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, 2021

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, 2021 as reported by the NYSE American on such date was approximately $24.1 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 16, 2022, the registrant has 31,458,547 shares of common stock, par value $0.0001, outstanding.

RA MEDICAL SYSTEMS, INC.

TABLE OF CONTENTS

PART I

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 medical device company leveraging its advanced excimer laser-based platform for use in the treatment of vascular immune-mediated inflammatory diseases. We believe our products enhance patients' quality of life by restoring blood flow in arteries.

Consistent with our business strategy to continue focusing on the peripheral artery disease, or PAD, market, we completed the sale of our Pharos laser business, or Dermatology Business, to STRATA Skin Sciences, Inc., or Strata, on August 16, 2021. Accordingly, the financial information and results of operations of the Dermatology Business has been presented as discontinued operations for all periods presented herein.

The Destruction of Arteriosclerotic Blockages by laser Radiation Ablation (DABRA) laser and single-use catheter, together referred to as DABRA, is used as a tool in the treatment of PAD which commonly occurs in the legs. DABRA is cleared by the United States Food and Drug Administration, or FDA, as a device 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. 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 business strategy is focused on multiple engineering efforts to improve and expand our catheter offering and explore new markets, as well as conducting a clinical study to obtain an atherectomy "indication for use" in the United States, or U.S. Key catheter engineering efforts currently underway include projects to:

- Extend our catheter's shelf life. During 2020, we identified the factors limiting our catheter's 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 we are currently implementing multiple remediations to address these issues. Our internal real time 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 completed the engineering work for this catheter and subsequently submitted to the FDA for clearance in February 2022; and
- Develop a version of the catheter that is compatible with a standard guidewire. We selected a design in December 2021 based on physician evaluation in a preclinical model. We expect to finalize the design for this catheter by mid-year 2022. Engineering validation and verification will follow design freeze, and we will 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 pre-specified 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 currently approved for up to 10 clinical sites and 125 subjects. In January 2022, primarily due to subject fallout for follow-up visits due to the novel coronavirus, or COVID-19, we filed a protocol amendment with the FDA to add an additional 25 subjects to the study. The protocol amendment was approved by the FDA in February 2022, increasing the total number of approved subjects from 100 to 125.

We enrolled the first subject in February 2020. Throughout much of 2021 and 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 21, 2022, we had enrolled 98 subjects and seven sites had 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, although we aim to complete study enrollment by the middle of 2022 and to complete the six-month follow-up in early 2023.

We are continuing to supply catheters to those sites involved in our atherectomy clinical study. We paused shipments of catheters to commercial sites while we conducted further studies on the stability of their shelf life. We submitted additional test data with respect to the DABRA catheter shelf life in a traditional 510(k) in March 2021, which was cleared by the FDA in July 2021. Although eligible, we have not resumed commercial sales as we continue evaluating our commercial catheter strategy.

Finally, we are conducting research to prove the feasibility of using our liquid-filled catheter and excimer laser technology to fracture calcium in arteries in a procedure known as lithotripsy. Preliminary research work has demonstrated that our laser system can be utilized to create shockwaves of sufficient magnitude to fracture calcium in arteries. Fracturing calcium in coronary or peripheral arteries can help make the arteries less rigid, thus making subsequent procedures easier and/or safer to perform. We are fabricating various prototype systems and intend to advance our initial benchtop results.

Recent Developments

Underwritten Public Offering

On February 4, 2022, we entered into an underwriting agreement, or the Underwriting Agreement, with Ladenburg Thalmann & Co. Inc., as representative of the underwriters named in the Underwriting Agreement, or the Underwriters, pursuant to which we issued and sold, in a firm commitment underwritten public offering by the Company, or the Public Offering, (i) 9,535,000 units priced at a public offering price of $0.50 per unit, with each unit consisting of one share of common stock, one warrant to purchase one share of common stock at an exercise price of $0.50 per share that expires on the first anniversary of the date of issuance, or Series A Warrant, and one warrant to purchase one share of common stock at an exercise price of $0.50 per share that expires on the seventh anniversary of the date of issuance, or Series B Warrant, and (ii) 14,467,893 pre-funded units priced at a public offering price of $0.4999 per unit, with each unit consisting of one pre-funded warrant to purchase one share of common stock at an exercise price of $0.0001 per share that expires on the twentieth anniversary of the date of issuance, or Pre-Funded Warrant, and together with the Series A Warrants and Series B Warrants, collectively referred to as the Warrants.

In addition, pursuant to the Underwriting Agreement, we granted the Underwriters a 45-day option, or Overallotment Option, to purchase up to (i) 3,600,000 additional shares of common stock, (ii) 3,600,000 additional Series A Warrants and/or (iii) 3,600,000 additional Series B Warrants, solely to cover overallotments. The Underwriters partially exercised the Overallotment Option on February 7, 2022 to purchase 3,600,000 Series A Warrants and 3,600,000 Series B Warrants.

The units were not certificated and the shares of common stock, Series A Warrants and Series B Warrants comprising such units were immediately separable and were issued separately in the Public Offering. The pre-funded units were not certificated and the Warrants comprising such units were immediately separable and were issued separately in the Public Offering. The securities were offered by the Company pursuant to the Registration Statement on Form S-1 (File No. 333-262195), or Registration Statement, which was initially filed with the Securities and Exchange Commission, or SEC, on January 14, 2022, amended on January 26, 2022, January 31, 2022 and February 3, 2022 and declared effective by the SEC on February 3, 2022.

On February 8, 2022, the Public Offering closed, and we issued and sold (i) 9,535,000 shares of common stock, (ii) 27,602,893 Series A Warrants (which includes 3,600,000 Series A Warrants sold pursuant to the exercise of the Overallotment Option), (iii) 27,602,893 Series B Warrants (which includes 3,600,000 Series B Warrants sold pursuant to the Overallotment Option), and (iv) Pre-Funded Warrants to purchase 14,467,893 shares of common stock, pursuant to the Registration Statement and the Underwriting Agreement. Our net proceeds, after deducting the underwriting discount and commissions and estimated offering expenses paid and payable by the Company, were approximately $10.2 million. On February 10, 2022, we issued and sold an additional 1,245,116 shares of common stock pursuant to the partial exercise of the Overallotment Option resulting in net proceeds, after deducting the underwriting discount, of approximately $0.5 million.

Each Series A Warrant is exercisable at a price per share of common stock of $0.50, each Series B Warrant is exercisable at a price per share of common stock of $0.50, and each Pre-Funded Warrant is exercisable at a price per share of common stock of $0.0001. Each Warrant is immediately exercisable. The exercise prices of the Warrants are subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. Subject to limited exceptions, a holder of Warrants will not have the right to exercise any portion of its Warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, upon election by a holder prior to the issuance of any Warrants, 9.99%) of the shares of common stock then outstanding. At the holder's option, upon notice to the Company, the holder may increase or decrease this beneficial ownership limitation not to exceed 9.99% of the shares of Common Stock then outstanding, with any such increase becoming effective upon 61 days' prior notice to the Company.

