long-lived assets, although these are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future; and

- Adjusted EBITDA further excludes stock-based compensation expense, which has been, and will continue to be for the foreseeable future, a significant recurring expense in our business and an important part of our compensation strategy.

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

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

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

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Statements of Operations Data:		
Net loss	$ (36,045)	$ (56,957)
Depreciation and amortization	2,365	1,750
Interest income	(129)	(1,038)
Interest expense	108	250
Income tax expense	7	15
EBITDA	(33,694)	(55,980)
Stock-based compensation	4,082	23,543
Adjusted EBITDA	$ (29,612)	$ (32,437)

Adjusted EBITDA was negative $29.6 million compared to negative $32.4 million for the years ended December 31, 2020 and 2019, respectively. The change in Adjusted EBITDA reflects decreased selling, general and administrative expenses, including salary, benefits and travel, due to reduced personnel, offset by increased research and development expenses and increased costs and loss estimates related to the ongoing litigation.

Liquidity and Capital Resources

As of December 31, 2020, we had cash and cash equivalents of $23.9 million and an accumulated deficit of $153.2 million. Our primary sources of capital have been from the sale of our products and services, the net proceeds of $67.3 million from our initial public offering, the net proceeds of $19.1 million from our 2020 public offerings and, to a lesser extent, private placements of common stock and equipment financing arrangements.

In May 2020, we entered into a $2.0 million Paycheck Protection Program Promissory Note and Agreement ("PPP Promissory Note") with a commercial bank under the Coronavirus Aid Relief, and Economic Security Act. The PPP Promissory Note bears interest at 1.0% per annum. Under the terms of the PPP Promissory Note, payments would be due monthly beginning November 1, 2020 and the principal amount of the PPP Promissory Note along with any unpaid interest would be due on May 3, 2022. On June 5, 2020, the Paycheck Protection Program Flexibility Act of 2020 (the "PPPFA") extended the deferral period for all loans to 10 months after the last day of the covered period. Under the revised terms, payments are due beginning August 2021 and the principal amount along with unpaid interest is due in July 2023. We have requested from our lender an extension of the loan maturity from two years to five years as permitted under the PPPFA. The principal and interest may be forgiven if the proceeds are used for forgivable purposes as defined by the terms in the PPP Promissory Note, and we believe we have used the proceeds from the PPP Promissory Note for forgivable purposes as defined by the terms of the PPP Promissory Note. It is our intent to apply for forgiveness under the provisions of the CARES Act. Forgiveness is subject to the sole approval of the Small Business Administration.

Management expects operating losses and negative cash flows to continue for the foreseeable future withour reduced commercial footprint, and as we continue to incur costs related to our atherectomy clinicaltrial, engineering efforts to improve the shelf-lifeof our catheters, and develop next generation products and legal costs associated with ongoing litigation. We also expect the COVID-19 pandemic to have a continued negative impact on its revenue and the timing of enrollment in its atherectomy clinical trial as well as the Company's ability to secure additional financing in a timely manner or on favorable terms, if at all. In the third quarter of 2019, we began implementing certain operational efficiency and cost savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives included targeted workforce reductions of our sales and marketing teams. We reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to five clinical specialists as of December 31, 2020. In addition, we may need to decrease or defer capital expenditures and development activities to further optimize our operations. Such measures may impair our ability to invest in developing, marketing and selling new and existing products.

We are incurring additional costs as a result of operating as a public company, including increases in legal, accounting, insurance and other expenses. Additionally, we expect legal and related expenses to remain high in the near term in connection with the legal proceedings discussed in Note 15, "Commitments and Contingencies," in the notes to the financial statements.

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

- our ability to complete our atherectomy trial in a timely manner or at all, which may be affected by reductions in voluntary medical procedures during the ongoing COVID-19 pandemic as well as by limitations in our DABRA catheter performance, as described above;
- the revenue generated by sales of our DABRA and Pharos products, related consumables, and other products that get approved in the U.S. and select non-U.S. markets, as well as the amount of sales personnel required to generate the revenue;
- our ability to remedy the inconsistencies in our DABRA catheter performance; including extended shelf life and reduce non-calibrations, reduced kinking, and identify future issues;
- our ability to further enhance our DABRA catheter performance with an improved design to make the catheter more kink-resistant when navigating tortuous anatomy;
- our ability to develop a guidewire-compatible version of our DABRA catheter designed to allow physicians to navigate the vasculature more easily;
- our ability to develop a larger diametercatheter to facilitate treatment of larger vessels more commonly seen in above-the-knee procedures;
- following our voluntary product recall, our ability to achieve market acceptance of DABRA;
- matters arising out of our completed Audit Committee investigation;
- the cost, timing and outcomes of any litigation involving our company, products, and business activities, including securities class actions and derivative lawsuits, and government investigations in which we are involved;
- the extent to which our products are adopted by the physician community;
- the ability of our customers to obtain adequate reimbursement from third-party payors for procedures performed using DABRA;
- the degree of success we experience in commercializing our excimer lasers and related consumables;
- the costs, timing and outcomes of any future clinical studies and regulatory reviews, including to seek and obtain approvals for new indications for our products;
- the costs and timing of developing variations of our excimer lasers, and, if necessary, obtaining FDA clearance to market such variations;
- the emergence of competing or complementary technologies;
- the number and types of future products we develop and commercialize;

- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the level of our selling, general and administrative expenses.

Although we bolstered our liquidity resources in 2020, have an effective shelf registration statement and an "at the market" offering to allow us to raise additional capital when the opportunities permit, and may receive additional funds from the exercise of its warrants depending on market conditions, management concluded that the aforementioned conditions, including the ongoing uncertainty related to the negative impacts of the COVID-19 pandemic, continue to raise substantial doubt about our ability to continue as a going concern within 12 months from the date of issuance of the financial statements. Our plans to address this uncertainty include raising additional funding, if necessary, through public or private equity or debt financings. However, we may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if we issue equity securities to raise additional funds, our existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of our existing stockholders.

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

Cash Flows

	Years Ended December 31,	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (28,304)	$ (33,173)
Investing activities	15,933	(16,032)
Financing activities	21,693	(526)
Net change in cash and cash equivalents	$ 9,322	$ (49,731)

Net cash used in operating activities

During the year ended December 31, 2020, net cash used in operating activities was $28.3 million, consisting primarily of a net loss of $36.0 million and a decrease in net operating assets of $1.0 million, partially offset by non-cash charges of $6.7 million consisting of primarily stock-based compensation expense and depreciation and amortization.

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

Net cash provided by (used in) investing activities

During the year ended December 31, 2020, net cash provided by investing activities was $15.9 million,consisting of $16.0 million from proceeds of maturities of investments offset by $0.1 million in purchases of equipment.

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

Net cash provided by (used in) financing activities

During the year ended December 31, 2020,net cash provided by financing activities was $21.7 million due toconsisting of $19.9 million proceeds, net of placement agent fees, received from our 2020 public offerings, $2.0

million proceeds under the PPP Promissory Note, and $0.8 million proceeds from the exercise of warrants, proceeds from issuance of common stock related to the employee stock purchase plan of $42,000, offset by payments of offering costs of $0.8 million and $0.3 million of payments on our financed equipment.

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

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, 2020, our contractual obligations due by period (in thousands):

	Payments due by period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations(1)	$ 3,323	$ 528	$ 877	$ 931	$ 987
Promissory note(2)	2,000	421	1,579	—	—
Equipment Financing(3)	265	265	—	—	—
Total	$ 5,588	$ 1,214	$ 2,456	$ 931	$ 987

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

(2) Consists of the Paycheck Protection Program Promissory Note, which we intend to apply for forgiveness under the provisions of the Coronavirus Aid, Relief, and Economic Security Act.

(3) 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.

Revenue recognition

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

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

We determine revenue recognition incorporating the following steps:

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

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

Catheter Revenue

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

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

Laser Sales

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

Warranty Service Revenue

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

Distributor Transactions

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

Contracts with multiple performance obligations

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

Significant Financing Component

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

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

Practical expedients elected

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

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

Contract Costs

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

Rental Income

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

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

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

Stock-based compensation

We evaluate whether an award should be classified and accounted for as a liability award or equity award for all stock-based compensation awards granted. There were no liability awards outstanding at December 31, 2020 or 2019.

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. The fair value of each share of underlying common stock is based on the closing price of our common stock as reported on the date of grant. Expected volatility is based on the historical volatilities of certain "guideline" companies.

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

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

Income taxes

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

We account for uncertainty in income taxes using a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining whether it is more likely

than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. An uncertain tax position is considered effectively settled on completion of an examination by a taxing authority if certain other conditions are satisfied. Should we incur interest and penalties relating to tax uncertainties, such amounts would be classified as a component of interest expense and other expense, respectively.

Jobs Act Accounting Election

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

New Accounting Pronouncements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Sensitivity

We had cash, cash equivalents of $23.9 million as of December 31, 2020, which came from sales of our products and services, the net proceeds from our initial public offering, the net proceeds of $19.1 million from our 2020 public offerings 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

Our revenue is denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is in the United States. As of December 31, 2020, 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, 2020. 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. Based upon our evaluation our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the year ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on the assessment, management has concluded that its internal control over financial reporting was effective as of December 31, 2020 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. Our independent registered public accounting firm, Deloitte & Touche LLP, is not required to and has not issued an attestation report as of December 31, 2020 due to a transition period established by the rules of the SEC for newly public companies that have not lost their "emerging growth company" status as defined in the JOBS Act.

Inherent Limitations on Effectiveness of Controls

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

ITEM 9B. OTHER INFORMATION

On January 31, 2021, Susanne Meline was appointed to the Board as a Class II director with a term expiring at the Company's 2023 annual meeting of stockholders, or until her successor has been duly elected and qualified. The appointment of Ms. Meline to the Board was reported under Item 5.02 of the Company's Current Report on Form 8-K filed with the SEC on February 4, 2021. At the time of her election, the Board had not decided upon which of the Board's committees Ms. Meline would serve. On March 12, 2021 the Board appointed Ms. Meline to serve on the Compensation Committee, effective immediately. In connection with this appointment, Ms. Meline will receive additional compensation of $7,000 per year, payable quarterly in arrears.

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 2021 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, 2020.

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 2021 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, 2020.

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 2021 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, 2020.

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

The information required by this item is incorporated by reference to our Proxy Statement relating to our 2021 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, 2020.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement relating to our 2021 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, 2020.

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	3.1	11/17/2020
4.1	Specimen common stock certificate of the Registrant.	S-1	333-226191	4.1	7/16/2018
4.2*	Description of Capital Stock				
10.1	Lease Agreement by and between the Registrant and Lloyd Wells Gift Trust dated November 24, 1987, for the premises located at 2070 Las Palmas Drive, Carlsbad, California 92011 dated as of August 17, 2017.	S-1	333-226191	10.1	7/16/2018
10.2+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-226191	10.2	8/24/2018
10.3+	Ra Medical Systems, Inc. 2018 Stock Compensation Plan and Forms of Award Agreement thereunder.	S-1	333-226191	10.3	7/16/2018
10.4+	Ra Medical Systems, Inc. 2018 Equity Incentive Plan and Forms of Award Agreement thereunder, as amended.	8-K	001-38677	99.1	10/13/2020
10.5+	Ra Medical Systems, Inc. 2018 Employee Stock Purchase Plan.	S-1	333-226191	10.5	9/17/2018
10.6+	Ra Medical Systems, Inc. Executive Incentive Compensation Plan.	S-1	333-226191	10.6	8/24/2018
10.7+	Ra Medical Systems, Inc. Form of At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement for executive officers.	S-1	333-226191	10.7	7/16/2018
10.8+	Change in Control and Severance Agreement, by and between the Registrant and Andrew Jackson, dated as of July 13, 2018.	S-1	333-226191	10.11	7/16/2018

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.9+	Change in Control and Severance Agreement, by and between the Registrant and Jeffrey Kraws, dated as of July 13, 2018.	S-1	333-226191	10.10	7/16/2018
10.10+	Change in Control and Severance Agreement, by and between the Registrant and Daniel Horwood, dated as of October 24, 2018.	10-Q	001-38677	10.1	11/14/2018
10.11+	Confirmatory Employment Letter, by and between the Registrant and Andrew Jackson, dated as of July 13, 2018.	S-1	333-226191	10.15	7/16/2018
10.12+	Confirmatory Employment Letter, by and between the Registrant and Jeffrey Kraws, dated as of September 12, 2018.	S-1	333-226191	10.14	9/17/2018
10.13+	Employment Letter by and between the Registrant and Daniel Horwood, dated as of October 12, 2018.	10-Q	001-38677	10.2	11/14/2018
10.14+	Change in Control and Severance Agreement, by and between the Registrant and Jonathan Will McGuire, dated as of March 30, 2020.	8-K	333-237701	10.11	4/16/2020
10.15+	Employment letter by and between the Registrant and Jonathan Will McGuire, dated as of March 9, 2020.	S-1	333-237701	10.15	4/16/2020
10.16	Paycheck Protection Program Promissory Note and Agreement as of May 3, 2020.	8-K	001-38677	10.1	5/7/2020
10.17	Form of Securities Purchase Agreement, dated as of May 20, 2020, by and among the Registrant and the purchasers named therein.	8-K	001-38677	10.1	5/22/2020
10.18	Form of Securities Purchase Agreement, dated as of July 30, 2020, by and among the Company and the purchasers named therein.	8-K	001-38677	10.1	8/3/2020

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.19*	Settlement Agreement, among the Company, among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services and the Defense Health Agency, acting on behalf of the TRICARE Program, and Robert Gruber, dated December 28, 2020.				
10.20*	Corporate Integrity Agreement, between the Company and the Office of Inspector General of the Department of Health and Human Services, dated December 28, 2020.				
23.1*	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (contained on signature page).				
31.1*	Certification of Principal 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 Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*^	Certifications of Principal 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 Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	XBRL Instance Document.				