The Underwriting Agreement contains representations, warranties and covenants made by the Company that are customary for transactions of this type. Under the terms of the Underwriting Agreement, the Company has agreed to indemnify the Underwriter against certain liabilities, including liabilities under the Securities Act of 1933, as amended. In addition, pursuant to the terms of the Underwriting Agreement, the Company and its executive officers and directors have entered into lock-up agreements providing that the Company and each of these persons may not, without the prior written approval of the Underwriter, subject to limited exceptions, offer, sell, transfer or otherwise dispose of the Company's securities for a period of 90 days following the date of the Underwriting Agreement.

On February 8, 2022, we entered into a warrant agency agreement with our transfer agent, American Stock Transfer & Trust Company LLC, who will also act as the warrant agent for the Company, setting forth the terms and conditions of the Warrants sold in the Public Offering.

We are contractually obligated to pay a former placement agent a tail fee equal to 7.5% cash compensation for the gross proceeds raised, and 7% warrant coverage of the number of shares of common stock placed, in any public or private offering consummated within twelve months of the expiration or termination of our engagement with such placement agent by any investor contacted by the placement agent during the term of our engagement. A number of the investors in the Public Offering had previously been contacted by such placement agent and, as a result, we may be obligated to pay such placement agent a cash fee in connection with the Public Offering which we estimate to be between approximately $0.7 million and $0.9 million. In addition, we may be obligated to issue between 1.4 million and 1.7 million warrants to purchase common stock valued at between $0.2 million and $0.3 million.

Termination of ATM Agreement

On January 18, 2022, H.C. Wainwright & Co. delivered written notice to us that it was terminating the ATM Agreement with us dated January 26, 2021. During the year ended December 31, 2021, we sold 3,811,170 shares of common stock for gross proceeds of approximately $16.0 million through the ATM equity offering facility, or ATM Facility, under the ATM Agreement. With the provision of such notice, the ATM Facility is no longer available to us.

Chief Executive Officer Health

Will McGuire, our Chief Executive Officer, was recently diagnosed with a serious illness not caused by COVID-19 and has been undergoing treatment for his disease. He continues to fulfill all of his duties and responsibilities and has stated his desire to continue in such roles. Our board of directors has discussed a plan of succession and will continue to evaluate and monitor our options on an ongoing basis, should Mr. McGuire need to relinquish any of his responsibilities or duties at any time as a result of his illness or otherwise.

Effects of COVID-19 and Market Conditions

The global effects of COVID-19 have created significant volatility, uncertainty and economic disruption. Although the number of reported cases of COVID-19 has recently decreased, the ultimate effects of COVID-19 on our business, operations and financial condition are unknown at this time. We expect that enrollment in our atherectomy clinical trial will continue to be affected by the uncertainty relating to COVID-19, as patients

may continue to elect to postpone voluntary treatments and physicians' offices are either remaining closed, operating at a reduced capacity or are in the process of reopening or returning to full capacity. Our manufacturing facility located in Carlsbad, California is currently operational. We have experienced delays in receiving shipments of parts which has had an impact on the timing of our key engineering efforts but has not affected our ability to support our atherectomy clinical study. 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.

We, like many companies, are also experiencing increased difficulty in attracting and retaining key personnel due to a tight labor market.

Securities Class Action and Shareholder Derivative Litigation Update

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 U.S. District Court for the Southern District of California against us, certain current and former officers and directors, and certain underwriters of our initial public offering, or 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, or Securities Act, 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, as amended, or Exchange Act. 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 March 24, 2021, the court issued an order granting defendants' motion to dismiss claims under the Securities Act in full and certain claims under the Exchange Act and denying defendants' motion to dismiss certain Exchange Act claims. Plaintiffs filed their second amended complaint on April 19, 2021, realleging the Securities Act claims and certain of the previously dismissed Exchange Act claims. On June 10, 2021, defendants moved to dismiss the second amended complaint. On November 12, 2021, following a private settlement mediation with the lead plaintiffs, the parties executed a stipulation of settlement that resolved the claims asserted in the securities class action. The settlement provides for a payment to the plaintiff class of $10.0 million. On March 18, 2022, we paid approximately $0.6 million towards the settlement and are working with our insurers to determine if we must pay an additional amount, up to an additional $0.4 million (total of $1.0 million), to satisfy our self-insured retention/deductible. Our insurers will pay the remaining amount towards the settlement. The proposed settlement requires both preliminary and final approval by the court. On February 11, 2022, the court granted preliminary approval of the settlement, scheduled a hearing on the final approval of the settlement for June 13, 2022, and denied the pending motion to dismiss without prejudice. Should the court not approve the proposed settlement or if the proposed settlement otherwise does not become final, the parties will be returned to their litigation postures prior to the execution of the stipulation of settlement. 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 such determination is made.

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 U.S. 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 Exchange Act. 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.

Settlement Agreements with the Department of Justice and Participating States

On December 28, 2020, we entered into a settlement agreement, or the Settlement Agreement, with the U.S. acting through the Department of Justice, or DOJ, and on behalf of the Office of Inspector General, or OIG, and other settlement agreements with certain state attorneys general to resolve investigations and a related civil action concerning our marketing of the DABRA laser system and DABRA-related remuneration to certain physicians. Pursuant to the terms of the Settlement Agreement and the agreement with the participating states, (a) if our revenue exceeds $10 million in fiscal years 2021-2024, we 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 before the end of 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 U.S. 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.

Our Product

DABRA 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. DABRA breaks down plaque to proteins, lipids and other chemical compounds, thereby eliminating blockages by essentially dissolving them without generating potentially harmful particulates. The accumulation of plaque in arteries, which is a result of lower extremity vascular disease, most commonly occurs in the pelvis and legs. Plaque accumulation, known as atherosclerosis, causes the narrowing of arteries, thereby reducing the flow of oxygenated blood to tissue and organs. If vascular blockages are left untreated, they can increase the risk of heart attack, stroke, amputation or death. Major risk factors for PAD include age, smoking, diabetes and obesity. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including 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 19-21 million people in the U.S. However, only 20-30% of PAD patients are actively 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 predominantly used as an adjunct therapy with angioplasty balloons, drug-coated balloons, stents, and other endovascular treatments. DABRA employs photoablation to remove cross 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.

Vascular Disease

Vascular disease refers to diseases of the blood vessels located throughout the body. The most common cause of vascular disease is atherosclerosis which 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 July 2019, the estimated prevalence of CLI in the U.S. was approximately 2 million. 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 19-21 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 2022 U.S. atherectomy and crossing chronic total occlusions market is projected to be approximately $900 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, or 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 percutaneous transluminal angioplasty 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.
- ***Bypass Surgery***. More severe cases of PAD may be treated by surgeons with bypass surgery. The blood flow is diverted around the occluded area using a synthetic graft or harvested vessel. Bypass surgery is performed by physicians in an operating room with the patient under general anesthesia and requires multi-day hospital stays for healing and rehabilitation. General anesthesia and the potential for surgical infections make this approach less suitable for patients with conditions such as high blood pressure, heart failure, chronic obstructive pulmonary disease or poor kidney function.
- ***Amputation***. CLI is a serious form of PAD caused by severe lack of blood flow to the legs. Physicians may recommend full or partial amputation of the leg or foot for patients with CLI. Up to 200,000 lower limb amputations occur annually in the U.S. as a result of PAD.

Our Solution

Strengths of Our Approach

The DABRA system includes a portable excimer laser combined with proprietary, single-use catheters that together represent a competitive plaque ablation 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. 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. No serious device-related adverse events were reported in our 2017 pivotal study.
- ***Efficacy***. Unlike many treatments for PAD that do not remove plaque, DABRA employs photoablation to dissolve plaque by breaking its chemical bonds, thereby reducing the plaque to proteins, lipids and other chemical compounds.
- ***Utility***. DABRA enables physicians to ablate plaque to treat lower extremities both above and below the knee.

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 internal accelerated and real time 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 was approved for up to 10 clinical sites and 100 subjects. In January 2022, primarily due to subject fallout for follow-up visits due to COVID-19, we filed a protocol amendment with the FDA to add an additional 25 subjects to the study. The protocol amendment was approved by the FDA in February 2022, increasing the total number of approved subjects from 100 to 125. We enrolled the first subject in February 2020. Throughout much of 2021 and 2020, the COVID-19 pandemic substantially impacted our ability to activate new sites and enroll additional subjects. Although the number of reported cases of COVID-19 has recently decreased, many sites or potential sites have been or are currently operating at a reduced capacity or are in the process of reopening at reduced or returning to full capacity, and some have been closed from time to time. In addition, potential study subjects may continue to voluntarily opt to postpone their procedures due to COVID-19 concerns. As of March 21, 2022, seven sites have been cleared to enroll subjects and 98 subjects have been enrolled in the trial. Due to the unpredictable impact the COVID-19 pandemic has had and continues to have on enrollment in this study, we currently cannot estimate when enrollment will be completed.

- ***Prove utility for lithotripsy.*** We are conducting research to prove the feasibility of using our liquid-filled catheter technology to fracture calcium in arteries in a procedure known as lithotripsy. Our research program has demonstrated that our laser system can be utilized to create shockwaves of sufficient magnitude to fracture calcium in arteries. An initial benchtop study demonstrated the ability to fracture medial calcium in cadaveric tissue. Fracturing calcium in coronary or peripheral arteries can help make the arteries less rigid, thus making subsequent procedures easier and/or safer to perform. We are fabricating various prototype systems and intend to conduct further preclinical studies in the next few months to advance our initial benchtop results.

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.

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 specifically designed for use with our excimer laser. The DABRA catheter uses a liquid-filled plastic tubing allowing for the efficient and precise delivery of the laser energy.

The current generation DABRA catheter is a single-use, 5 French wireless (no guidewire lumen) catheter 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 ablation catheter, delivering fast ablation of a wide variety of plaque, without the "dead-space" of fiber optic bundle laser 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. They have been used in both above and below the knee procedures, using both antegrade and retrograde approaches, and from femoral, popliteal access and pedal access.

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 proteins, lipids and other chemical compounds, minimizing downstream debris.

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. Once calibrated, the physician sets the treatment settings on the touch screen. The physician then inserts the catheter into the vasculature and under fluoroscopy, 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.

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 lesion crossing by way of 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 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 subjects 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 is currently approved to enroll up to 125 subjects with symptoms of PAD (Rutherford Class 2-45). In January 2022, primarily due to subject fallout for follow-up visits due to COVID-19, we filed a protocol amendment with the FDA to add an additional 25 subjects to the study. The protocol amendment was approved by the FDA in February 2022, increasing the total number of approved subjects from 100 to 125. 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 subject'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 at six months will be the safety and clinical success endpoints.

Customers

For the years ended December 31, 2021 and 2020, we had three and four individual customers, respectively, that represented more than 10% of our total revenues.

Sales and Marketing

We are continuing to supply catheters to those sites involved in our atherectomy clinical study. We paused shipments of catheters to commercial sites while we conducted further studies on the stability of their shelf life. We submitted additional test data with respect to the DABRA catheter shelf life in a traditional 510(k) in March 2021 which was cleared by the FDA in July 2021. Although eligible, we have not resumed commercial sales as we continue evaluating our commercial catheter strategy.

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 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.

Reimbursement

Our customers do not receive reimbursement for the purchase of our products. However, procedures performed using DABRA 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 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 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. Please refer to the "*Risk Factors*" section of this Annual Report on Form 10-K for risks related to reimbursement.

Market acceptance of the DABRA device 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 device 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. 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. 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.

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 16, 2022, we owned ten 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 three issued U.S. patents, one issued Chinese patent and one granted European patent which has been validated in Switzerland, Germany, Denmark, France, United Kingdom, Italy, Netherlands and Sweden. Two 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 five 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 two continuation applications in this family still pending. The patent family titled "Liquid Filled Ablation Catheter with Overjacket" includes one issued U.S. patent and one pending U.S. continuation application. 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 2034 and 2039, irrespective of any patent term adjustment or patent term extension and 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 trademarks such as DABRA.

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

United States Medical Device Regulation

In the U.S., medical devices are subject to extensive regulation by the FDA, 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, or PMA, applications, 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 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. DABRA is a Class II device.

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 conducts 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 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. 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. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA is obtained.

We have received 510(k) premarket clearances from the FDA to market our excimer laser and catheter systems 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 FDCA, 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 pathway. According to the most recent FDA performance review goals, the agency will attempt to issue a decision within 150 days of receipt on 70% of de novo classification requests received during fiscal year 2022.

Pre-Market Approval

A product not eligible for 510(k) clearance or de novo classification must follow the PMA 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 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 Regulations, 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 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, 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. Pivotal clinical trials supporting premarket applications for devices 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 commercialization. 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."

Post-Market 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 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 corrective actions to address the December 2019 inspectional observations 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.

The Federal Trade Commission, or FTC, also oversees the advertising and promotion of our products (other than labeling) pursuant to its broad authority to police deceptive advertising for goods or services within the U.S. The FDA and FTC work together to regulate different aspects of activities by medical product manufacturers, consistent with the inter-agency Memorandum of Understanding. Under the Federal Trade Commission Act, or FTCA, the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. In the context of performance claims for products such as our devices and services, compliance with the FTC Act includes ensuring that there is scientific data to substantiate the claims being made, that the advertising is neither false nor misleading, and that any user testimonials or endorsements we or our agents disseminate related to the devices or services comply with disclosure and other regulatory requirements.

Violations of the FDCA or FTCA 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, including 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 and other applicable regulatory requirements 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. If the FDA believes we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements and patients are being subjected to serious risks, the agency can shut down our manufacturing operations, require recalls of our medical device products, refuse to approve new marketing applications, initiate legal proceedings to detain or seize products, enjoin future violations, or assess civil and criminal penalties against us or our officers or other employees.

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 applicable 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 DABRA vascular system in the third quarter of 2016.

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 Act, 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 applicable 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), non-physician healthcare professionals (defined to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives) and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members; 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

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 U.S. 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.