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
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 16, 2021

By: /s/ Jonathan Will McGuire
Jonathan Will McGuire
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jonathan Will McGuire, Andrew Jackson and Daniel Horwood, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, to sign any and all amendments (including post-effective amendments) to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each of said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each of said attorneys-in-facts and agents, or his substitute or substitutes, or any of them, shall do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Jonathan Will McGuire Jonathan Will McGuire	Director and Chief Executive Officer (Principal Executive Officer)	March 16, 2021
/s/ Andrew Jackson Andrew Jackson	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 16, 2021
/s/ Martin Colombatto Martin Colombatto	Chairman of the Board of Directors	March 16, 2021
/s/ William R. Enquist, Jr. William R. Enquist, Jr.	Director	March 16, 2021
/s/ Richard Mejia, Jr. Richard Mejia, Jr.	Director	March 16, 2021
/s/ Susanne Meline Susanne Meline	Director	March 16, 2021
/s/ Mark E. Saad Mark E. Saad	Director	March 16, 2021
/s/ Joan Stafslien Joan Stafslien	Director	March 16, 2021

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, 2020 and 2019, the related statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2020 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

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

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ DELOITTE & TOUCHE LLP

San Diego, California
March 16, 2021

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, 2020	December 31, 2019
ASSETS		
Current Assets		
Cash and cash equivalents	$ 23,906	$ 14,584
Short-term investments	—	15,993
Accounts receivable, net	238	786
Inventories	2,218	2,777
Prepaid expenses and other current assets	1,258	1,860
Total current assets	27,620	36,000
Property and equipment, net	3,211	5,050
Operating lease right-of-use-assets	2,484	2,835
Other non-current assets	123	196
TOTAL ASSETS	$ 33,438	$ 44,081
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 571	$ 1,532
Accrued expenses	4,348	2,642
Current portion of deferred revenue	1,801	2,029
Current portion of equipment financing	265	293
Current portion of promissory note	421	—
Current portion of operating lease liabilities	356	318
Total current liabilities	7,762	6,814
Deferred revenue	686	1,232
Promissory note	1,579	—
Operating lease liabilities	2,264	2,620
Equipment financing	—	265
Total liabilities	12,291	10,931
Commitments and contingencies (Note 15)		
Stockholders' Equity		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized at December 31, 2020 and 2019; none issued	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized at December 31, 2020 and 2019; 3,188,679 and 550,814 issued and outstanding at December 31, 2020 and 2019, respectively	7	1
Additional paid-in capital	174,342	150,280
Accumulated deficit	(153,202)	(117,157)
Accumulated other comprehensive income	—	26
Total stockholders' equity	21,147	33,150
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 33,438	$ 44,081

See notes to financial statements.

Ra Medical Systems, Inc.

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

	Year Ended December 31,	
	2020	**2019**
Net revenue		
Product sales	$ 1,407	$ 3,859
Service and other	2,998	3,340
Total net revenue	4,405	7,199
Cost of revenue		
Product sales	2,890	5,856
Service and other	2,592	2,994
Total cost of revenue	5,482	8,850
Gross loss	(1,077)	(1,651)
Operating expenses		
Selling, general and administrative	25,974	51,549
Research and development	9,008	4,530
Total operating expenses	34,982	56,079
Operating loss	(36,059)	(57,730)
Other income (expense), net		
Interest income	129	1,038
Interest expense	(108)	(250)
Total other income (expense), net	21	788
Loss before income tax expense	(36,038)	(56,942)
Income tax expense	7	15
Net loss	(36,045)	(56,957)
Basic and diluted net loss per share	$ (21.22)	$ (108.28)
Basic and diluted weighted average common shares outstanding	1,699	526

See notes to financial statements.

Ra Medical Systems, Inc.

Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,	
	2020	**2019**
Net loss	$ (36,045)	$ (56,957)
Other comprehensive income:		
Unrealized (loss) gain related to short-term investments	(26)	26
Total other comprehensive income	$ (26)	$ 26
Comprehensive loss	$ (36,071)	$ (56,931)

See notes to financial statements.

Ra Medical Systems, Inc.

Statements of Stockholders' Equity
(in thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid- in- Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balances at January 1, 2019	508	$ 1	$ 126,925	$ —	$ (60,200)	$ 66,726
Common stock issued	43	—	(188)	—	—	(188)
Stock-based compensation	—	—	23,543	—	—	23,543
Other comprehensive income	—	—	—	26	—	26
Net loss	—	—	—	—	(56,957)	(56,957)
Balances at December 31, 2019	551	$ 1	$ 150,280	$ 26	$ (117,157)	$ 33,150
Common stock issued	2,551	5	11,620	—	—	11,625
Warrants issued, net	—	—	7,492	—	—	7,492
Exercise of warrants	74	1	826	—	—	827
Common stock issued pursuant to the vesting of restricted stock units and ESPP	13	—	42	—	—	42
Stock-based compensation	—	—	4,082	—	—	4,082
Other comprehensive loss	—	—	—	(26)	—	(26)
Net loss	—	—	—	—	(36,045)	(36,045)
Balances at December 31, 2020	3,189	$ 7	$ 174,342	$ —	$ (153,202)	$ 21,147

See notes to financial statements.

Ra Medical Systems, Inc.

Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (36,045)	$ (56,957)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,365	1,750
Provision for doubtful accounts	180	283
Stock-based compensation	4,082	23,543
Loss on disposal of property and equipment	99	123
Changes in operating assets and liabilities:		
Accounts receivable	368	251
Inventories	352	(2,185)
Prepaid expenses and other assets	642	(338)
Accounts payable	(961)	407
Accrued expenses	1,706	(184)
Deferred revenue	(774)	417
Other liabilities	(318)	(283)
Net cash used in operating activities	(28,304)	(33,173)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of available-for-sale securities	—	(36,461)
Proceeds from maturities of available-for-sale securities	16,000	20,697
Purchases of property and equipment	(67)	(268)
Net cash provided by (used in) investing activities	15,933	(16,032)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and warrants, net of placement agent fees of $2,113	19,887	—
Proceeds from issuance of common stock in connection with the exercise of warrants	827	—
Proceeds from issuance of common stock in connection with the employee stock purchase plan	42	37
Proceeds from promissory note	2,000	—
Payments of offering costs related to the issuance of common stock and warrants	(770)	—
Payments on equipment financing	(293)	(338)
Payments for restricted stock tax liability on settlement	—	(225)
Net cash provided by (used in) financing activities	21,693	(526)
NET CHANGE IN CASH AND CASH EQUIVALENTS	9,322	(49,731)
CASH AND CASH EQUIVALENTS, beginning of year	14,584	64,315
CASH AND CASH EQUIVALENTS, end of year	$ 23,906	$ 14,584
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Transfer from inventories to property and equipment for lasers	$ 207	$ 1,505
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for interest	$ 28	$ 49
Cash payments for taxes	$ —	$ 30

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 laser systems for use in the treatment of vascular and dermatological diseases. The Company's product development centers around proprietary applications of its advanced excimer laser technology for use as a tool in the treatment of peripheral artery disease ("PAD") and psoriasis, vitiligo, atopic dermatitis and leukoderma.

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

***Initial Public Offering*—**On October 1, 2018, the Company closed its initial public offering ("IPO"). 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 October 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.

Reverse Stock Split —In November 2020, the board of directors approved a Reverse Stock Split ratio of 1-for-25 On the effective date of November 16, 2020, the number of the Company's issued and outstanding shares of common stock was decreased from 73.0 million shares to 2.9 million shares. The number of authorized shares and par value per common share remained unchanged. No fractional shares were issued as a result of the reverse stock split. Stockholders who would otherwise have been entitled to receive a fractional share received a cash payment in lieu thereof. The financial statements have been retrospectively adjusted to reflect the 1-for-25 reverse stock split of our common stock.

COVID-19—The global spread of the novel coronavirus (COVID-19) has created significant volatility, uncertainty and economic disruption. The ultimate effects of the COVID-19 on the Company's business, operations and financial condition are unknown at this time. In the near term, the Company expects that its revenue will continue to be adversely impacted and enrollment in its atherectomy clinical trial will continue to be delayed or slowed, as patients elect to postpone voluntary treatments and many physicians' offices have been either closed or operating at a reduced capacity. In addition, some customers are requesting more flexible payment terms on a temporary basis. The Company's manufacturing facility located in Carlsbad, California is currently operational. Employee travel is limited to essential travel only and many employees are working from home when feasible. The Company has experienced minor delays in receiving shipments of parts, which has not had a material impact on the timing of its key engineering efforts, nor ability to support its atherectomy indication clinical trial. However, the extent to which COVID-19 impacts its business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain it or treat its impact, among others.

Going Concern —The Company has experienced recurring net losses from operations and negative cash flows from operating activities, has a significant accumulated deficit and expects to continue to incur net losses into the foreseeable future. The Company had an accumulated deficit of $153.2 million at December 31, 2020. In 2020, the Company used $28.3 million in cash for operating activities.

As of December 31, 2020 the Company had cash and cash equivalents of $23.9 million.

Management expects operating losses and negative cash flows to continue for the foreseeable future with the Company's reduced commercial footprint, and as the Company continues to incur costs related to its atherectomy

clinical trial, engineering efforts to improve the shelf-life of its catheters and develop next generation products and legal costs associatedwith ongoing litigation. In September 2020, the Company paused commercial sales of DABRA catheters not being used for the atherectomy clinical trial while it conducts further studies on the stability of its shelf life. We submitted additional test data in March 2021, whichwill need to be cleared by the FDA prior to resuming commercial shipments of catheters.The Company also expects the COVID-19 pandemic to have a continued negative impact on its revenue andthe timing of enrollment in its atherectomy clinical trial as well as the Company's ability to secure additional financing in a timely manner or on favorable terms, if at all.

Although the Company bolstered its liquidity resources in 2020, has an effective shelf registration statement and an "at the market" offering to allow it to raise additional capital when the opportunities permit and may receive additional funds from the exercise of its warrants depending on market conditions, management concluded that the aforementioned conditions, including the ongoing uncertainty related to the negative impacts of the COVID-19 pandemic, continue to raise substantial doubt about the Company's ability to continue as a going concern within 12 months from the date of issuance of the financial statements. Management's plans to address this uncertainty include raising additional funding, if necessary, through public or private equity or debt financings. However, the Company may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity securities to raise additional funds, its existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of the Company's existing stockholders.

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

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 liabilities at the dates of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates. The Company's financial statements are based upon a number of estimates, including but not limited to, allowance for doubtful accounts, reserves for warranty costs including product recalls, evaluation of probable loss contingencies, fair value of stock option awards granted and revenue recognition for multiple performance obligations.

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

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

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

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

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

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

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

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

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

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

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

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

The Company maintains an allowance for doubtful accounts for balances that appear to have specific collection issues and expected credit losses. 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,	
	2020	**2019**
Balance at beginning of period	$ 355	$ 214
Provision for doubtful accounts	180	283
Deductions	(264)	(142)
Balance at end of period	$ 271	$ 355

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

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

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

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

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

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

Impairment of long-lived assets—The Company periodically reviews its long-lived assets for impairment when certain events or changes in circumstances indicate that the carrying value of the long-lived assets may not be recoverable. Should the sum of the undiscounted expected future net cash flows be less than the carrying value, the Company would recognize an impairment loss at that date. The inconsistencies in the DABRA catheter performance, the voluntary product recall and the reduction in the sales force resulted in lower current and expected revenues for the vascular segment, led the Company to accelerate its annual testing for asset impairment into the third quarter of 2019. There were no impairment charges for the years ended December 31, 2020 or 2019.

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. Accordingly, the Company generally replaces catheters that kink or fail to calibrate. The product warranty liability is determined based on historical information such as past experience, product failure rates or number of units repaired, estimated cost of material and labor. The product warranty liability also includes the estimated costs of a product recall.

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

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

Revenue recognition—The Company adopted ASC Topic 606 (Topic 606), *Revenue from Contracts with Customers*, on January 1, 2019 using the modified retrospective method to all contract agreements not completed as of January 1, 2019. Results for reporting periods beginning after January 1, 2019 are presented under Topic 606

while, as permitted by Topic 606, prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. The Company recorded a cumulative catch up adjustment to beginning accumulated deficit to reflect the impact of adopting Topic 606. The adoption of Topic 606 did not have a material effect on our results of operations for the year ended December 31, 2019.

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

The Company determines revenue recognition incorporating the following steps:

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

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

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

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

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

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

included in service and other revenue in the statements of operations. Deferred revenue, on January 1, 2020 and 2019, was $3.3 million and $2.8 million, respectively. Revenue recognized in the years ended December 31, 2020 and 2019 relating to amounts previously included in deferred revenue was $2.0 million and $1.9 million, respectively. The deferred revenue greater than one year will be recognized during the remaining service period through 2024.

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

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

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

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

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

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

Contract Costs
The Company capitalizes costs to obtain contracts that are considered incremental and recoverable, such as sales commissions. The capitalized costs are amortized to selling, general and administrative expense over the estimated period of benefit of the asset, which is the contract term. The Company elected to use the practical expedient to expense the costs to obtain a contract when the amortization period is less than one year. The Company has contract costs of $0.2 million and $0.4 million capitalized at December 31, 2020 and December 31, 2019, respectively.

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

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

These lease arrangements contain one lease component (the laser) and one nonlease component (warranty service) for which the Company elected the practical expedient to not separate the nonlease component from the lease component. The Company accounts for the combined lease component as an operating lease and recognizes lease income on a straight-line basis over the lease term. Rental income from lease arrangements for the years ended December 31, 2020 and 2019 was $0.6 million and $0.7 million, respectively.

Shipping and handling costs—Shipping and handling charged to customers is included in net product sales. Shipping and handling costs are included in selling, general and administrative expenses in the accompanying statements of operations. Shipping and handling costs were $0.1 million and $0.5 million for the years ended December 31, 2020 and 2019, respectively.

Advertising expense—The Company expenses advertising costs as incurred. There was no advertising expense for the year ended December 31, 2020. Advertising expense for the year ended December 31, 2019 was $0.1 million.

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. There were no liability awards outstanding at December 31, 2020 or 2019.

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

The Company recognizes stock-based compensation expense as follows:

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

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

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

Concentrations of credit risk—Credit risk represents the accounting loss that would be recognized at the reporting date if counterparties failed completely to perform as contracted. Concentrations of credit risk that arise from financial instruments exist for groups of customers or counterparties when they have similar economic characteristics that would cause their ability to meet contractual obligations to be similarly affected by changes in economic or other conditions described below.

Financial instruments, which potentially subject the Company to concentration of credit risk, consist of cash, cash equivalents and short-term investments balances maintained in excess of Federal Depository Insurance Corporation limits, and accounts receivable which have no collateral or security. The Company monitors the financial condition of the banks in which it currently has deposits. The Company has not experienced any significant losses in this respect and believes that it is not exposed to any significant related risk.

Exposure to losses on accounts receivable is dependent on the individual customer’s financial condition. The Company monitors its exposure to credit losses and reserves for those accounts receivable that it deems to be not collectible.

No individual customer represented greater than 10% of total net revenue for the years ended December 31, 2020 and 2019. One individual customer represented 10% of accounts receivable for each of the years ended December 31, 2020 and 2019, respectively.

Recently Adopted Accounting Pronouncements— As an emerging growth company, the Company may elect to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than public companies must adopt the standards. The Company has elected to take advantage of the extended transition period afforded by the JOBS Act and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies, which are the dates included below.

In June 2018, the FASB issued ASU 2018-07,*Improvements to Nonemployee Share-Based Payment Accounting.* ASU 2018-07 expands the scope of Topic 718, *Compensation—Stock Compensation*, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU 2018-07 supersedes Subtopic 505-50, *Equity—Equity-Based Payments to Non-Employees*. The amendments are effective for fiscal years beginning after December 15, 2019. Early adoption is permitted, but no earlier than a company's adoption date of Topic 606, Revenue from Contracts with Customers. The Company adopted this guidance on January 1, 2020 and there was no impact on the financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13,*Fair Value Measurement (Topic 820) - Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, which is designed to improve the effectiveness of disclosures by removing, modifying and adding disclosures related to fair value measurements. ASU No. 2018-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and the ASU allows for early adoption in any interim period after issuance of the update. The Company adopted this guidance on January 1, 2020 and there was no impact on the financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326), to require the measurement of expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions and reasonable forecasts and applies to all financial assets, including trade receivables. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. ASU No. 2016-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company adopted this guidance on January 1, 2020 and there was no material impact on the financial statements.

Note 3—Short-term Investments

A summary of debt securities by major security type is as follows as of December 31, 2019 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt Securities-available-for-sale:				
U.S. agency securities	$ 1,000	$ —	$ —	$ 1,000
U.S. government securities	14,967	26	—	14,993
Total debt securities	$ 15,967	$ 26	$ —	$ 15,993

All debt securities were due in less than one year.

The following table presents the hierarchy for assets measured at fair value on a recurring basis (in thousands):

	Total Fair Value	Quoted Market Prices for Identical Assets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
As of December 31, 2020				
Money market funds	$ 18,394	$ 18,394	$ —	$ —
As of December 31, 2019				
Money market funds	$ 13,219	$ 13,219	$ —	$ —
U.S. government securities	$ 14,993	$ 14,993	$ —	$ —
U.S. agency securities	$ 1,000	$ —	$ 1,000	$ —

Note 4—Inventories

Inventories consisted of the following (in thousands):

	December 31,	
	2020	2019
Raw materials	$ 1,739	$ 2,300
Work in process	270	215
Finished goods	209	262
Inventories	$ 2,218	$ 2,777

Note 5—Property and Equipment, net

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

	December 31,	
	2020	2019
Lasers	$ 4,677	$ 4,671
Machinery and equipment	866	841
Automobiles	1,054	1,109
Computer hardware and software	353	348
Leasehold improvements	119	119
Furniture and fixtures	48	48
Construction in progress	51	23
Property and equipment, gross	7,168	7,159
Accumulated depreciation	(3,957)	(2,109)
Property and equipment, net	$ 3,211	$ 5,050

Depreciation expense was $2.0 million and $1.4 million for the years ended December 31, 2020 and 2019, respectively.

Note 6—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2020	2019
Compensation and related benefits	$ 2,602	$ 1,163
Accrued warranty (Note 7)	242	338
Accrued services	1,504	1,141
Accrued expenses	$ 4,348	$ 2,642

Note 7—Accrued Warranty
Activity in the product warranty accrual is included in accrued expenses above and consists of the following (in thousands):

	Year ended December 31,	
	2020	2019
Balance at beginning of period	$ 338	$ 112
Increase in warranty accrual	87	889
Change in liability for pre-existing warranties	(2)	(28)
Claims satisfied	(181)	(635)
Accrued warranty	$ 242	$ 338

Warranty expense was $0.1 million and $0.9 million for the years ended December 31, 2020 and 2019, respectively. The accrued warranty balances at December 31, 2020 and 2019 include $0.1 million and $0.2 million, respectively, relating to the voluntary recall of catheters, which was initiated in September 2019. Warranty expense is included in cost of revenue in the accompanying statements of operations.

Note 8—Paycheck Protection Program Promissory Note
In May 2020, the Company entered into a $2.0 million Paycheck Protection Program Promissory Note and Agreement ("PPP Promissory Note") with a commercial bank under the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act. The PPP Promissory Note bears interest at 1.0% per annum. Under the terms of the PPP Promissory Note, payments would be due monthly beginning November 1, 2020 and the principal amount of the PPP Promissory Note along with any unpaid interest would be due on May 3, 2022. On June 5, 2020, the Paycheck Protection Program Flexibility Act of 2020 (the "PPPFA") extended the deferral period for all loans to 10 months after the last day of the covered period. Under the revised terms, payments are due beginning August 2021 and the principal amount along with unpaid interest is due in May 2022. The Company has requested from its lender an extension of the loan maturity from two years to five years as permitted under the PPPFA. The principal and interest may be forgiven if the proceeds are used for forgivable purposes as defined by the terms in the PPP Promissory Note, and the Company believes it has used the proceeds from the PPP Promissory Note for forgivable purposes as defined by the terms of the PPP Promissory Note. The Company intends to apply for forgiveness under the provisions of the CARES Act. Forgiveness is subject to the sole approval of the Small Business Administration. Interest expense for the year ended December 31, 2020 was $13,000.

Note 9—Leases
The Company recognized non-cash right-of-use assets and lease liabilities of $3.2 million upon adoption of ASU 2016-02 on January 1, 2019.The Company has two operating leases for office and manufacturing space which requires it to pay base rent and certain utilities. Monthly rent expense is recognized on a straight-line basis over the terms of the leases, which expire in 2027 and 2021.

At December 31, 2020 the weighted average remaining lease term was seven years. The operating leases are included in the balance sheet at the present value of the lease payments at a 7% discount rate using the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and amount equal to the lease payments in a similar economic environment as the leases do not provide an implicit rate.

For the years ended December 31, 2020 and 2019, operating lease expense and cash paid were each $0.5 million. Operating lease right-of-use assets amortization was $0.4 million and $0.3 million for the years ended December 31, 2020 and 2019, respectively. Variable costs are de minimis.

The following table presents the lease liabilities within the balance sheet, related to the Company's operating leases as ofDecember 31, 2020 (in thousands):

Years Ending December 31,		
2021	$	528
2022		432
2023		445
2024		459
2025		472
Thereafter		987
Total operating lease payments	$	3,323
Less: imputed interest		(703)
Total operating lease liabilities	$	2,620

Note 10—Equipment Financing
During 2018, the Company entered into four loan agreements to finance 25 automobiles. The loans mature in 2021 and bear interest at a weighted average interest rate of 6.5%. These loans are secured by the automobiles. Interest expense for the years ended December 31, 2020 and 2019 was $28,000 and $48,000, respectively. The outstanding balance at December 31, 2020 was $0.3 million and included in equipment financing. The loans were repaid in March 2021.

Note 11—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. A net loss cannot be diluted, so when the Company is in a net loss position, basic and diluted loss per common share are the same. If in the future the Company achieves profitability, the denominator of a diluted earnings per common share calculation will include both the weighted-average number of shares outstanding and the number of common stock equivalents, if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants, stock options and non-vested restricted stock awards and units using the treasury stock method, along with the effect, if any, from outstanding convertible securities.

The Company's outstanding warrants to purchase common stock have participation rights to any dividends that may be declared in the future and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, no loss is allocated to the participating securities since the holders have no contractual obligation to share in the losses of the Company.

Anti-dilutive common share equivalents excluded from the computation of diluted net loss per share at December 31, 2020 consisted of warrants of 2,345,033, stock options of 142,171, restricted stock units of 33,548, restricted stock awards of 290,536 and Employee Stock Purchase Plan shares of 3,200.

Anti-dilutive common share equivalents excluded from the computation of diluted net loss per share at December 31, 2019 consisted of stock options of 125,579, restricted stock units of 10,864 and Employee Stock Purchase Plan shares of 2,473.

Note 12—Stockholders' Equity
Common stock —In May 2020, the Company completed a public offering (the "May 2020 Offering") of an aggregate of 888,888 shares of common stock, together with accompanying warrants to purchase up to an aggregate of 888,888 shares of common stock, at a public offering price of $11.25 per share and accompanying warrant. Each share of common stock was sold in the offering with one warrant to purchase one share of common stock. The warrants have an exercise price of $11.25 per share, are immediately exercisable, and expire five years following the date of issuance. Placement agent warrants were issued to purchase up to an aggregate of 62,222 shares of common stock, are immediately exercisable for an exercise price of $14.0625, and expire five years following the date of issuance. The Company received approximately $8.7 million in net proceeds, after deducting placement agent's fees and other offering expenses of $1.3 million payable by it.

The warrants and placement agent warrants were valued at an aggregate $3.5 million using the Black-Scholes option pricing model based on the following assumptions; expected volatility 59.86%, risk-free interest rate 0.34%, expected dividend yield 0.00% and an expected term of 2.5 years.

In June 2020, the Company issued 73,506 shares of common stock in connection with the exercise of warrants issued in the May 2020 Offering.

At December 31, 2020, the Company had 815,382 shares and 62,222 shares of common stock reserved for issuance pursuant to the warrants and placement agent's warrants, respectively, issued by the Company in the May 2020 Offering, at an exercise price of $11.25 per share and $14.0625 per share, respectively.

In August 2020, the Company completed another public offering (the "August 2020 Offering") of an aggregate of 1,371,429 shares of common stock, together with accompanying warrants to purchase up to an aggregate of 1,371,429 shares of common stock, at a public offering price of $8.75 per share and accompanying warrant. Each share of common stock was sold in the offering with one warrant to purchase one share of common stock. The warrants have an exercise price of $8.75 per share, are immediately exercisable, and expire five years following the date of issuance. Placement agent warrants were issued to purchase up to an aggregate of 96,000 shares of common stock, are immediately exercisable for an exercise price of $10.9375, and expire five years following the date of issuance. The Company received approximately $10.4 million in net proceeds, after deducting placement agent's fees and other estimated offering expenses of $1.6 million payable by it.

The warrants and placement agent warrants were valued at an aggregate $4.0 million using the Black-Scholes option pricing model based on the following assumptions; expected volatility 59.72%, risk-free interest rate 0.17%, expected dividend yield 0.00% and an expected term of 2.5 years.

At December 31, 2020, the Company had 1,371,429 shares and 96,000 shares of common stock reserved for issuance pursuant to the warrants and placement agent's warrants, respectively, issued by the Company in the August 2020 Offering, at an exercise price of $8.75 per share and $10.9375 per share, respectively.

Preferred stock— At December 31, 2020 and 2019, the Company has no shares of preferred stock outstanding.

Note 13—Stock-Based Compensation

On June 4, 2018, the 2018 Stock Compensation Plan was established (the "Compensation Plan") whereby 132,000 shares of the Company's common stock were reserved for issuance. On June 4, 2018, the Company's board of directors authorized 76,076 replacement equity awards of stock options for awards that had been granted under a previous plan, and, on June 8, 2018, 53,633 restricted stock units (collectively, the "Replacement Awards") to eligible employees, directors, consultants and service providers. The Compensation Plan terminated in connection with the adoption of the Company's 2018 Equity Incentive Plan, described below, and, accordingly no new awards are available for issuance under this plan. The Compensation Plan continues to govern awards granted thereunder.

Stock options granted under the Compensation Plan, including those granted as a component of the Replacement Awards, generally vest 33% on the first anniversary of the grant date with the balance vesting monthly over the remaining two years. The restricted stock units granted under the Compensation Plan, including those granted as a component of the Replacement Awards, include a service condition and a performance condition. The service condition generally begins on the grant date and continues through January 2020 and the restricted stock units vest at various times commencing March 27, 2019 until January 2020. The performance condition related to the Company completing its IPO and the vesting of the restricted stock units were contingent upon the achievement of such IPO, which was achieved on October 1, 2018.

The restricted stock units granted under the Compensation Plan, including those granted as a component of the Replacement Awards, include a service condition and a performance condition. The service condition generally begins on the grant date and continues through January 2020 and the restricted stock units vest at various times commencing the day following the expiration of the lock-up until January 2020. The performance condition related to the Company completing its IPO and the vesting of the restricted stock units were contingent upon the achievement of such IPO, which was achieved on October 1, 2018. Stock options granted under the 2018 Plan

generally vest 25% on the first anniversary of the vesting commencement date with the balance vesting monthly over the remaining three years. Restricted stock units granted under the 2018 plan generally have a vesting schedule with one third of the total number of shares underlying the restricted stock units vesting on the first anniversary of the vesting commencement date and one sixth of the total shares vesting every six months thereafter such that the award will be fully vested on the third anniversary of the vesting commencement date.

In September 2018, the Company's board of directors adopted, and the Company's stockholders approved, the Company's 2018 Equity Incentive Plan (the "2018 Plan"). As of December 31, 2020, 110,329 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 132,000 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) 65,285 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.

In March 2020 the Company adopted the 2020 Inducement Equity Incentive Plan (the "2020 Plan") with the purpose of attracting, retaining and incentivizing employees in furtherance of the Company's success. The 2020 Plan was adopted without stockholder approval pursuant to Rule 303A.08 of the New York Stock Exchange rules. In accordance with New York Stock Exchange rules, this plan is used to offer equity awards as material inducements for new employees to join the Company. On adoption, 32,000 shares of common stock were reserved solely for the granting of inducement stock options, restricted stock, restricted stock units and other awards. The 2020 Plan provides for the granting of stock options with exercise prices equal to the fair market value of our common stock on the date of grant. During the year ended December 31, 2020 there were 18,000 stock options granted with a weighted average exercise price of $25.50. There are 3,375 exercisable options in the 2020 Plan at December 31, 2020. During the year ended December 31, 2020, 5,000 restricted stock awards were granted, of which 625 vested, with a grant date fair value of $0.1 million, under the 2020 Plan.

A summary of the activity and related information of the stock options issued under the 2018 Equity Incentive Plan and the Compensation Plan is presented below:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	76,804	$ 714.75	9.43	$ —
Granted	60,854	30.50		
Forfeited	(12,079)	670.25		
Outstanding at December 31, 2019	125,579	$ 387.50	9.43	$ —
Granted	11,729	30.69		
Forfeited	(13,137)	297.57		
Outstanding at December 31, 2020	124,171	$ 363.31	6.42	$ —
Exercisable at December 31, 2020	84,376	$ 466.78	5.89	$ —
Vested and expected to vest at December 31, 2020	124,171	$ 363.31	6.42	$ —

A summary of the activity and related information of the restricted stock units is presented below:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2018	59,767	$ 672.75
Granted	12,010	98.75
Vested and released	(48,269)	698.25
Forfeited	(12,644)	497.75
Outstanding at December 31, 2019	10,864	$ 128.82
Granted	32,019	10.82
Vested and released	(7,906)	114.55
Forfeited	(1,429)	101.79
Outstanding at December 31, 2020	33,548	$ 21.93

A summary of the activity and related information of the restricted stock awards is presented below:

	Restricted Stock Awards (in shares)	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2019	—	$ —
Granted	286,161	4.77
Forfeited	—	—
Vested	—	—
Outstanding at December 31, 2020	286,161	$ 4.77

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

	Year Ended December 31,	
	2020	2019
Selling, general and administrative	$ 3,302	$ 20,392
Research and development	447	1,537
Stock-based compensation in operating expenses	$ 3,749	$ 21,929

Stock-based compensation amounts of $0.3 million and $1.6 million were capitalized to property and equipment and inventory during the years ended December 31, 2020 and 2019, respectively.

Unrecognized compensation expense for stock options issued as of December 31, 2020 was $1.8 million and is expected to be recognized over a weighted-average period of 1.2 years. Unrecognized compensation expense for the restricted stock units as of December 31, 2020 was $0.6 million and is expected to be recognized over a weighted-average period of 1.9 years. Unrecognized compensation expense for the restricted stock awards as of December 31, 2020 was $1.4 million and is expected to be recognized over a weighted-average period of 2.8 years.