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. 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 June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the PPACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the PPACA. The PPACA thus remains in effect in its current form. Further legislative and regulatory changes under the PPACA remain possible, although the new federal administration under President Biden has signaled that it plans to build on the PPACA and expand the number of people who are eligible for health insurance subsidies under it. It is unclear how healthcare measures promulgated by the Biden administration will impact the implementation of the PPACA, our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the PPACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

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 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of the sequester. 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.

Human Capital

As of March 16, 2022, we had 58 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 the Company by motivating such individuals to perform to the best of their abilities and achieve the Company's objectives.

Segment Information

After the sale of the Dermatology Business in August 2021, we began operating our business in one segment, which includes all activities related to the research, development and manufacture of the DABRA system. The chief operating decision-maker reviews the operating results on an aggregate basis and manages the operations as a single operating segment.

Geographic Information

During the years ended December 31, 2021 and 2020, all of our long-lived assets were located in and our revenues came from within the U.S.

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 Exchange Act. 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 require additional capital to finance our operations, which may not be available to us on acceptable terms or at all.
- We have determined that there is substantial doubt about our ability to continue as a going concern, and we will need to undertake additional financings in order to execute our business plan and fund our operations. We may not be able to obtain such funding on a timely basis, or on commercially reasonable terms, or at all. Any capital-raising transaction we are able to complete may result in substantial dilution to our existing stockholders, require us to relinquish significant rights, or restrict our operations.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- 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.
- The military action launched by Russian forces in Ukraine, and the actions that have been and could be taken by other countries, including new and stricter sanctions and actions taken in response to such sanctions, have impacted and may continue to impact, our business and results of operations, including our supply chain.
- Our ability to successfully complete our atherectomy trial may continue to be hindered or delayed by the effects of the COVID-19 pandemic and DABRA catheter performance limitations that are currently being addressed by various engineering efforts.
- We are required to devote significant resources to complying with the terms and conditions of our Settlement Agreement and Corporate Integrity Agreement (as described below) 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 Government Regulation 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. 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.
- Our future operating results depend upon our ability to obtain components in sufficient quantities on commercially reasonable terms or according to schedules, prices, quality and volumes that are acceptable to us, and suppliers may fail to deliver components, or we may be unable to manage these components effectively or obtain these components on such terms.
- 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 require additional capital to finance our operations, which may not be available to us on acceptable terms or at all.

Our current cash resources are not sufficient to fund operations at the expected level of activity beyond the fourth quarter of 2022. We will need additional capital to continue operations at the current level and to continue our atherectomy indication trial and engineering efforts.

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development and commercialization efforts. As of December 31, 2021, we had cash and cash equivalents of $15.0 million and an accumulated deficit of $178.3 million. For the years ended December 31, 2021 and 2020, we used cash of $27.6 million and $28.3 million, respectively, in operating activities from continuing and discontinued operations. 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 have suspended sales of DABRA catheters not related to our atherectomy clinical trial. We submitted additional test data with respect to the DABRA catheter shelf life in March 2021, which was cleared by the FDA in July 2021. Further cost reductions 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 sufficient 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 the securities class action and derivative lawsuits, as well as compliance with, and payments under, the terms of our Settlement Agreement and Corporate Integrity Agreement associated with our settlements with the DOJ and the participating states. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development and these lawsuits and the government investigation, 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;
- 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 for its 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 or develop and/or commercialize our products with third parties through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements, we may have to develop our products on a slower timeline or 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 continuing economic uncertainty resulting from the effects of the COVID-19 pandemic and Russia's invasion of Ukraine to have a negative impact on our ability to secure additional financing in a timely manner or on favorable terms, if at all.

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 not be able to obtain such funding on a timely basis, or on commercially reasonable terms, or at all. Any capital-raising transaction we are able to complete may result in substantial dilution to our existing stockholders, require us to relinquish significant rights, or restrict 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 seeking to reduce our recurring operation costs, by engaging in regular and ongoing reviews of our business model and strategic options to help ensure that we are focusing our cash resources on advancing our key corporate initiatives. We also intend to raise additional capital in order to fund our operations and grow our business and have an effective shelf registration statement. We may seek to raise capital through strategic transactions, such as a sale of one or more of our assets, a license to our technology, a business combination or other partnership transaction, and in connection with such transaction, we may be required to relinquish valuable rights that would dilute our current and future value. However, no assurance can be provided that we will be able to do so on commercially reasonable terms, or at all. We may incur significant costs in pursuing, evaluating and negotiating particular capital-raising and/or strategic or partnering transactions, even if our efforts prove unsuccessful. Our failure to raise capital or consummate any of these transactions as needed would have a material adverse effect on

our financial condition and ability to pursue our business strategy and we may be unable to continue as a going concern and required to liquidate our assets and dissolve our company. To the extent that we are unable to be, and even to the extent we are, successful in consummating one or more of these transactions, 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. If we determine our financial resources are insufficient to fund our operations even after implementing additional cost saving measures and reducing the scope of our operations, we may be required to dispose of or liquidate our assets at values significantly less than what we believe their values to be and at which they are carried on our financial statements.

If our board of directors decides to dissolve our company and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to our stockholders after paying our debts and other obligations and setting aside funds for potential future claims. If we attempt to continue to operate our business, focusing on our atherectomy indication trial or potentially expanding the use of our technology to be used for lithotripsy, we would need to raise significant additional funds to fund our operations and execute on our business strategy and we may not be successful in those efforts.

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. Will McGuire, our Chief Executive Officer, has been diagnosed with a serious illness not caused by COVID-19 and has been undergoing treatment for his illness. He continues to fulfill all of his duties and responsibilities and has stated his desire to continue in such roles. We do not expect our Chief Executive Officer to relinquish any of his responsibilities or duties in the short term as a result of this diagnosis, however, his condition may change and prevent him from doing so. The Board has discussed a plan of succession and will continue to evaluate and monitor our options on an ongoing basis should Mr. McGuire need to relinquish any of his responsibilities or duties at any time as a result of his illness or otherwise. 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.

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 upgrade the DABRA laser's functionality and user interface and maintain necessary regulatory clearances;
- 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 complete 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 investigation 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 continue to be hindered or delayed by the effects of the COVID-19 pandemic and DABRA catheter performance limitations that are currently being addressed by various engineering efforts.

The effects of the COVID-19 pandemic and the DABRA catheter performance limitations have impacted our ability to complete our atherectomy study in a timely manner. For example, enrollment in our atherectomy clinical trial, and patients' completion of our atherectomy trial, may be further delayed or slowed by any increases in COVID-19 cases or other effects of the COVID-19 pandemic, 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. Laboratories may read or interpret clinical data differently than our clinical trial physicians' initial assessment, which may lead to delays in the ultimate conclusion of our trial. 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 are required to devote significant resources to complying with 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 Office of Inspector General, or 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 or any potential strategic transaction, such as a sale of one or more of our assets, a license to our technology, a business combination or other partnership transaction.

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;
- our ability to upgrade the DABRA laser's functionality and user interface, and maintain necessary regulatory clearances;
- 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 relative to alternative treatment methods;
- matters arising out of our completed Audit Committee investigation, securities class action and derivative lawsuit, 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 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.