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,	
	2020	2019
Risk-free interest rate	1.3 %	1.6 %
Volatility	58.96 %	59.26 %
Expected dividend yield	0.00 %	0.00 %
Expected life (in years)	5.8	5.9

The fair value of the stock options issued under the 2020 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, 2020
Risk-free interest rate	0.5 %
Volatility	58.33 %
Expected dividend yield	0.00 %
Expected life (in years)	6.3

The Company's 2018 Employee Stock Purchase Plan (ESPP) became effective in September 2018. A total of 19,463 shares of common stock were available for sale under our ESPP as of December 31, 2020. Under the Company's ESPP, eligible employees are allowed to purchase the Company's stock at a discounted price, which is 85% of the lower market price of the Company's common stock at the beginning or at the end of the six-month purchase period. The Company issued 5,278 and 368 shares in exchange for $42,000 and $37,000 in the years ended December 31, 2020 and 2019, respectively, under the ESPP. The number of shares of common stock that will be available for sale under the ESPP also includes an annual increase on the first day of each fiscal year beginning with our 2019 fiscal year, equal to the least of (1) 11,870 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 14—Income Taxes

A reconciliation of the differences between the United States statutory federal income tax rate and the effective tax rate as provided in the statements of operations is as follows:

	Year Ended December 31,	
	2020	2019
Tax computed at the federal statutory rate	21.0 %	21.0 %
State income taxes, net of federal benefits	5.1	1.9
Nondeductible expenses	(0.1)	(0.4)
Stock-based compensation	(2.2)	(9.5)
Deferred tax adjustments	(57.0)	—
Change in valuation allowance	33.2	(13.0)
	—	—

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

	Year Ended December 31,	
	2020	2019
Current		
Federal	$ —	$ —
State	7	15
	7	15
Deferred		
Federal	—	—
State	—	—
	—	—
Income tax expense	$ 7	$ 15

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,	
	2020	2019
Deferred Tax Assets:		
Net operating loss carryforwards	$ 3,720	$ 16,096
Operating lease liabilities	691	766
Other accruals	101	61
Accrued compensation	448	—
Reserves	299	301
Deferred revenue	642	850
Intangible assets	32	253
Stock-based compensation	4,910	4,821
Total gross deferred tax assets	$ 10,843	$ 23,148
Deferred Tax Liabilities:		
Property and equipment	(805)	(1,026)
Operating lease right-of-use assets	(655)	(739)
Other	(61)	(92)
Total gross deferred tax liabilities	$ (1,521)	$ (1,857)
Valuation allowance	(9,322)	(21,291)
Total deferred taxes	$ —	$ —

At December 31, 2020, the Company had available federal and state net operating loss carryforwards of approximately $14.3 million and $13.4 million, respectively, which may be used to offset future federal and state taxable earnings. The federal net operating loss can be carried forward indefinitely and the state net operating losses begin expiring in 2032. Use of these net operating loss carryforwards may be significantly limited under the tax rules regarding the use of losses following an ownership change under Internal Revenue Code ("IRC") Section 382. The Company has completed an IRC Section 382 analysis regarding the limitation of net operating losses through December 31, 2020 and determined that an ownership change occurred in May 2020. The Company calculated the limitation on net operating losses and other tax attributes and reduced the value of the deferred tax assets resulting in a tax expense impact of $20.8M. The tax expense was offset by tax benefit recorded on the reduction in valuation allowance recorded for the deferred tax assets for the year ended December 31, 2020.

As of December 31, 2020, the Company does not have any unrecognized tax benefits. The Company does not anticipate that the amount of unrecognized tax benefits will significantly increase in the next 12 months. There were no interest and penalties accrued as of December 31, 2020. The Company files U.S. federal and various states income tax returns, which are subject to examination by the taxing authorities for years 2016 and later. However, the federal net operating loss carryover may be adjusted three years from the date the loss is utilized on an income tax return.

ASC 740, *Income Taxes*, requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is not currently more likely than not to be realized and, accordingly, has provided a full valuation allowance at December 31, 2020 and 2019.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748) which includes a number of provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. Under ASC 740, the effects of new legislation are recognized upon enactment. Accordingly, the effects of the CARES Act have been incorporated into the income tax provision computation for the year ended December 31, 2020. These provisions did not have a material impact on the income tax provision.

The Consolidated Appropriations Act, 2021 (CAA 2021), which was signed into law on December 27, 2020, provided that deductions are allowed for otherwise deductible expenses paid with the proceeds of a Paycheck Protection Program (PPP) loan that is forgiven and that the tax basis and other attributes of the borrower's assets will not be reduced as a result of the loan forgiveness. Prior to the enaction of the CCA, the deductions paid with proceeds of a PPP loan that was forgiven were not allowed. These provisions did not have a material impact on the income tax provision.

Note 15—Commitments and Contingencies

Legal—In the normal course of business, the Company is at times subject to pending and threatened legal actions. In management's opinion, any potential loss resulting from the resolution of these matters will not have a material effect on the results of operations, financial position or cash flows of the Company.

Securities Litigation

On June 7, 2019, a putative securities class action complaint captioned *Derr v. Ra Medical Systems, Inc., et. al.,* (Civil Action no. 19CV1079 LAB NLS) was filed in the United States District Court for the Southern District of California against the Company, certain current and former officers and directors, and certain underwriters of the Company's IPO. Following the appointment of a lead plaintiff and the filing of a subsequent amended complaint, the lawsuit alleges that the defendants made material misstatements or omissions in the Company's registration statement in violation of Sections 11 and 15 of the Securities Act of 1933 and between September 27, 2018 and November 27, 2019, inclusive, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. Management intends to vigorously defend the Company against this lawsuit. On March 11, 2020, lead plaintiffs voluntarily dismissed the underwriter defendants without prejudice. On March 13, 2020, defendants filed a motion to dismiss the amended complaint. On July 14, 2020, the court informed the parties that the motion to dismiss is suitable for decision without oral argument. At this time, the Company cannot predict how a court or jury will rule on the merits of the claims and/or the scope of the potential loss in the event of an adverse outcome. Should the Company ultimately be found liable, the liability could have a material adverse effect on the Company's financial condition and its results of operations for the period or periods in which it is incurred. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

On October 1, 2019, a shareholder derivative complaint captioned *Noel Borg v. Dean Irwin, et. al* (Civil Action no. 1:99-cm-09999) was filed in the United States District Court for the District of Delaware against certain current and former officers and directors, purportedly on behalf of the Company, which is named as a nominal defendant in the action. The complaint alleges breaches of fiduciary duty, unjust enrichment, waste, and violations of Section 14(a) of the Securities Exchange Act of 1934. On October 21, 2019, pursuant to the parties' stipulation, the court stayed the derivative lawsuit until the related class action is resolved. While the Company has obligations to indemnify and/or advance the defendants' legal fees and costs in connection with this lawsuit, any monetary recovery from the defendants would be to the benefit of the Company. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

Government Investigations

As previously announced in the Form 8-K filed on August 12, 2019, the Audit Committee of the Company's Board of Directors (the "Audit Committee") conducted an investigation of certain allegations raised by a former employee. The Company announced the Audit Committee's findings in the Form 8-K filed on October 31, 2019. The primary investigative findings were: (i) the DABRA catheter frequently failed to calibrate and occasionally overheated, posing a risk of injury to physicians and patients; (ii) the Company's explanations regarding its fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because they did not explicitly reference

inconsistent DABRA catheter performance and catheter failures; (iii) the Company failed to timely make at least two Medical Device Reports, or MDRs, to the FDA; (iv) the Company, out of a concern for the DABRA catheters' performance, engaged in systematic efforts to replace product held by customers, which constituted product recalls, but were not documented as such, (v) the Company lack documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, and as to three physicians did not accurately reflect the purpose and nature of approximately $300,000 of payments, which could be perceived as an improper attempt to obtain business or to gain special advantage, (vi) while the indication for use in the 510(k) clearance the Company obtained for the DABRA system is not for atherectomy, the Company's salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes, (vii) the Company's determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects, and (viii) the Company received complaints regarding regulatory or compliance concerns that, because they implicated executive officers, should have been brought to the attention of the Board or the Audit Committee, but were not. The Audit Committee, in reviewing the allegations, identified certain behavior inconsistent with the Company's Code of Ethics and Conduct and related policies.

On December 28, 2020, the Company entered into a Settlement Agreement with the United States of America, acting through the DOJ and on behalf of the OIG, to resolve the pending DOJ investigation and a related civil action concerning our marketing of the DABRA laser system and DABRA-related remuneration to certain physicians. In connection with the Settlement Agreement, the Company also has reached tentative agreements that, if executed by participating states, resolve previously disclosed related investigations conducted by certain state attorneys general.

The Settlement Agreement recites that a complaint filed by a former employee on behalf of the federal government in the United States District Court for the Eastern District of Michigan, and subsequently amended to assert claims on behalf of certain states, alleged, among other things, that the Company violated the False Claims Act, 31 U.S.C. § 3729, and certain state false claims acts by paying kickbacks to certain physicians in order to induce them to use the DABRA laser system, promoting off-label use of the DABRA laser system, failing to report adverse events to the United States Food and Drug Administration, marketing a device that does not work as advertised, and failing to adhere to Current Good Manufacturing Practices. The complaint, which was settled in connection with the Settlement Agreement, also alleged that we unlawfully retaliated against the former employee. Separate from the former employee's allegations in the civil action, the United States and the participating states contend that from May 1, 2017 through October 31, 2019, the Company (a) paid illegal remuneration to certain physicians to induce them to use the DABRA laser system in violation of the federal anti-kickback statute and (b) marketed the DABRA laser system for off-label use in atherectomy procedures despite product performance issues causing calibration and overheating problems, which posed a risk to physicians and patients (the "Covered Conduct"). The Company denies the allegations in the civil action and those asserted by the United States and the participating states, and the settlement does not constitute an admission of liability or wrongdoing by the Company.

Under the Settlement Agreement, and the tentative agreements with the participating states, the Company is required to make an initial payment of $2.5 million, of which the Company paid $2.4 million in December 2020 and will pay the remaining $0.1 million when the agreements with the participating states are finalized. Pursuant to the terms of the Settlement Agreement, (a) if its revenue exceeds $10 million in any of the next four fiscal years (2021-2024), it also is required to pay an additional amount in settlement for the corresponding year: $500,000 for 2021, $750,000 for 2022, $1 million for 2023, and $1.25 million for 2024; (b) if it is acquired or is otherwise involved in a change in control transaction in the years 2020 through 2024, it is required to pay an additional settlement amount of $5 million, plus 4% of the value attributed to the Company in the transaction, so long as the attributed value is in excess of $100 million, with the total change in control payment never to exceed $28 million; and (c) if its obligations under the Settlement Agreement are avoided by bankruptcy, the United States may rescind the releases and bring an action against the Company in which the Company agrees is not subject to an automatic stay, is not subject to any statute of limitations, estoppel or laches defense, and is a valid claim in the amount of $56 million, minus any prior change in control payments. Under the Settlement Agreement, the Company also paid the former employee's reasonable expenses, costs and attorneys' fees, which amount to $0.2 million. The Company has expensed $2.7 million and has remaining accrued expenses of $0.3 million at December 31, 2020 relating to this matter.

The OIG has agreed, conditioned upon our full payment of amounts owed in the Settlement Agreement, and in consideration of the Company's obligations under a Corporate Integrity Agreement, to release its permissive exclusion rights and refrain from instituting any administrative action seeking to exclude it from participating in

Medicare, Medicaid, or other federal health care programs as a result of the Covered Conduct. The CorporateIntegrity Agreement has a five-year term and imposes monitoring, reporting, certification, documentation, oversight, screening, and training obligations on the Company, including the hiring of a compliance officer and independent review organization.

Pursuant to the terms of the Settlement Agreement, the United States and the former employee have dismissed the complaint against the Company with prejudice, and have released the Company from any civil or administrative monetary liability arising under the Covered Conduct. The Settlement Agreement does not include a release for any conduct other than the Covered Conduct or any criminal liability related to the Covered Conduct. The Settlement Agreement does not release any claims under investigation by the SEC.

As also previously announced, the Company voluntarily contacted the SEC's Enforcement Division regarding the Audit Committee's investigation. On November 13, 2019, the SEC notified the Company that it is conducting an investigation. The Company has been, and intends to continue, cooperating with the SEC in this ongoing investigation. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

On November 21, 2019, the Company became aware that the Criminal Division, Fraud Section of the DOJ has an open investigation related to the Company. At this time, it is unclear if the Company is a target in this investigation. The Company has been, and intends to continue, cooperating with the DOJ in its active and ongoing investigation. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

Other Litigation

On August 30, 2018, Strata Skin Sciences, Inc. ("Strata") and Uri Geiger, a member of the board of directors of Strata Skin Sciences, Inc. (collectively "Strata") filed an action against the Company in Court of Common Pleas of, Montgomery County, Pennsylvania (Civil Action No. 18-21421) (the "Pennsylvania Case"), requesting declaratory relief that: (1) Strata and Mr. Geiger are not liable for tortious interference, defamation, libel, or unfair competition based on an e-mail by Mr. Geiger to an investment bank (the "Geiger Email"); (2) Strata and Mr. Geiger made no actionable statements about the Company to such investment bank; (3) the Company cannot enforce the 2011 settlement and release agreement between the Company and PhotoMedex, Inc. ("Settlement Agreement") against Strata; and (4) that any dispute regarding the Geiger Email does not relate to the Settlement Agreement. The action filed by Strata and Mr. Geiger does not request any monetary damages.

On May 16, 2019, the Company filed an action against Strata, Mr. Geiger and Accelmed Growth Partners, L.P. (collectively, the "Strata Parties") in the United States District Court for the Southern District of California (Civil Action No. 19-cv-0920-AJB-MSB (the "California Case")) alleging (1) breach of the Settlement Agreement, (2) intentional interference in contractual relations, (3) intentional interference in prospective economic relations, and (4) trade libel. In the California Case, the Company alleges, among other things, that the statements in the Geiger Email regarding alleged patent infringement constitute a breach of the Settlement Agreement, that the Strata Parties employed deceptive practices designed to delay the Company's initial public offering and reduce the amount of capital raised by the Company, and that statements in the Geiger Email regarding patent infringement, off label promotion and reimbursement constitute trade libel.

On August 11, 2020, the Company and the Strata Parties executed a settlement agreement, dated as of August 6, 2020, that includes a mutual release of claims and an agreement to terminate the Pennsylvania Case and the California Case.

On February 12, 2020, Dean Irwin, the Company's former Chief Executive Officer, filed a Demand for Arbitration, alleging that the Company attempted to coerce him into signing a non-standard separation agreement and release of claims, contrary to the terms of his Severance Agreement. Mr. Irwin claims that he was willing to sign the Company's standard separation agreement and release of claims. Based on this allegation, Mr. Irwin is claiming nonpayment of wages, penalties for nonpayment of wages, failure to provide wage statements, breach of contract, and breach of implied covenant of good faith and fair dealing. On December 21, 2020, the arbitrator granted summary judgment in favor of the Company on four of the five issues raised by Mr. Irwin in the arbitration. The Company and Mr. Irwin executed a settlement agreement, effective as of January 19, 2021, whereby the Company paid Mr. Irwin $265,000 in exchange for a mutual release of claims and dismissal of the arbitration.The Company has accrued this settlement amount at December 31, 2020.