If we do not adequately educate physicians about PAD and the existence and proper use of our products, DABRA may not gain market acceptance, as many physicians do not routinely screen for PAD while screening for 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 of the government investigation 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 sales. We submitted this additional test data with respect to the DABRA shelf life in March 2021 in a traditional 510(k) and received clearance by the FDA in July 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 titled "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 losses from continuing operations of $27.3 million and $35.3 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $178.3 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 investigation, as applicable. In addition, our general and administrative expenses have increased following our IPO and we expect these costs to continue due to the additional costs associated with being a public company. The 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.

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 facility 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 recent 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 was characterized as a global pandemic and how long and how extensive the economic effects will last, has not been determined. The extent to which the effects of COVID-19 impact our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge regarding COVID-19 and the actions to contain it or treat its impact, among others. A return of the pandemic or a new pandemic could cause the temporary closure of our manufacturing facility 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 caused, and its effects will likely continue to cause, delays in enrollment in our atherectomy indication trial. In addition, we have experienced delays in receiving shipments of parts which has had an impact on the timing of our key engineering effortsbut has not affected our ability to support our atherectomy indication clinical trial. The effects of 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 16. *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 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, AngioDynamics 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.

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. For example, our competitors with laser-based products may develop upgrades to their lasers that make them easier to use, more efficient or more functional and they may more quickly obtain necessary FDA and non-U.S. regulatory clearances and approvals for such improvements. 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 is 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. 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. Submitting the required applications for additional indications may require substantial additional funding beyond our cash and cash equivalents as of December 31, 2021. 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 ourongoing 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, 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. 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. Without admitting any liability or wrongdoing, on December 28, 2020, we entered into a Settlement Agreement with the DOJ, other settlement agreements with certain state attorneys general and a related Corporate Integrity Agreement that resolved civil investigations and a related civil lawsuit. 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 nine months following a DABRA procedure, using a consistent assessment tool. As discussed above, we are currently conducting a clinical study intended to support our FDA regulatory application for the atherectomy indication for use.

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 andthe 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, andn connection with the Settlement Agreement, we also have reached agreements with certain state attorneys general.

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 the previously disclosed and concluded SEC investigation, 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 investigation 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 investigation, whether actions will be commenced, whether this investigation can be settled before or after actions are commenced, and the terms on which this investigation 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 securitiesclass action and shareholder derivative 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 U.S., 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 our sales and operations outside the U.S., 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 may result in a materially significant diversion of managements attention and resources and significant defense costs and other professional fees. Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, healthcare laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe

criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, financial condition, and results of operations 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 have sold DABRA outside of the U.S. in the past. 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 U.S., 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.

The impact of the military action in Ukraine has affected and may continue to affect our business.

On February 24, 2022, Russian forces launched significant military action against Ukraine, and sustained conflict and disruption in the region is possible. The impact to Ukraine, as well as actions taken by other countries, including new and stricter sanctions imposed by Canada, the United Kingdom, the European Union, the U.S. and other countries and companies and organizations against officials, individuals, regions and industries in Russia and Ukraine, and actions taken by Russia in response to such sanctions, and each country's potential response to such sanctions, tensions and military actions could have a material adverse effect on our operations. Any such material adverse effect from the conflict and enhanced sanctions activity may disrupt our supply chains and affect the delivery of our products and services or impair our ability to complete financial or banking transactions.

We also cannot predict the impact of any heightened geopolitical instability or the results that may follow, including reductions in consumer confidence, heightened inflation, cyber disruptions or attacks, higher natural gas costs, higher manufacturing costs and higher supply chain costs. The impact of Russia's invasion of Ukraine could cause our results to differ materially from the outlook presented in this Annual Report on Form 10-K.

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.

In addition to current and proposed economic sanctions on Russia, which may increase or continue for an indefinite period of time as a result of Russia's invasion of Ukraine, 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.

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.

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, as well as for accounting, financial reporting, data storage, compliance, purchasing and inventory management. We do not have redundant information technology systems at this time. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures and user errors, among other malfunctions. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks. Technological interruptions would impact our business operations would disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and

otherwise adequately service our customers or disrupt our customers' ability use our products for treatments. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition, and results of operations. Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount, subject to deductibles, and we cannot be certain that such potential losses will not exceed our policy limits. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition, and results of operations.

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

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. As an "emerging growth company," we will avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an "emerging growth company" 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 March 16, 2022, we had 58 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.

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.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we may become exposed to, or collect and store sensitive data, including procedure-based information and legally protected health information, credit card, and other financial information, insurance information, and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology, or IT, and infrastructure, and that of our third-party billing and collections provider and other technology partners, may be vulnerable to cyber attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. We rely extensively on IT systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided and/or used by third-parties or their vendors, to assist in conducting our business. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. We are investing in protections and monitoring practices of our data and IT to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems that could adversely affect our business.

Risks Related to Government Regulation 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 applicable 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 into the Settlement Agreement, and the agreements with the participating states, resolving a DOJ civil investigation concerning certain Covered Conduct (as defined in the Settlement Agreement), 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," Class II medical devices are also subject to "special controls," including in many cases 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 agreements that resolve previously disclosed related investigations conducted by certain state attorneys general. Under the Settlement Agreement, and the 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 $0.1 million in April 2021. 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. This settlement and our ongoing obligations under the Corporate Integrity Agreement 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 are also 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.

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 product. 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. 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. The FDA terminated this recall on November 1, 2021. 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 law. This field correction was completed in March 2021. The Company considers this recall complete and submitted to the FDA a final status report in March 2021 requesting termination of this field correction. In October 2020, we initiated a voluntary recall of our DABRA lasers to replace the footswitch with a footswitch that meets specification for protection from ingress of solids or liquids. We formally notified the FDA of this recall in accordance with applicable law. This recall was classified as a Class II recall by the FDA. This field correction was completed in October 2021, and the Company received notice in February 2022 that the FDA has terminated this field correction. 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 related to the DABRA catheter shelf life in a traditional 510(k), which was cleared by the FDA in July 2021.

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 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 facility has 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 facility 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, the 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, 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, the PPACA 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 U.S. 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.

On December 18, 2019, the U.S. 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 June 2021, the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the PPACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the PPACA. Thus, the PPACA will remain in effect in its current form. Further, legislative and regulatory changes under the PPACA remain possible, although the new federal administration under President Biden has signaled that it plans to build on the PPACA and expand the number of people who are eligible for health insurance under it. It is unclear how future litigation and healthcare measures promulgated by the Biden administration will impact the implementation of the PPACA and our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the PPACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

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 2031, with the exception of a temporary suspension

implemented under various COVID-19 relief legislation from May 1, 2020 throughMarch 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of the sequester. 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. As a result of reform of the U.S. healthcare system, changes in reimbursement policies or healthcare cost containment initiatives may limit or restrict coverage and reimbursement for procedures using our products and cause our revenue to decline. 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 procedural technology, or 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 Centers for

Medicare and Medicaid Services, or 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 have historically sold into foreign markets and plan to continue to do so when we re-commercialize DABRA. Conducting international operations subjects us to risks that could be different than those faced by us in the U.S. 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 incurred, 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. If such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in government 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 applicable 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) non-physician healthcare professionals (defined to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives) and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members; 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.

In 2019, 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.

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 and 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.

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 U.S. 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, 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 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 U.S. 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 U.S. 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 U.S., 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 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 U.S. 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. 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, or the '327 patent, U.S. Pat. No. 7,261,729, or the '729 patent, and U.S. Pat. No. 8,387,621, or the '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 have experienced, and are currently experiencing, inconsistencies in our DABRA catheter performance, as more fully described in the risk factor titled "—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." 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, including as a result of the ongoing military conflict between Russia and Ukraine. Key components and sub-assemblies of DABRA 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.

Our future operating results depend upon our ability to obtain components in sufficient quantities on commercially reasonable terms or according to schedules, prices, quality and volumes that are acceptable to us, and suppliers may fail to deliver components, or we may be unable to manage these components effectively or obtain these components on such terms.

Because we currently obtain certain components globally, some of which are uniquely customized, from limited sources, we are subject to significant supply and pricing risks and exposed to multiple potential sources of component shortages. Many components, including those that are available from multiple sources, are at times subject to industry-wide shortages and significant commodity pricing fluctuations that could materially adversely affect our financial condition and operating results. We are sourcing alternative parts to mitigate the challenges caused by these shortages, but there is no guarantee we may be able to continually do so as we scale production to meet our growth targets. The unavailability of any component or supplier could result in production delays, idle manufacturing facilities, product design changes and loss of access to important technology and tools for producing and supporting our products, as well as impact our capacity production. Our suppliers may not be willing or able to sustainably meet our timelines or our cost, quality and volume needs, or to do so may cost us more, which may require us to replace them with other sources. If our supply of components for a new or existing product continues to be delayed or constrained for any reason, including if an outsourcing partner delayed shipments of completed products to us or additional time is required to obtain sufficient quantities from the original source, or if we have to identify and obtain sufficient quantities from an alternative source, then our financial condition and operating results

could be materially adversely affected. In addition, the continued availability of these components at acceptable prices, or at all, can be affected for any number of reasons, including if suppliers decide to concentrate on the production of common components or components for other customers instead of components customized to meet our requirements. While we have entered into agreements for the supply of many components, there can be no assurance that we will be able to extend or renew these agreements on similar terms, or at all. Component suppliers may suffer from poor financial conditions, which can lead to business failure for the supplier or consolidation within a particular industry, further limiting our ability to obtain sufficient quantities of components on commercially reasonable terms. While we believe that we will be able to secure additional or alternate sources or develop our own replacements for most of our components, there is no assurance that we will be able to do so quickly or at all. Additionally, we may be unsuccessful in our continuous efforts to negotiate with existing suppliers to obtain cost reductions and avoid unfavorable changes to terms, source less expensive suppliers for certain parts and redesign certain parts to make them less expensive to produce. Any of these occurrences may harm our business, prospects, financial condition and operating results.

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 suppliers' 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.

We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies, or failing to comply with regulatory requirements.

We do not have the ability to independently conduct our clinical trials. We currently rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our current and planned clinical trials and we expect to continue to rely upon third parties to conduct clinical trials of our investigational products. Third parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, it would delay our drug development activities.

Our reliance on these third parties for such medical device development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMP or quality system regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing authorization process.

Misconduct by our CROs or other third-party contractors could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by third parties we contract with, and the precautions we take to detect and prevent this activity 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 comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, damages, reputational harm, and the curtailment or restructuring of our operations, among others.

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 New York Stock Exchange 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 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 shareholder 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, 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.

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, 2021, we had net operating loss carryforwards, or NOLs, of approximately $39.2 million for federal income tax purposes, and $41.2 million for state income tax purposes. 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 $20.8 million. The tax expense was offset by a 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 U.S. federal income tax and U.S. state income tax obligations. In addition, as a result of the Tax Cuts and Jobs Act of 2017, as modified by the 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, however, the deductibility of our federal NOLs generated in such years will be limited to 80% of taxable income if utilized in taxable years beginning after December 31, 2020. Federal net operating losses incurred in years beginning before January 1, 2018 are subject to a twenty-year carryforward but are not limited to 80% of taxable income.

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 IPO, 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 IPO, (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 GAAP, 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 IPO. 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 March 16, 2022, we had outstanding 31,458,547 shares of our common stock.

In connection with the sale of the Dermatology Business in 2021, we issued a warrant to the broker. In connection with our 2020 equity offerings, we issued warrants to investors and our placement agent, H.C. Wainwright & Co., LLC. We had an aggregate of 2,419,280 warrants outstanding as of December 31, 2021. We have an effective shelf registration statement and had an effective at-the-market, or ATM, offering thereunder until January 18, 2022. During the year ended December 31, 2021, we sold 3,811,170 shares of common stock under the ATM offering. In addition, pursuant to our 2018 Equity Incentive Plan, or 2018 Plan, equity incentive awards representing up to an aggregate of 188,307 shares of our common stock were available for issuance to our employees, directors and consultants as of December 31, 2021. 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 4,764 shares were available for purchase under our ESPP as of December 31, 2021. 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 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, 2021. 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, SEC regulations limit the amount of funds we can raise during any 12-month period pursuant to our shelf registration statement on Form S-3. We are currently subject to General Instruction I.B.6 to Form S-3, or the Baby Shelf Rule, and the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates. We are currently limited by the Baby Shelf Rule as of the filing of this Annual Report on Form 10-K, until such time as our public float exceeds $75 million. If we are required to file a new registration statement on another form, we may incur additional costs and be subject to delays due to review by SEC staff.

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 U.S. 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 U.S. 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.

The continued listing of our common stock on the NYSE American is contingent on our continued compliance with a number of listing standards. The NYSE American retains substantial discretion to, at any time and without notice, suspend dealings in or remove any security from listing. 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. For example, the NYSE American will consider suspending dealings in, or delisting, securities of an issuer that has stockholders' equity of less than $6 million if that issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. We have had a loss from operations and net loss in each of our five most recent fiscal years. As of December 31, 2021, our stockholders' equity was $13.7 million. If our stockholders' equity falls below $6 million, the NYSE American may determine that we are no longer suitable for listing and may commence delisting proceedings pursuant Section 1003(a)(iii) of the NYSE MKT Company Guide.

Delisting from the 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.

We may be required to raise additional financing by issuing new securities, which may have terms or rights superior to those of our shares of common stock, which could adversely affect the market price of our shares of common stock and our business.

We will require additional financing to fund research, development and commercialization of our technology, to obtain and maintain patents and other intellectual property rights in our technology, and for working capital and other purposes. We may not be able to obtain financing on favorable terms, if at all. If we raise additional funds by issuing equity securities, the percentage ownership of our then-current shareholders will be reduced. Further, we may have to offer new investors in our equity securities rights that are superior to the holders of common stock, which could adversely affect the market price and the voting power of shares of our common stock. If we raise additional funds by issuing debt securities, the holders of these debt securities would similarly have some rights senior to those of the holders of shares of common stock, and the terms of these debt securities could impose restrictions on operations and create a significant interest expense for us which could have a materially adverse effect on our business.