401(k) **—**In January 2019, the Company established a defined contribution plan under Section 401(k) of the Internal Revenue Code ("401(k) Plan") that the Company administers for participating employees' contributions. All full-time employees are eligible under the 401(k) Plan. The Company will make contributions, based on a match of 100% of each employee's contribution up to 3% and 50% of contributions between 3% and 5%, with the match-eligible contribution being limited to 4% of the employee's eligible compensation. The Company match expense was $0.3 million for each of the years ended December 31, 2020 and 2019.

Note 16—Segment Information

The Company has organized its business into two operating segments based on the product specialties: the vascular segment and the dermatology segment.

In deciding how to allocate resources and assess performance, the Company's chief operating decision maker regularly evaluates the sales and gross profit of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to the Company and not specific to a particular segment; therefore, these amounts are not evaluated by the Company's chief operating decision maker on a segmented basis.

The following tables summarize segment performance (in thousands):

	Year Ended December 31,	
	2020	2019
Vascular	$ 259	$ 1,275
Dermatology	4,146	5,924
Net revenue	$ 4,405	$ 7,199
Vascular	$ 1,970	$ 4,036
Dermatology	3,512	4,814
Cost of revenue	$ 5,482	$ 8,850
Vascular	$ (1,711)	$ (2,761)
Dermatology	634	1,110
Gross (loss) profit	$ (1,077)	$ (1,651)

Generally, all assets are common assets, except for lasers, which are a subset of property and equipment. The net book value of the lasers aggregated in the vascular segment was $1.9 million and $2.6 million as of December 31, 2020 and 2019, respectively. The net book value of the lasers placed with customers aggregated in the dermatology segment was $0.7 million and $0.9 million as of December 31, 2020 and 2019, respectively.

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

	Year Ended December 31,	
	2020	2019
United States	$ 4,181	$ 6,568
All other countries	224	631
Net revenue	$ 4,405	$ 7,199

EXHIBIT 4.2

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes certain terms of our capital stock and certain provisions of our amended and restated certificate of incorporation. We have adopted an amended and restated certificate of incorporation and amended and restated bylaws, and this description summarizes certain of the provisions that are included in those documents. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, copies of which are filed with the SEC as exhibits to this Annual Report on Form 10-K, and to the applicable provisions of Delaware law.

Our authorized capital stock consists of 310,000,000 shares of capital stock, of which 300,000,000 shares are designated as common stock, $0.0001 par value per share, and 10,000,000 shares are designated as preferred stock, $0.0001 par value per share. Our board of directors is authorized, without stockholder approval, except as required by the listing standards of the NYSE, to issue shares of our preferred stock. As of March 10, 2021, there were 3,259,340 shares of common stock issued and outstanding and there were 68 holders of record of our common stock.

Common Stock

The holders of common stock are entitled to one vote per share on all matters submitted to a vote of our stockholders and do not have cumulative voting rights. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. Subject to preferences that may be applicable to any preferred stock outstanding at the time, the holders of outstanding shares of common stock are entitled to receive ratably any dividends declared by our board of directors out of assets legally available. See the section captioned "*Dividend Policy*" for additional information. Upon our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any then outstanding shares of preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock.

Preferred Stock

Pursuant to our amended and restated certificate of incorporation, our board of directors has the authority, without further action by the stockholders, to issue from time to time up to 10,000,000 shares of preferred stock in one or more series. Our board of directors may designate the rights, preferences, privileges and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, redemption rights, liquidation preference, sinking fund terms and the number of shares constituting any series or the designation of any series. The issuance of preferred stock could have the effect of restricting dividends on the common stock, diluting the voting power of the common stock, impairing the liquidation rights of the common stock or delaying, deterring or preventing a change in control. Such issuance could have the effect of decreasing the market price of the common stock. We currently have no plans to issue any shares of preferred stock.

Anti-Takeover Effects of Delaware law and our Certificate of Incorporation and Bylaws

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions and certain provisions of Delaware law, which are summarized below, may have the effect of discouraging takeover bids, coercive or otherwise. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Issuance of Undesignated Preferred Stock. As discussed above under "*Description of Capital Stock—Preferred Stock*," our board of directors has the ability to designate and issue preferred stock with voting or other rights or preferences that could deter hostile takeovers or delay changes in our control or management.

Limits on Ability of Stockholders to Act by Written Consent or Call a Special Meeting. Our amended and restated certificate of incorporation provides that our stockholders may not act by written consent. This limit on the ability of stockholders to act by written consent may lengthen the amount of time required to take stockholder actions. As a result, the holders of a majority of our capital stock would not be able to amend the amended and restated bylaws or remove directors without holding a meeting of stockholders called in accordance with the amended and restated bylaws. In addition, our amended and restated bylaws provide that special meetings of the stockholders may be called only by the chairperson of the board, our chief executive officer or president (in the absence of a chief executive officer) or a majority of our board of directors. A stockholder may not call a special meeting, which may delay the ability of our stockholders to force

consideration of a proposal or for holders controlling a majority of our capital stock to take any action, including the removal of directors.

Advance Requirements for Advance Notification of Stockholder Nominations and Proposals. Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of the board of directors. These advance notice procedures may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed and may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempt to obtain control of our company.

Board Classification. Our amended and restated certificate of incorporation provides that our board of directors are divided into three classes, one class of which is elected each year by our stockholders. The directors in each class will serve for a three-year term. For more information on the classified board of directors, see Part III, "*Directors, Executive Officers and Corporate Governance*." Our classified board of directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us because it generally makes it more difficult for stockholders to replace a majority of the directors.

Election and Removal of Directors. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that establish specific procedures for appointing and removing members of our board of directors. Under our amended and restated certificate of incorporation and amended and restated bylaws, vacancies and newly created directorships on our board of directors may be filled only by a majority of the directors then serving on the board of directors.

Under our amended and restated certificate of incorporation and amended and restated bylaws, directors may be removed only for cause by the affirmative vote of the holders of a majority of the shares then entitled to vote at an election of directors.

No Cumulative Voting. The Delaware General Corporation Law provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless our amended and restated certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation and amended and restated bylaws do not expressly provide for cumulative voting. Without cumulative voting, a minority stockholder may not be able to gain as many seats on our board of directors as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence our board of directors' decision regarding a takeover.

Amendment of Charter Provision. Any amendment of the above provisions in our amended and restated certificate of incorporation would require approval by holders of at least 66 2/3% of our then outstanding capital stock entitled to vote, voting together as a single class.

Delaware Anti-Takeover Statute. We are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board

of directors does not approve in advance. We also anticipate that Section 203 may discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

The provisions of Delaware law and the provisions of our amended and restated certificate of incorporation and amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts.

These provisions might also have the effect of preventing changes in our management. It is also possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

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

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219, and its telephone number is 718-921-8300. Our shares of common stock are issued in uncertificated form only, subject to limited circumstances.

Market Listing

Our common stock is listed on the NYSE American under the symbol "RMED."

Exhibit 10.19

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS") and the Defense Health Agency ("DHA"), acting on behalf of the TRICARE Program (collectively, the "United States"), Ra Medical Systems, Inc. ("RMS"), and Robert Gruber (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. RMS is a Delaware corporation with its principal place of business in Carlsbad, California. At all relevant times herein, RMS distributed, marketed, and sold medical devices in the United States, including devices marketed under the trade name DABRA Laser System ("DABRA Laser"). During the relevant time period, the DABRA Laser was cleared by the U.S. Food and Drug Administration ("FDA") only for use in crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease. During the relevant period, RMS sought FDA clearance for the DABRA Laser for use in atherectomy, but the FDA declined the request in May 2017. The DABRA Laser has never had any FDA clearance or approval for use in atherectomy.

B. On July 10, 2019, Robert Gruber ("Relator") filed a qui tam action in the United States District Court for the Eastern District of Michigan captioned *United States, et al., ex rel. Gruber v. Ra Medical Systems, Inc., et al.* (E.D. Mich.) pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action").

C. RMS has entered or will be entering into separate settlement agreements, described in Paragraph 1.b., below (hereinafter referred to as the "Medicaid State Settlement Agreements"), with certain states and the District of Columbia in settlement of the Covered Conduct. States with which RMS executes a Medicaid State Settlement Agreement in the form to which RMS and the State Negotiating Team have agreed, or in a form otherwise agreed to by RMS and an individual State, shall be defined as "Medicaid Participating States."

D. The United States contends that RMS submitted or caused to be submitted claims for payment to: the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395111 ("Medicare"), the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid"), and the TRICARE Program, 10 U.S.C. §§ 1071-1110b ("TRICARE").

E. The United States contends that it has certain civil claims against RMS for engaging in the following conduct during the period from May 1, 2017 through October 31, 2019 (hereinafter referred to as the "Covered Conduct"):

(1) RMS knowingly offered and paid illegal remuneration to certain physicians to induce them to use the DABRA Laser in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). The United States contends that the illegal remuneration consisted of cash payments and fees paid in connection with purported training events and consulting services. The United States further contends that RMS tracked utilization of its high-volume physician customers using an internal document titled "Who Deserve[] Love," which was used to identify physicians that RMS should target with offers of improper remuneration.

(2) RMS knowingly marketed the DABRA Laser for use in atherectomy procedures, where plaque is mechanically removed from occluded blood vessels in patients suffering

from peripheral artery disease, an affliction affecting a person ’s arteries that is a complication associated with smoking, obesity, and especially diabetes. The DABRA Laser was not approved or cleared by the FDA for use in atherectomy procedures. In addition, RMS knowingly marketed the DABRA Laser despite product performance issues causing frequent calibration and overheating problems, which posed a risk to physicians and patients and prompted a Class 2 recall in August 2019. Some of these uses were not reasonable and necessary for the diagnosis or treatment of an illness or injury under 42 U.S.C. § 1395y(a)(1(A), and thus were not covered by Medicare, Medicaid, or TRICARE.

As a result of the foregoing Covered Conduct, the United States alleges that RMS knowingly submitted or caused the submission of false or fraudulent claims for the DABRA Laser to be submitted to, or caused purchases by, Medicare, Medicaid and TRICARE.

F. This Settlement Agreement is neither an admission of liability by RMS nor a concession by the United States that its claims are not well founded.

G. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator’s reasonable expenses, attorneys’ fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. RMS shall pay to the United States and the Medicaid Participating States collectively the sum of $2,500,000 (“Settlement Amount”), which constitutes restitution to the United

States and the Medicaid Participating States. The Settlement Amount shall be paid to the United States and the Medicaid Participating States as follows:

(a) RMS shall pay to the United States the sum of $2,363,483.46 ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than five (5) business days after this Agreement is fully executed by the Parties and delivered to RMS' attorneys.

(b) RMS shall pay the Medicaid Participating States the sum of $136,516.54, to be disbursed in accordance with written instructions from the State Negotiating Team and under the terms and conditions of the agreements that RMS will enter into with the Medicaid Participating States.

2. Conditioned upon the United States receiving the Federal Settlement Amount from RMS and as soon as feasible after receipt, the United States agrees to pay Relator the sum of $496,331.53 as Relator's share of the proceeds pursuant to 31 U.S.C. § 3730(d). Conditioned upon the United States receiving the payments from RMS identified in paragraphs 21 or 22, the United States agrees that it shall pay to Relator by electronic funds transfer 21 percent of each such payment received under the Settlement Agreement as soon as feasible after receipt of the payment. No other Relator payments shall be made by the United States with respect to the matters covered by this Agreement.

3. Subject to the exceptions in Paragraph 7 (concerning excluded claims) below, and conditioned upon RMS's full payment of the Federal Settlement Amount, and subject to Paragraphs 21 through 23, below (concerning revenues, sales, or bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the United States releases RMS from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42

U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. In consideration of the obligations of RMS in this Settlement Agreement, and conditioned upon the payments and non-monetary consideration described in the Settlement Agreement, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, agrees to release and forever discharge RMS and its present and former parents, subsidiaries, affiliates, agents, servants, employees, attorneys, representatives, partners, employers, insurance carriers, officers, directors, assigns, employee benefit plans, predecessors in interest and successors in interest (collectively the "RMS Released Entities") of and from any and all claims, actions, damages, liabilities, losses, expenses, compensations, reimbursements, actions, rights, suits, proceedings and causes of action of whatsoever kind or nature, in law or in equity, known or unknown, suspected or unsuspected, contingent or non-contingent, matured or unmatured, whether or not concealed or hidden, and without regard to the subsequent discovery or existence of such different or additional facts, of any kind of nature whatsoever, now existing or arising in the future, based on any act, omission, event, occurrence or nonoccurrence from the beginning of time to the date of execution of this Agreement, including but not limited to, any claims or causes of action arising out of or in any way relating to, or which have been or could have been made in, the Civil Action, except for Relator's claims against RMS for reasonable expenses, attorneys' fees and costs under 31 U.S.C. § 3730(d), and for retaliation under 31 U.S.C. § 3730(h), both of which are the subject of separate agreements. Also, this release does not include any of the defendants named in the Civil Action, other than RMS.

5. In consideration of the obligations of RMS in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and RMS, and conditioned upon RMS's full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal

health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against RMS under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 7 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude RMS from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

6. In consideration of the obligations of RMS set forth in this Agreement, and upon the United States' receipt of full payment of the Settlement Amount, DHA shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against RMS under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in this paragraph and in Paragraph 7 (concerning reserved claims), below. DHA expressly reserves authority to exclude RMS from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii) (mandatory exclusion), based upon the Covered Conduct. Nothing in this paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding the releases given in Paragraphs 3, 5, and 6 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement; and

f. Any liability of individuals;

8. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the payment described in Paragraph 2, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

9. Relator and RMS have reached separate agreements regarding both Relator's retaliation claims under 31 U.S.C. § 3730(h), as well as Relator's claims for reasonable attorneys' fees, costs, and expenses under 31 U.S.C. § 3730(d). Releases for those claims, which are reserved in this Agreement, will be contained in those separate agreements between Relator and RMS.

10. RMS has provided sworn financial disclosure statements ("Financial Statements") to the United States, and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement. RMS warrants that the Financial Statements are complete, accurate, and current. If the United States learns of asset(s) in which RMS had an interest at the time of this Agreement that were not disclosed in the Financial Statements, or if the United States learns

of any misrepresentation by RMS on, or in connection with, the Financial Statements, and if such nondisclosure or misrepresentation changes the estimated net worth set forth in the Financial Statements by $250,000 or more, the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct, or (b) let the Agreement stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth in excess of the $250,000 previously undisclosed. RMS agrees not to contest any collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorney's fees and expenses.

11. In the event that the United States, pursuant to Paragraph 10 (concerning disclosure of assets) above, opts to rescind this Agreement, RMS agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 90 calendar days of written notification to RMS that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of the Agreement.