We have not paid dividends in the past and have no immediate plans to pay dividends.

We plan to reinvest all of our earnings, to the extent we have earnings, in order to market our products and to cover operating costs and to otherwise become and remain competitive. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend.

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 the vascular market. 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 Class Action and Shareholder Derivative 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 U.S. 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 initial public offering. 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 and between September 27, 2018 and November 27, 2019, inclusive, in violation of Sections 10(b) and 20(a) of the Exchange Act. 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 March 24, 2021, the court issued an order granting defendants' motion to dismiss claims under the Securities Act in full and certain claims under the Exchange Act and denying defendants' motion to dismiss certain Exchange Act claims. Plaintiffs filed their second amended complaint on April 19, 2021, realleging the Securities Act claims and certain of the previously dismissed Exchange Act claims. On June 10, 2021, defendants moved to dismiss the second amended complaint. On November 12, 2021, following a private settlement mediation with the lead plaintiffs, the parties executed a stipulation of settlement that resolved the claims asserted in the securities class action. The settlement provides for a payment to the plaintiff class of $10.0 million. On March 18, 2022, we paid approximately $0.6 million towards the settlement and are working with our insurers to determine if we must pay an additional amount, up to an additional $0.4 million (total of $1.0 million), to satisfy our self-insured retention/deductible. Our insurers will pay the remaining amount towards the settlement. The proposed settlement requires both preliminary and final approval by the court. On February 11, 2022, the court granted preliminary approval of the settlement, scheduled a hearing on final approval of the settlement for June 13, 2022, and denied the pending motion to dismiss without prejudice. Should the court not approve the proposed settlement or if the proposed settlement otherwise does not become final, the parties will be returned to their litigation postures prior to the execution of the stipulation of settlement. 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 such determination is made.

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 U.S. 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 Exchange Act. 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.

Settlement Agreements with the Department of Justice and Participating States

On December 28, 2020, the Company entered into a Settlement Agreement with the U.S., acting through the DOJ and on behalf of the OIG, and other settlement agreements with certain state attorneys general to resolve investigations and a related civil action concerning its marketing of the DABRA laser system and DABRA-related remuneration to certain physicians. Pursuant to the terms of the Settlement Agreement and the agreements with the participating states, (a) if the Company's revenue exceeds $10 million in any of fiscal years 2021-2024, the Company also is required to pay for the corresponding year: $500,000 for 2021, $750,000 for 2022, $1 million for 2023, and $1.25 million for 2024; (b) if the Company is acquired or is otherwise involved in a change in control transaction before the end of 2024, the Company 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 the Company's obligations under the Settlement Agreement are avoided by bankruptcy, the U.S. 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.

Other Litigation

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 16, 2022, the last reported sales price of our common stock was $0.42 and, according to our transfer agent, as of March 16, 2022, there were 66 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 February 3, 2022, the Registration Statement relating to our public offering was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of (i) 9,535,000 shares of common stock, (ii) 27,602,893 Series A Warrants (which includes 3,600,000 Series A Warrants sold pursuant to the exercise of the Overallotment Option), (iii) 27,602,893 Series B Warrants (which includes 3,600,000 Series B Warrants sold pursuant to the Overallotment Option), and (iv) Pre-Funded Warrants to purchase 14,467,893 shares of common stock. The aggregate offering price for shares sold in the offering was $13.8 million, including the 15% Overallotment Option. Ladenburg Thalmann & Co., Inc. and Joseph Gunnar & Co., LLC acted as joint underwriters for the offering. On February 8, 2022, we closed the sale of such shares, resulting in aggregate cash proceeds of approximately $10.2 million, net of $1.1 million of underwriting discounts and commissions and $0.8 million of offering expenses paid or payable by us. In addition, we may incur additional offering expenses of approximately $0.7 million to $0.9 million for the tail fee owed to our former placement agent. On February 10, 2022, we issued and sold an additional 1,245,116 shares of common stock pursuant to the partial exercise of the Overallotment Option resulting in net proceeds, after deducting the underwriting discount, of approximately $0.5 million. 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.

As stated in the Registration Statement, we intend to use the net proceeds for general corporate purposes, including working capital, our atherectomy indication trial and engineering efforts. We may use a portion of the net proceeds to acquire complementary products, technologies or businesses, however, we currently have no agreements or commitments to complete any such transactions and are not involved in negotiations to do so. We may also use a portion of the net proceeds to reserve against certain existing liabilities, debts, contractual liabilities as well as reserve for potential future claims.

We may also be required to apply a portion of the net proceeds for litigation expenses and to pay in connection with a judgment or settlement of private and government claims against us, including the payment of any government fines or penalties. For more information on these matters, see *Risk Factors*, *Securities Class Action and*

Shareholder Derivative Litigation Update and *Settlement Agreements with the Department of Justice and Participating States*

Recent Repurchases of Equity Securities

None.

ITEM 6. [Reserved]

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 medical device company leveraging our advanced excimer laser-based platform for use in the treatment of vascular immune-mediated inflammatory diseases. We believe our products enhance patients' quality of life by restoring blood flow in arteries.

Consistent with our business strategy to continue focusing on the peripheral artery disease, or PAD, market, we completed the sale of our Pharos laser business, or Dermatology Business, to STRATA Sciences, Inc., or Strata, on August 16, 2021. Accordingly, the financial information of the Dermatology Business has been presented as discontinued operations for all periods presented. See *Note 3. Discontinued Operations* to the financial statements for additional information on discontinued operations. Unless otherwise noted, amounts for all periods discussed below reflect the results of operations and financial condition from our continuing operations.

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 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 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 completed the engineering work for this catheter and subsequently submit to the FDA for clearance in February 2022; and
- Develop a version of the DABRA catheter that is compatible with a standard guidewire. We selected a design in December 2021 based on physician evaluation in a preclinical model. We expect to finalize the design for this catheter by mid-year 2022. Engineering validation and verification will follow design freeze, and we will 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. In January 2022, primarily due to subject fallout for follow-up visits due to COVID-19, we filed a protocol amendment with the FDA to add an additional 25 subjects to the study. The protocol amendment was approved by the FDA in February 2022, increasing the total number of approved subjects from 100 to 125.

We enrolled the first subject in February 2020. Throughout much of 2021 and 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 21, 2022, we have enrolled 98 subjects and seven 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, although we aim to complete study enrollment by the middle of 2022 and to complete the six-month follow-up in early 2023.

We are continuing to supply catheters to those sites involved in our atherectomy clinical study. We paused shipments of catheters to commercial sites while we conducted further studies on the stability of their shelf life. We submitted additional test data with respect to the DABRA catheter shelf life in a traditional 510(k) in March 2021, which was cleared by the FDA in July 2021. Although eligible, we have not resumed commercial sales as we continue evaluating our commercial catheter strategy.