12. RMS waives and shall not assert any defenses RMS may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

13. RMS fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that RMS has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

14. RMS fully and finally releases Relator, his heirs, personal representatives, legal representatives, successors, attorneys, agents and assigns, from any and all claims, actions, damages, liabilities, losses, expenses, compensations, reimbursements, actions, rights, suits, proceedings and causes of action of whatsoever kind or nature, in law or in equity, known or unknown, suspected or unsuspected, contingent or non-contingent, matured or unmatured, whether or not concealed or hidden, and without regard to the subsequent discovery or existence of such different or additional facts, of any kind of nature whatsoever, now existing or arising in the future, based on any act, omission, event, occurrence or nonoccurrence from the beginning of time to the date of execution of this Agreement, including but not limited to, any claims (including claims for attorneys' fees, costs, and expenses of every kind and however denominated) that RMS has asserted, could have asserted, or may assert in the future against Relator, himself individually, his heirs, personal representatives, legal representatives, successors, attorneys, agents and assigns, related to the Covered Conduct and Relator's investigation and prosecution thereof.

15. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier; TRICARE carrier or payer) or any state payer, related to the Covered Conduct; and RMS agrees not to resubmit to any Medicare contractor, TRICARE carrier or payer, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

16. RMS agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395111-1 and 1396-1396w-5; and the regulations and official program directives promulgated

thereunder) incurred by or on behalf of RMS, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(3) RMS's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement;

(5) the payment RMS makes to the United States pursuant to this Agreement and any payments that RMS may make to Relator, including costs and attorneys fees; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS.

are unallowable costs for government contracting purposes and under the Medicare Program, the Medicaid Program, and the TRICARE Program (hereinafter referred to as Unallowable Costs). However, nothing in paragraph 16.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to RMS.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by RMS, and RMS shall not charge such Unallowable Costs directly or

indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by RMS or any of its subsidiaries or affiliates to the Medicare, Medicaid, or TRICARE Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: RMS further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by RMS or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. RMS agrees that the United States, at a minimum, shall be entitled to recoup from RMS any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by RMS or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on RMS or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine RMS's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

17. RMS agrees to cooperate fully and truthfully with the United States ' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, RMS shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. RMS further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

18. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 32 and 33, below.

19. RMS agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

20. RMS warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to RMS, within the meaning of 11 U.S.C. § 547(c)(1), and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a

reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which RMS was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

21. If within any of the next four full fiscal years after the effective date of this settlement (2021, 2022, 2023, and 2024) RMS's fiscal year revenues exceed $10 million, the Company agrees to pay the United States and Medicaid Participating States, per the terms of paragraph 24, an additional: (i) $500,000 for 2021, (ii) $750,000 for 2022, (iii) $1,000,000 for 2023, and (iv) $1,250,000 for 2024, for each corresponding fiscal year where the Company's revenue exceeds $10 million. Payment will be made within 90 days after the end of the fiscal year. Within 90 days after the end of the fiscal year, RMS will provide a certified statement from a responsible corporate officer to the United States stating RMS's revenues for the concluded fiscal year and will attach audited financial statements for that year.

22. If a Change in Control Transaction (as defined below) closes on or before the fourth anniversary of the Effective Date of this Agreement, a portion of the value attributed to RMS in that Change in Control Transaction shall be due and payable to the United States and Medicaid Participating States, per the terms of paragraph 24, within 30 calendar days as follows:

a. First, RMS shall pay a total of $5 million;

b. Second, RMS shall pay an additional 4% of the value attributed to RMS in the Change in Control Transaction if the value attributed to RMS is in excess of $100 million. (For example, if RMS were sold for $200 million, the United States and Medicaid Participating States would be paid $5 million pursuant to subsection (a) above and another $8 million ($200 million x 4% = $8 million) for a total of $13 million.)

The total payment by RMS pursuant to this paragraph 22 shall not exceed $28 million.

For purposes of this paragraph 22, Change in Control Transaction shall mean (A) the date of acquisition of legal title of more than 50 percent of RMS's then issued and outstanding common stock by a person, entity or group (as such terms are defined in Section 13(d)(3) of the Securities Exchange Act of 1934); (B) a merger, reorganization, consolidation, or similar transaction resulting in a business combination where RMS shareholders before the transaction own less than 50 percent of the new entity, or a person, entity, or group own more than 50 percent of the shares of the new entity; or (C) an event (including but not limited to any sale, license agreement, or other conveyance of significant income producing assets, including any intellectual property) which causes RMS to assign, sell, give up, or otherwise transfer more than 50 percent of RMS's assets.

23. If within 91 days of the Effective Date of this Agreement or of any payment made under this Agreement, RMS commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of RMS's debts, or seeking to adjudicate RMS as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for RMS or for all or any substantial part of RMS's assets, RMS agrees as follows:

a. RMS's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and RMS shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) RMS's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) RMS was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States or the Medicaid Participating States; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to RMS.

b. If RMS's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy

Code, the United States, at its sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against RMS for the claims that would otherwise be covered by the releases provided in Paragraphs 3, 5, and 6, above, RMS agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceedings described in the first clause of this Paragraph, and RMS shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) RMS shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding that are brought by the United States within 90 calendar days of written notification to RMS that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on July 10, 2019; and (iii) the United States has a valid claim against RMS in the amount of $56,000,000, minus any payments to the United States pursuant to Paragraph 22, and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

c. RMS acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

24. Any payment pursuant to Paragraph 21 or 22 shall be treated as restitution and shall be paid as follows:

a. 94.54% percent shall be paid pursuant to wire instructions provided by the United States;

b. 5.46% percent shall be paid in accordance with written instructions from the Medicaid Participating States' Negotiating Team and under the terms and conditions of the agreements that RMS will enter into with the Medicaid Participating States.

25. Upon receipt of the payment described in Paragraph 1, above, the United States and Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of RMS with prejudice from the Civil Action pursuant to Rule 41(a)(1).

26. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement, except as to Relator's claim for attorneys' fees, costs, and expenses under 31 U.S.C. § 3730(d), reserved in Paragraph 4.

27. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

28. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Eastern District of Michigan. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

29. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

30. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

31. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

32. This Agreement is binding on RMS's successors, transferees, heirs, and assigns.

33. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

34. All Parties consent to RMS's and the United States' disclosure of this Agreement, and information about this Agreement, to the public.

35. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date of this Agreement"). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: December 28, 2020

BY: /s/ Jonny Zajac
Jonny Zajac
Assistant United States Attorney
United States Attorney's Office
Eastern District of Michigan

DATED: December 28, 2020

BY: /s/ Lisa M. Re
Lisa M. Re
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: December 28, 2020

BY: /s/ Salvatore M. Maida
Salvatore M. Maida
General Counsel
Defense Health Agency
United States Department of Defense

RMS – DEFENDANT

DATED: 12/22/2020

BY: /s/ Will McGuire
Will McGuire
Chief Executive Officer

DATED: December 21, 2020

BY: /s/ Michael C. Theis
Michael C. Theis
Hogan Lovells US LLP
Counsel for Ra Medical Systems, Inc.

ROBERT GRUBER RELATOR

DATED: 12/22/20

BY: /s/ Robert Gruber
Robert Gruber

DATED: 12/22/20

BY: /s/ J. Marc Vezina
J. Marc Vezina
Counsel for **Robert Gruber**

DATED: 12/22/20

BY: /s/ Ryon McCabe
Ryon McCabe
Counsel for **Robert Gruber**

Exhibit 10.20

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
RA MEDICAL SYSTEMS, INC.

I. PREAMBLE

Ra Medical Systemcs, Inc. (RMS) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, RMS is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by RMS under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) RMS's final Annual Report; or (2) any additional materials submitted by RMS pursuant to OIG's request, whichever is later.

C. The scope of this CIA is governed by the following definitions:

1. For purposes of this CIA, the term "Covered Persons" includes: (a) all owners of RMS who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading or private placement) and all officers and directors of RMS; (b) all employees of RMS ; and (c) all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of RMS, and in that capacity either: (i) interact directly with healthcare professionals (HCPs) and healthcare institutions (HCIs); or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a RMS employee who is a Covered Person prior to execution or dissemination.

Nothwistanding the above, the term Covered Person does not include part-time or per-diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year."

2. "Government Reimbursed Products" refers to all RMS products that are: (a) marketed or sold by RMS in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

3. The term "Covered Functions" includes: (a) the selling, marketing, advertising, promoting, or branding of Government Reimbursed Products; (b) the preparation or external dissemination of promotional materials or information about, or the provision of services relating to, Government Reimbursed Products, including those functions relating to RMS's review and approval processes for promotional materials and any applicable review committee(s); (c) the preparation or external dissemination of non-promotional materials about Government Reimbursed Products, including those functions relating to RMS's review and approval process for any non-promotional materials and any applicable review committees; (d) contracting with health care professionals (HCPs) for consulting services (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and any research-related activities, and authorship of articles or other publications relating ot Government Reimbursed Products), or other fee-for service arrangements relating to Government Reimbursed Products; (e) reviewing and/or approving requests for grants or charitable contributions.

4. The term "Sponsorships" shall mean support for a program, event, or organization in return for the advertisement, or promotion of RMS products, including healthcare-related conventions and conference sponsorships, promotional booths, exhibit space, advertisements, memberships, signage rights, naming rights, and subscriptions.

5. The term "Third Party Educational Activity" shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by RMS, including but not limited to, continuing medical education (CME), disease awareness, or symposia at medical conferences.

III. CORPORATE INTEGRITY OBLIGATIONS

RMS shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations

1. *Compliance Officer.* Within 90 days after the Effective Date, RMS shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of RMS; shall report directly to the Chief Executive Officer of RMS; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for RMS. The Compliance Officer shall be responsible for, without limitation:

a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in

this CIA and with Federal health care program and FDA requirements;

b. making periodic (at least quarterly) reports regarding compliance matters in person to the Board of Directors of RMS (Board) and shall be authorized to report on such matters to the Board at any time. Written documentation of the Compliance Officer's reports to the Board shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by RMS as well as any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

RMS shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five business days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, RMS shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as sales, marketing, legal, medical affairs/medical information, regulatory affairs, research and development, human resources, audit, finance, manufacturing, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of RMS's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

RMS shall report to OIG, in writing, any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 business days after such a change.

3. *Board Compliance Obligations*. The Board (or the Audit Committee of the Board of Directors) of RMS ("Board") shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board must include independent (i.e., non-employee and non-executive) members.

The Board shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee RMS's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and

c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board, summarizing its review and oversight of RMS's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

> "The Board has made a reasonable inquiry into the operations of RMS's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, RMS has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at RMS.

RMS shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 business days after such a change.

4. *Management Certifications*. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain RMS employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable RMS department is in compliance with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Financial Officer; Vice President of Operations; Director of Marketing; Head of Sales for Dermatology. For each Reporting Period, each Certifying Employee shall sign a certification that states:

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and RMS policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of RMS is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity

Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 90 days after the Effective Date, RMS shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards

1. Policies and Procedures. Within 90 days after the Effective Date, RMS shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and RMS's compliance with Federal health care program and FDA requirements (Policies and Procedures). Throughout the term of this CIA, RMS shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons. At a minimum, the Policies and Procedures shall address the following:

a. appropriate ways to conduct Covered Functions in compliance with all: (i) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements;

b. the materials and information that may be distributed by RMS sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which RMS sales representatives respond to requests for information about non-FDA approved (or "off-label") uses of Government Reimbursed Products;

c. the materials and information that may be distributed by RMS and the mechanisms through, and manner in which RMS receives and responds to requests for information from an HCP or another individual or entity about off-label uses of Government Reimbursed Products; the form and content of information disseminated by RMS in response to such requests; and the internal review process for the information disseminated;

d. the manner and circumstances under which RMS medical and/ or regulatory personnel interact with or participate in meetings or

events with HCPs, HCIs, or payors (either alone or with RMS sales representatives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to requests for information about off-label uses of Government Reimbursed Products;

e. the materials and information that may be distributed or made available by RMS through social media and/or direct-to-consumer advertising;

f. the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other RMS representatives who promote and sell Government Reimbursed Products;

g. the development, implementation, and review of all plans for the distribution of Government Reimbursed Products for evaluation purposes (Evaluation Products). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive Evaluation Products (including, separately, from sales representatives, or through other channels);

h. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;

i. agreements or arrangements with HCPs or HCIs for the purchase or licensing of intellectual property (including but not limited to, patents, patent applications, and the payment of roylaties);

j. programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;

k. review and approval of, and payment for, travel and related expenses for HCPs including those in connection with HCP participation in educational, research, training, or other RMS-sponsored programs or activities;

l. sponsorship or funding of grants (including educational grants) or charitable contributions;

m. funding of, or participation in, any Sponsorships or Third Party Educational Activity as defined in Section II.C.4 and II.C.5 above;

n. review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside RMS by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during RMS's review and approval process and are elevated when appropriate;

o. compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representative and their managers;

p. medical device reporting, including the development of medical device reporting procedures and establishing and maintaining medical device reporting event files, as required by 21 CFR Part 803 and other applicable FDA requirements; and

q. disciplinary policies and procedures for violations of RMS's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

At least annually (and more frequently, if appropriate), RMS shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education

1. *Covered Persons Training*. Within 90 days after the Effective Date, RMS shall develop a written plan (Training Plan) that outlines the steps RMS will take to ensure that: (a) all Covered Persons receive at least annual training regarding RMS's CIA requirements and compliance program, and (b) all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions and (ii) all RMS Policies and Procedures and other requirements applicable to Covered Functions. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons and required to attend each training session, length of the training session(s), schedule for training, and format of the training. RMS shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Training*. In addition to the training described in Section III.C.1, within 90 days after the Effective Date, each member of the Board shall receive training regarding the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically,

the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of OIG's guidance on Board member responsibilities.

New members of the Board shall receive the Board Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

3. *Training Records.* RMS shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided as required.

D. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, RMS shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each Government Reimbursed Product, including risks associated with the Covered Functions. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted annually and shall require RMS to: (1) identify and prioritize risks, (2) develop work plans related to the identified risk areas, (3) implement the work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. RMS shall maintain the risk assessment and internal review process for the term of the CIA.

E. Review Procedures

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, RMS shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Retention of Records.* The IRO and RMS shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and RMS) related to the reviews.

c. *Access to Records and Personnel.* RMS shall ensure the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E., and that all records furnished to the IRO are accurate and complete.

2. *System, Transaction, and Additional Items Reviews*. As set forth more fully in Appendix B, the IRO reviews shall consist of three components: Systems Reviews and Transactions Reviews relating to the Covered Functions and an Additional Items Review.

a. *Systems Review*. The Systems Reviews shall assess RMS's systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in RMS's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the first and fourth Reporting Periods. If RMS materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendix B.

b. *Transactions Review*. The Transactions Reviews shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.

c. *Additional Items Review*. Each IRO review shall also include a review of up to three additional areas or practices of RMS identified by OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the IRO review for a particular Reporting Period, OIG will consult with RMS and may consider internal audit and monitoring work conducted by RMS, the Government Reimbursed Product portfolio, the nature and scope of RMS's promotional and other practices, the nature and scope of RMS's arrangements with HCPs and HCIs, and other information known to OIG.

3. *IRO Review Reports*. The IRO shall prepare a report based upon each IRO review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendices A-B.

4. *Independence and Objectivity Certification*. The IRO shall include in its report(s) to RMS a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of current and prior engagements between RMS and IRO.

F. Disclosure Program

Within 90 days after the Effective Date, RMS shall establish a Disclosure Program that includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to

disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with RMS's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. RMS shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of RMS's Covered Persons shall be expected to report suspected violations of any Federal health care program or FDA requirements to the Compliance Officer or other appropriate individual designated by RMS. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, RMS shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record all disclosures, whether or not related to a potential violation of criminal, civil or administrative law related to Federal health care programs or FDA requirements, in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the individual or department responsible for reviewing the disclosure, the status of the review, and any corrective action taken in response to the review.

G. Ineligible Persons

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded from participation in the Federal health care programs; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.

b. "Exclusion List" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at http://www.oig.hhs.gov).

2. *Screening Requirements*. RMS shall ensure that all prospective and current Covered Persons are not Ineligible Persons by implementing the following screening requirements.

a. RMS shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. RMS shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on an annual basis thereafter.

c. RMS shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects RMS's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. RMS understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that RMS may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether RMS meets the requirements of Section III.G.

3. *Removal Requirement*. If RMS has actual notice that a Covered Person has become an Ineligible Person, RMS shall remove such Covered Person from responsibility for, or involvement with, RMS's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation is paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If RMS has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, RMS shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, RMS shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to RMS conducted or brought by a governmental entity or its agents involving an allegation that RMS has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding.

RMS also shall provide written notice to OIG within 30 days after the resolution of the matter and describe the findings and/or results of the investigation or proceeding, if any.

I. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

b. a matter that a reasonable person would consider a probable violation of FDA requirements relating to the promotion of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

d. the filing of a bankruptcy petition by RMS. A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events*. If RMS determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, RMS shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Sections III.I.1.a and III.I.1.b.* For Reportable Events under Sections III.I.1.a and b, the report to OIG shall include:

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;

c. the Federal health care programs affected by the Reportable Event, if any;

d. a statement of the FDA requirements probably violated by the Reportable Event, if any; and

e. a description of RMS's actions taken to correct the Reportable Event and prevent it from recurring.

4. Reportable Events under Section III.I.1.c. For Reportable Events under Section III.I.1.c, the report to OIG shall include:

a. the identity of the Ineligible Person and the job duties performed by that individual;

b. the dates of the Ineligible Person's employment or contractual relationship;

c. a description of the Exclusion List screening that RMS completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Ineligible Person was identified; and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. Reportable Events under Section III.I.1.d. For Reportable Events under Section III.I.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA requirements implicated.

J. Notification of Communications with FDA

Within 30 days after the date of any written or electronic report, correspondence, or communication between RMS and the FDA that materially discusses RMS's or a Covered Person's actual or potential unlawful or improper promotion of RMS's products (including any improper dissemination of information about off-label indications) or that involves adverse events required to be reported to the FDA under 21 C.F.R. Part 803, RMS shall provide a copy of the report, correspondence, or communication to OIG. RMS shall also provide written notice to OIG within 30 days after the resolution of any such disclosed improper promotional matter, and shall provide OIG with a description of the findings and/or results of the matter, if any.

K. Field Force Monitoring and Review Efforts

Within 90 days after the Effective Date, RMS shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: (1) direct field observations (Observations) of sales personnel and (2) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Observations*. As a component of the FFMP, RMS compliance or other appropriately trained RMS personnel who are independent from the functional area being monitored, or third party consultants appropriately trained by and under the supervision of RMS (Monitoring Personnel) shall conduct observations of sales representatives (including any contract sales personnel) to assess whether the messages delivered and materials distributed to HCPs and HCIs are consistent with applicable legal requirements and with RMS's Policies and Procedures. These observations shall be full day ride-alongs with field sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs and HCIs during the workday. The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, include a review of each actively promoted Government Reimbursed Product, and be conducted across the United States.

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes:

1) the identity of the sales representative;

2) the identity of the Monitoring Personnel who conducted the Observation;

3) the date and duration of the Observation;

4) the Government Reimbursed Product(s) promoted during the Observation;

5) an overall assessment of compliance with RMS Policies and Procedures; and

6) the identification of any potential off-label promotional activity or other improper conduct by the field sales representative.

Monitoring Personnel shall conduct at least 3 Observations during each Reporting Period.

Monitoring Personnel shall have access to all relevant records and information necessary to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

2. *Records Reviews.* As a component of the FFMP, RMS shall also review various types of records to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

a. For each Reporting Period, RMS shall develop and implement a plan for conducting Records Reviews associated with at least 2 Government Reimbursed Products. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate district and/or region (as applicable) who promoted the products under review.

b. The Records Reviews shall include the monitoring and review of:

i. records and systems associated with sales representatives' interactions with HCPs and HCIs (including records relating to consulting and other fee-for-service arrangements, speaker program activities, , travel and entertainment, expense reports, any payments to HCPs or HCIs, and sales communications from managers);

ii. records relating to requests for medical information about or inquiries relating to, the Government Reimbursed Products under review;

iii. sales representative call notes;

iv. sales representatives' e-mails and other electronic records; and

v. recorded results of the Observations of sales force representatives, coaching guides, and manager notes.

3. *Reporting and Follow-up*. Results from the FFMP shall be compiled and reported to the Compliance Officer for review and remediation as appropriate.

L. Requirements Relating to Certain Promotional and Non-Promotional Activities

RMS shall develop policies, procedures, and systems to implement the requirements outlined below relating ot the following types of activites: (1) arrangements with HCPs to serve as presenters on behalf of RMS or participate in training programs related to such presentations (Speaker Programs), (2) arrangements with HCPs for services other than Speaker Programs, referred to herein as "consulting arrangement activities," and (3) grant and charitable contribution activities

1. *Speaker Programs*. To the exent that RMS engages in Speaker Programs, RMS shall establish and implement the following requirements:

a. A process to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements regarding the use of RMS approved materials and requirements that speakers may not directly or indirectly promote the product for off-label uses).

b. A centralized, electronic system to initiate and track all Speaker Programs that includes controls designed to ensure that Speaker Programs are used for legitimate and lawful purposes in accordance with all applicable Federal health care program and FDA requirements.

c. A process to ensure speakers are paid according to a centrally managed, pre-set rate structure determined based on an independent fair-market value analysis.

d. A comprehensive list of Speaker Program attendees through its centralized system. In addition, RMS shall use its centralized system to handle all logistics and spending associated with Speaker Programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with Speaker Programs.

e. A requirement for certifications by sales representatives or other RMS personnel that a Speaker Program complied with RMS requirements, or in the event of non-compliance, RMS shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

2. *Consulting Arrangement Activities.* To the extent that RMS engages HCPs for services other than for speaker programs (e.g., training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities, and any other financial engagement or arrangement with an HCP), such HCPs shall be referred to herein as Consultants. Within 90 days of the Effective Date, RMS shall:

a. Require all Consultants to enter written agreements describing the scope of work to be performed, the consultant fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on an independent fair-market value analysis.

b. Establish a process to develop an annual budgeting plan that specifies (i) the business needs for, and the estimated numbers of, the various Consultant engagements and activities to occur during the following year and (ii) the budgeted amounts to be spent on Consultant-related activities. RMS compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan, for the purpose of ensuring that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and RMS Policies and Procedures.

c. Establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information

about the numbers and qualifications of the HCPs and HCIs to be engaged, the agenda for any proposed meeting, and a description of the proposed work to be done and the type of work product to be generated). Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by RMS compliance personnel.

d. Amend its policies and procedures in a manner designed to ensure that each Consultant performs the work for which the Consultant is engaged and that, as applicable, RMS receives the work product generated by the Consultant.

3. Grant and Charitable Contribution Activities. Within 90 days of the Effective date, RMS shall:

a. Establish a centralized system which shall be the exclusive mechanism through which requestors may request or be awarded amounts for Third Party Educational Activities, other grant activities involving HCPs and HCIs (referred to below as "Grants"), and charitable contributions supported by RMS (referred to below as "Contributions").

b. Establish a process to review requests for Grants and Contributions according to standardized, objective criteria developed by RMS (such as based upon the qualifications of the requestor, or the quality of the program funded by the Grant or Contribution) and to ensure that Grants or Contributions are provided only pursuant to a written agreement with the funding recipient and that payments to the funding recipient are consistent with the written agreement. RMS's sales and marketing personnel shall have no involvement in, or influence over, the review and approval of requests for Grants or Contributions.

M. Reporting of Physician Payments

1. Reporting of Payment Information. Within 90 days after the Effective Date, RMS shall post on its website a description of the types of Payments it makes to Covered Recipients and include a link to CMS's Open Payments Data website (www.openpaymentsdata.cms.gov). RMS also shall include on its website instructions regarding how to utilize the CMS Open Payments Data search tool to search for information regarding Payments provided to Covered Recipients from RMS.

2. Definitions. For purposes of this Section III.M, the terms "Payments" and "Covered Recipient" are defined as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by CMS.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, RMS proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA; or (b) purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any such new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. RMS shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, RMS wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, RMS must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, RMS shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A.2;

3. the names of the Board members who are responsible for satisfying the Board compliance obligations described in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

5. a list of the Policies and Procedures required by Section III.B.1;

6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);

7. a description of the risk assessment and internal review process required by Section III.D;

8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to RMS that includes a summary of all current and prior engagements between RMS and the IRO;

9. a description of the Disclosure Program required by Section III.F;

10. a description of the Ineligible Persons screening and removal process required by Section III.G;

11. a description of the FFMP required by Section III.K;

12. a description of the policies, procedures, and systems implemented pursuant to the Requirements Relating to Certain Promotional and Non-Promotional Activities outlined in Section III.L;

13. a certification from the Compliance Officer that information regarding Payments has been posted on RMS's website as required by Section III.M;

14. a list of all of RMS's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; and the locations' Medicare and state Medicaid provider number and/or supplier number(s) if any;

15. a description of RMS's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

16. the certifications required by Section V.C.

B. Annual Reports

RMS shall submit a written report to OIG on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board compliance obligations; and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, and Certifying Employees;

2. a description of any changes to the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

3. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);

4. the Board resolution required by Section III.A.3, a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution, and the Compliance Expert report as required in Section III.A.3.d.;

5. a list of any new or revised Policies and Procedures required by Section III.B.1 developed during the Reporting Period;

6. a description of any changes to RMS's Training Plan developed pursuant to Section III.C and a summary of any Board training provided during the Reporting Period;

7. a description of any changes to the risk assessment and internal review process required by Section III.D, including the reasons for such changes;

8. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed; (b) any internal audits performed; (c) corrective action plans developed in response to any internal audits; and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

9. a complete copy of all reports prepared pursuant to Section III.E and RMS's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

10. a certification from the IRO regarding its professional independence and objectivity with respect to RMS, including a summary of all current and prior engagements between RMS and the IRO;

11. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or Government Reimbursed Products, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

12. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period;

15. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.J. This summary shall include a description of each matter and the status of each matter;

16. a summary of any changes the FFMP and the results of the FFMP required by Section III.K, including copies of the Observations for any instances in which it was determined that improper conduct occurred and a description of the action(s) that RMS took as a result of such determinations;

17. a summary of the any changes to the policies, procedures, and systems relating to the Requirements for Certain Promotional and Non-Promotional Activities described in Section III.L, including the reasons for such changes;;

18. a certification from the Compliance Officer that information regarding Payments has been posted on RMS's website as required by Section III.M;

19. a description of all changes to the most recently provided list of RMS's locations (including addresses) as required by Section V.A.14;

20. a description of any changes to RMS's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and

21. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications

1. *Certifying Employees*. In each Annual Report, RMS shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Compliance Officer and Chief Executive Officer*. The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

a. to the best of his or her knowledge, except as otherwise described in the report, RMS has implemented and is in compliance with all requirements of this CIA;

b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and

c. he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

RMS shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. RMS shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
A. 330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

RMS:

Will McGuire

Chief Executive Officer

Ra Medical Systems, Inc.
B. 2070 Las Palmas Drive
Carlsbad, CA 92011
Phone: (760) 804-1648
Fax: (760) 804-1657
wmcguire@ramed.com

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, RMS may be required to provide OIG with an additional copy of each notification or report required by this CIA in OIG's requested format (electronic or paper).

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of or

copy RMS's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of RMS's locations for the purpose of verifying and evaluating: (a) RMS's compliance with the terms of this CIA and (b) RMS's compliance with Federal health care program requirements and with all applicable FDA requirements. The documentation described above shall be made available by RMS to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of RMS's owners (who are Covered Persons), employees, contractors and directors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. RMS shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. RMS's owners, employees, contractors and directors may elect to be interviewed with or without a representative of RMS present.

VIII. DOCUMENT AND RECORD RETENTION

RMS shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify RMS prior to any release by OIG of information submitted by RMS pursuant to its obligations under this CIA and identified upon submission by RMS as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, RMS shall have the rights set forth at 45 C.F.R. § 5.42 (a).

X. BREACH AND DEFAULT PROVISIONS

RMS is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, RMS and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) per obligation for each day RMS fails to establish, implement or comply with any of the following obligations as described in Section III:

   a. Compliance Officer;

   b. Compliance Committee;

c. the Board compliance obligations;

d. the management certification obligations and the development and implementation of a written process for Certifying Employees, as required by Section III.A.4;

e. written Policies and Procedures;

f. the development of a written training plan and the training and education of Covered Persons and Board members;

g. a risk assessment and internal review process;

h. a Disclosure Program;

i. Ineligible Persons screening and removal requirements;

j. notification of Government investigations or legal proceedings;

k. reporting of Reportable Events;

l. notification of written communications with FDA;

m. the FFMP;

n. the Requirements Relating to Certain Promotional and Non-Promotional Activities; and

o. posting of any Payment-related information.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day RMS fails to engage and use an IRO as required by Section III.E and Appendix B.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day RMS fails to timely submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day RMS fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

5. A Stipulated Penalty of $1,500 for each day RMS fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date RMS fails to grant access.)

6. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of RMS as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $2,500 for each day RMS fails to grant the IRO access to all records and personnel necessary to complete the reviews required by Section III.E and for each day RMS fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix B; and

8. A Stipulated Penalty of $1,000 for each day RMS fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to RMS stating the specific grounds for its determination that RMS has failed to comply fully and adequately with the CIA obligation(s) at issue and steps RMS shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 business days after the date RMS receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-7 of this Section.

B. Timely Written Requests for Extensions

RMS may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after RMS fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after RMS receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter*. Upon a finding that RMS has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify RMS of: (a) RMS's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 business days after the receipt of the Demand Letter, RMS shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event RMS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until RMS cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed

time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination*. Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that RMS has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:

a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure by RMS to report a Reportable Event and take corrective action as required in Section III.I;

c. a failure to engage and use an IRO in accordance with Section III.E and Appendix B; or

d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by RMS constitutes an independent basis for RMS's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that RMS has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify RMS of: (a) RMS's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure*. RMS shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. the alleged material breach has been cured; or

b. the alleged material breach cannot be cured within the 30 day period, but that: (i) RMS has begun to take action to cure the material breach; (ii) RMS is pursuing such action with due diligence; and (iii) RMS has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, RMS fails to satisfy the requirements of Section X.D.3, OIG may exclude RMS from participation in the Federal health care programs. OIG shall notify RMS in writing of its determination to exclude RMS (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of RMS's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, RMS may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights*. Upon OIG's delivery to RMS of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, RMS shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether RMS was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. RMS shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders RMS to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless RMS requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether RMS was in material breach of this CIA and, if so, whether:

a. RMS cured such breach within 30 days of its receipt of the Notice of Material Breach; or

b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following RMS's receipt of the Notice of Material Breach: (i) RMS had begun to take action to cure the material breach within that period; (ii) RMS pursued such action with due diligence; and (iii) RMS provided to OIG within that period a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for RMS, only after a DAB decision in favor of OIG. RMS's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude RMS upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that RMS may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. RMS shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of RMS, RMS shall be reinstated effective on the date of the original exclusion.

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

RMS and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) RMS's responsibility to follow all applicable Federal health care program and FDA requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program or FDA requirements.

D. The undersigned RMS signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically-transmitted signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF RMS

/s/ Will McGuire — 12/21/2020

WILL MCGUIRE — DATE
Chief Executive Officer
Ra Medical Systems, Inc.

/s/ Michael C. Theis — 12/21/2020

MICHAEL C. THEIS — DATE
Hogan Lovells US LLP

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/s/ Gregory Demske
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

12/28/2020
DATE

/s/ Dennis Pangindian
DENNIS A. PANGINDIAN
Associate Counsel
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

12/28/2020
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

A. IRO Engagement

1. RMS shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by RMS in response to a request by OIG, whichever is later, OIG will notify RMS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, RMS may continue to engage the IRO.

2. If RMS engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, RMS shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by RMS at the request of OIG, whichever is later, OIG will notify RMS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, RMS may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the medical device industry and have expertise in all applicable Federal health care program and FDA requirements relating to Covered Functions, including but not limited to expertise relating to marketing and promotional activities associated with medical devices and the Federal Anti-Kickback Statute and False Claims Act;

2. assign individuals to design and select the samples for the Transactions Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each IRO Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;

3. respond to all OIG inquires in a prompt, objective, and factual manner; and

4. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform each IRO Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *RMS and IRO*. If RMS terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, RMS must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. RMS must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO*. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify RMS in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. RMS shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG' s review of any information provided by RMS regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify RMS in writing that RMS shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. RMS must engage a new IRO within 60 days of its receipt of OIG’s written notice. The final determination as to whether or not to require RMS to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

IRO REVIEWS

A. IRO Engagement, General Description

As specified more fully below, RMS shall retain an IRO to perform engagements to assist RMS in assessing and evaluating certain of its systems, processes, policies, and procedures related to RMS's Covered Functions (IRO Review). The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. RMS may engage, at its discretion, a single entity to perform both components of the IRO Reviews, provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in RMS's systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform the Systems Review of certain systems, processes, policies and procedures relating to Covered Functions (as set forth below) for the first and fourth Reporting Periods. If RMS materially changes its systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review as set forth above. The additional Systems Review(s) shall consist of: (1) an identification of the material changes, and (2) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

B. IRO Systems Review

The Systems Review shall be a review of RMS's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Covered Functions. More specifically, the IRO shall review RMS's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures):

1. RMS's systems, policies, processes, and procedures relating to the materials and information that may be distributed by RMS sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which RMS sales representatives respond to requests for information about non-FDA approved (or "off-label") uses of Government Reimbursed Products;

2. RMS's systems, policies, processes, and procedures relating to the materials and information that may be distributed and the mechanisms through, and manner in which, RMS receives and responds to requests for information from an HCP or another individual or entity about off-label uses of Government Reimbursed Products; the form and content of information disseminated by RMS in response to such requests; and the internal review process for the information disseminated;

3. RMS's systems, policies, processes, and procedures relating to the manner and circumstances under which RMS medical personnel interact with or participate in meetings or

events with HCPs, HCIs, or payors (either alone or with RMS sales representatives) and the role of RMS medical personnel at such meetings or events, as well as how they handle responses to requests for information about off-label uses of Government Reimbursed Products;

4. RMS's systems, policies, processes, and procedures relating to the materials and information that may be distributed or made available by RMS through social media and/or direct-to-consumer advertising;

5. RMS's systems, policies, processes, and procedures relating to the development, implementation, and review of policies relating to the distribution of Government Reimbursed Products for evaluation purposes (Evaluation Product). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive Evaluation Product from RMS (including, separately, from sales representatives, or through other channels);

6. RMS's systems, policies, processes, and procedures relating to consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;

7. RMS's systems, policies, processes, and procedures relating to agreements or arrangements with HCPs or HCIs for the purchase or licensing of intellectual property (including, but not limited to, patents, patent applications, and payment of royalties);

8. RMS's systems, policies, processes, and procedures relating to programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;

9. RMS's systems, policies, processes, and procedures relating to the review and approval of, and payment for, travel and related expenses for HCPs including those in connection with an HCP's participation in educational, research, training, or other RMS-sponsored programs or activities;

10. RMS's systems, policies, processes, and procedures relating to the sponsorship or funding of grants (including educational grants) or charitable contributions;

11. RMS's systems, policies, processes, and procedures relating to funding of, or participation in, any Sponsorships or Third Party Educational Activity as defined in Section II.E.4 and II.E.5 of the CIA;

12. RMS's systems, policies, processes, and procedures relating to the review of promotional, reimbursement-related, and disease state materials and information intended to be disseminated outside RMS by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical

concerns are properly addressed during RMS's review and approval process and are elevated when appropriate;

13. RMS's systems, policies, processes, and procedures relating to compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives and their managers;

14. RMS's systems, policies, processes, and procedures relating to medical device reporting, including the development of medical device reporting procedures and establishing and maintaining medical device reporting event files, as required by 21 CFR Part 803 and other applicable FDA requirements; and

15. RMS's systems, policies, processes, and procedures relating to disciplinary policies and procedures for violations of RMS's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

C. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review performed. For each of the Reviewed Policies and Procedures identified in Section B above, the report shall include the following items:

1. a description of the documentation (including policies) reviewed and any personnel interviewed;

2. a detailed description of RMS's systems, policies, processes, and procedures relating to the items identified in Sections B.1-15 above, including a general description of RMS's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections B.1-14 above are made known or disseminated within RMS;

4. findings and supporting rationale regarding any weaknesses in RMS's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

5. recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

D. IRO Transactions Review

The Transactions Review shall include a review of: (1) a sample of consultant or other fee-for-service arrangements entered into with HCPs (including all events and expenses related to such engagements or arrangements), (2) a sample of Payments, and (3) up to three additional items identified by the OIG in accordance with Section III.E.2.c of the CIA (hereafter "Additional Items"). The IRO shall report on all aspects of its reviews in the Transactions Review Report.

1. Review of Consulting Activities. For purposes of this Appendix B , the term “Consulting Activities” shall include all consulting and other fee for service arrangements entered with HCPs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship and authorship-related activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements.

a. For the first Reporting Period, the IRO shall select and review a sample of 3 Consulting Activities entered into with HCPs and all related expenses. For the second and subsequent Reporting Periods, the IRO shall review a total of at least 3 Consulting Activities which shall include a review of specified numbers of each type of Consulting Activities as determined by the OIG. Prior to the determination of the number of each type of Consulting Activity to be reviewed during the second and subsequent Reporting Periods, RMS shall provide to the OIG the information specified below in the next paragraph within 60 days prior to the end of the applicable preceding Reporting Period.

b. The IRO shall select its sample of Consulting Activities for review in consultation with OIG after the provision of information about the Consulting Activities to the OIG. RMS shall provide the following information to the OIG: 1) a description of each type of Consulting Activity undertaken during the Reporting Period and a description of the services to be provided under each Consulting Activity; 2) the number of each type of RMS Consulting Activity undertaken during the Reporting Period; and 3) the overall budgeted amount to be spent in connection with each type of Consulting Activity during the Reporting Period.

c. For each Consulting Activity reviewed the IRO shall determine whether:

i. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and related expenses to be paid for the Consulting Activity, and the compliance obligations for the Consultant;

ii. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure established by RMS;

iii. the rate structure was established based on an independent FMV analysis;

iv. the Consulting Activity was identified in the annual Consultant budgeting plan developed by RMS;

v. a needs assessment that identifies the business need for the Consulting Activity and provides details about the Consulting Activity was completed prior to the initiation of the Consulting Activity;

vi. the Consulting Activity was reviewed and approved in accordance with RMS Policies and Procedures;

vii. RMS collected and retained a record of the specific activity performed by the HCP and, if applicable, a copy of the work product generated by the HCP in connection with the Consulting Activity; and

viii. the activity undertaken by the Consultant and/or the work product generated by the HCP was used by RMS in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity.

2. Review of Payments. For purposes of this Appendix B, the term "Control Documents" shall include all material documents or electronic records associated with each RMS Payment reflected in the Open Payments database for that calendar year. For example, the term "Control Documents" includes, but is not limited to, documents relating to the nature, purpose, and amount of the Payment; contracts relating to the Payment; documents relating to the occurrence of Payment; documents reflecting any work product generated in connection with the Payment; documents submitted by sales representatives or headquarters personnel to request approval for the Payment; and business rationale or justification forms relating to the Payment.

a. For each Reporting Period, the OIG shall have the discretion to identify up to 30 Covered Recipients who received Payments from RMS during the prior calendar year and will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the Covered Recipients subject to the IRO Review. If the OIG elects not to exercise its discretion, the IRO shall randomly select 30 Covered Recipients to be included in the review.

b. For each selected Covered Recipient, the IRO shall review the Control Documents associated with the Payments to the Covered Recipient for all categories reflected in the Open Payments Data website except for the Food/Beverage and Travel/Lodging categories of Payments. Specifically, for each Covered Recipient selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reported to CMS to evaluate the following:

i. whether Control Documents are available relating to each Payment;

ii. whether the Control Documents were completed and archived in accordance with the requirements set forth in RMS's policies;

iii. whether the aggregate value of the Payment as reflected in the Open Payments Database is consistent with the value of the Payment reflected in the Control Documents; and

iv. whether the Control Documents reflect that RMS's policies were followed in connection with the Payment e.g., all required written approvals for the activity were obtained in accordance with RMS's policies.)

3. Review of Additional Items. As set forth in Section III.E.2.c of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items"). No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify RMS of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or RMS shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in RMS's systems, processes, policies, and procedures based on its review of each Additional Item).

a. RMS may propose to OIG that its internal audit(s), reviews, or monitoring activities, including those conducted as part of the Field Force Monitoring Program described in Section III. K and/or other reviews conducted by outside entities at RMS's request be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow RMS's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

b. In making its decision, the OIG agrees to consider, among other factors, the nature and scope of RMS's planned internal audit work or compliance monitoring or audit activities, the results of the Transactions Review(s) during prior Reporting Period(s), and RMS's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies RMS's request to permit its internal audit work or compliance monitoring or audit activities to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, RMS shall engage the IRO to perform the Review as outlined in this Section III. E.

c. If the OIG agrees to permit certain of RMS's internal audit work or compliance monitoring or audit activities for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO.

E. Transactions Review Report

A. General Elements to be Included in the Report. For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

1. Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;

2. Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and

3. Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

B. Results to be Included in Report. The following results shall be included in each Transactions Review Report:

1. Relating to the Review of Consulting Activities

a. a description of each type of Consulting Activity reviewed, including the number of each type of Consulting Activity reviewed and an identification of the types of documents and information reviewed for each Consulting Activity;

b. for each Consulting Activity reviewed, the IRO's findings and supporting rationale as to whether:

i. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and expenses to be paid for each Consulting Activity, and the compliance obligations for the Consultant;

ii. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure set by RMS;

iii. the rate structure was established based on an independent FMV analysis;

iv. the Consulting Activity was identified in the annual Consulting budgeting plan developed by RMS;

v. a needs assessment that identifies the business need for the Consulting Activity and provides detail about the activity was prepared prior to the initiation of the Consulting Activity;

vi. the Consulting Activity was reviewed and approved in accordance with RMS Policies and Procedures,

vii. RMS collected and retained a record of the specific activity performed by the HCP and, if applicable, a copy of the work product generated in connection with the Consulting Activity; and

viii. the activity undertaken by the Consultant and/or the work product generated was used by RMS in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity;

c. any weaknesses in RMS's systems, processes, policies, procedures and/or practices relating to Consulting Activities identified by the IRO; and

d. any recommendations for improvements to RMS's systems, processes, policies, procedures and/or practices relating to Consulting Activities.

2. Relating to the Review of Payments

a. a description of the entry in the Open Payments Database for each Payment sampled and a description of Control Documents reviewed in connection with each sampled Payment; and

b. for each sampled Payment, findings and supporting rationale as to whether:

i. all required Control Documents exist;

ii. each Control Document was completed in accordance with all of the requirements set forth in the applicable RMS policy;

iii. the aggregate value of the Payment as reflected in the Open Payments Database is consistent with the value of the Payment reflected in the Control Documents;

iv. each Control Document reflects that RMS's policies were followed in connection with the underlying activity reflected in the document (all required approvals were obtained); and

v. any corrective action or disciplinary action was undertaken in those instances in which RMS policies were not followed.

3. Relating to the Review of Additional Items. For each Additional Item reviewed:

a. a description of the review conducted;

b. the IRO's findings based on its review;

c. the findings and supporting rationale regarding any weaknesses in RMS's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and

d. recommendations, if any, for changes in RMS's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-250094, 333-237096, 333-237488, 333-227696 and 333-230332 on Form S-8 and Registration Statement Nos 333-252432 on Form S-3 of our report dated March 16, 2021, relating to the financial statements of Ra Medical Systems, Inc., appearing in this Annual Report on Form 10-K for the year ended December 31, 2020.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
March 16, 2021

Exhibit 31.1

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

I, Jonathan Will McGuire, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ra Medical Systems,Inc.;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 16, 2021

By: /s/ Jonathan Will McGuire
Jonathan Will McGuire
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Andrew Jackson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ra Medical Systems,Inc.;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 16, 2021

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, Jonathan Will McGuire, hereby certify that, to my knowledge:

(i) the Company's Annual Report on Form 10-K for the year ended December 31, 2020 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 16, 2021

By: /s/ Jonathan Will McGuire
Jonathan Will McGuire
Chief Executive Officer
(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 EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Andrew Jackson, hereby certify that, to my knowledge:

(i) the Company's Annual Report on Form 10-K for the year ended December 31, 2020 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 16, 2021

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.