Finally, we are conducting research to prove the feasibility of using our liquid-filled catheter and excimer laser technology to fracture calcium in arteries in a procedure known as lithotripsy. Preliminary research work has demonstrated that our laser system can be utilized to create shockwaves of sufficient magnitude to fracture calcium in arteries. Fracturing calcium in coronary or peripheral arteries can help make the arteries less rigid, thus making subsequent procedures easier and/or safer to perform. We are fabricating various prototype systems and intend to advance our initial benchtop results.

Recent Developments

Underwritten Public Offering

On February 4, 2022, we entered into the Underwriting Agreement with Ladenburg Thalmann & Co. Inc., as representative of the Underwriters, pursuant to which we issued and sold in the Public Offering (i) 9,535,000 units, priced at a public offering price of $0.50 per unit, with each unit consisting of one share of common stock, one Series A Warrant and one Series B Warrant, and (ii) 14,467,893 pre-funded units, priced at a public offering price of $0.4999 per unit, with each unit consisting of one Pre-Funded Warrant, one Series A Warrant and one Series B Warrant.

In addition, pursuant to the Underwriting Agreement, we granted the Underwriters the Overallotment Option to purchase up to (i) 3,600,000 additional shares of common stock, (ii) 3,600,000 additional Series A Warrants and/or (iii) 3,600,000 additional Series B Warrants, solely to cover overallotments. The Underwriters partially exercised the Overallotment Option on February 7, 2022 to purchase 3,600,000 Series A Warrants and 3,600,000 Series B Warrants.

The units were not certificated and the shares of common stock, the Series A Warrants and the Series B Warrants comprising such units were immediately separable and were issued separately in the Public Offering. The pre-funded units were not certificated and the Warrants comprising such units were immediately separable and were issued separately in the Public Offering. The securities were offered by the Company pursuant to the Registration Statement.

On February 8, 2022, the Public Offering closed, and we issued and sold (i) 9,535,000 shares of common stock, (ii) 27,602,893 Series A Warrants (which includes 3,600,000 Series A Warrants sold pursuant to the exercise of the Overallotment Option), (iii) 27,602,893 Series B Warrants (which includes 3,600,000 Series B Warrants sold pursuant to the Overallotment Option), and (iv) Pre-Funded Warrants to purchase 14,467,893 shares of common stock, pursuant to the Registration Statement and the Underwriting Agreement. The net proceeds to the Company, after deducting the underwriting discount and commissions and offering expenses paid or payable by the Company, were approximately $10.2 million. On February 10, 2022, we issued and sold an additional 1,245,116 shares of common stock pursuant to the Overallotment Option resulting in net proceeds, after deducting the underwriting discount, of approximately $0.5 million.

Each Series A Warrant is exercisable at a price per share of common stock of $0.50, each Series B Warrant is exercisable at a price per share of common stock of $0.50 and each Pre-Funded Warrant is exercisable at a price per share of common stock of $0.0001. Each Warrant is immediately exercisable. The exercise prices of the Warrants are subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting the Company's common stock. Subject to limited exceptions, a holder of Warrants will not have the right to exercise any portion of its Warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, upon election by a holder prior to the issuance of any Warrants, 9.99%) of the shares of common stock then outstanding. At the holder's option, upon notice to the Company, the holder may increase or decrease this beneficial ownership limitation not to exceed 9.99% of the shares of Common Stock then outstanding, with any such increase becoming effective upon 61 days' prior notice to the Company.

The Underwriting Agreement contains representations, warranties and covenants made by the Company that are customary for transactions of this type. Under the terms of the Underwriting Agreement, the Company has agreed to indemnify the Underwriter against certain liabilities, including liabilities under the Securities Act of 1933, as amended. In addition, pursuant to the terms of the Underwriting Agreement, the Company and its executive officers and directors have entered into lock-up agreements providing that the Company and each of these persons may not, without the prior written approval of the Underwriter, subject to limited exceptions, offer, sell, transfer or otherwise dispose of the Company's securities for a period of 90 days following the date of the Underwriting Agreement.

On February 8, 2022, we entered into the Warrant Agency Agreement with our transfer agent, American Stock Transfer & Trust Company LLC, who will also act as our warrant agent.

We are contractually obligated to pay a former placement agent a tail fee equal to 7.5% cash compensation for the gross proceeds raised, and 7% warrant coverage of the number of shares of common stock placed, in any public or private offering consummated within twelve months of the expiration or termination of our engagement with such placement agent by any investor contacted by the placement agent during the term of our engagement. A number of the investors in the Public Offering had previously been contacted by such placement agent and, as a result, we may be obligated to pay such placement agent a cash fee in connection with the Public Offering which we estimate to be between approximately $0.7 million and $0.9 million. In addition, we may be obligated to issue between 1.4 million and 1.7 million warrants to purchase common stock valued at between $0.2 million and $0.3 million.

Termination of ATM Agreement

On January 18, 2022, H.C. Wainwright & Co. delivered written notice to us that it was terminating the "at the market", or ATM, Agreement with us dated January 26, 2021. During the year ended December 31, 2021, we sold 3,811,170 shares of common stock for gross proceeds of approximately $16.0 million through the ATM equity offering facility, or ATM Facility, under the ATM Agreement. With the provision of such notice, the ATM Facility is no longer available to us.

Chief Executive Officer Health

Will McGuire, our Chief Executive Officer, was recently diagnosed with a serious illness not caused by COVID-19 and has been undergoing treatment for his disease. He continues to fulfill all of his duties and responsibilities and has stated his desire to continue in such roles. Our board of directors has discussed a plan of succession and will continue to evaluate and monitor our options on an ongoing basis should Mr. McGuire need to relinquish any of his responsibilities or duties at any time as a result of his illness or otherwise.

Effects of COVID-19 and Market Conditions

The global effects of COVID-19 have created significant volatility, uncertainty and economic disruption. Although the number of reported cases of COVID-19 has recently decreased, the ultimate effects of COVID-19 on our business, operations and financial condition are unknown at this time. We expect that enrollment in our atherectomy clinical trial will continue to be affected by the uncertainty relating to COVID-19, as patients may continue to elect to postpone voluntary treatments and physicians' offices are either remaining closed, operating

at a reduced capacity or are in the process of reopening or returning to full capacity. Our manufacturing facility located in Carlsbad, California is currently operational. We have experienced delays in receiving shipments of parts which has had an impact on the timing of our key engineering efforts but has not affected our ability to support our atherectomy clinical study. 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.

We, like many companies, are also experiencing increased difficulty in attracting and retaining key personnel due to a tight labor market.

Components of our Results of Operations

Net Revenues

Product sales revenues consisted of the sales of catheters for use with the DABRA laser. We are currently not selling commercial product and are only selling catheters for use on our atherectomy clinical trial.

Service and other revenues consisted primarily of billable services, including fees related to DABRA laser commercial usage agreements, which are recognized when the services are provided.

We have historically used 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 Revenues

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

Gross Profit (Loss)

We calculate gross profit (loss) as revenues less cost of revenues. 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, manufacturing costs, product yields, headcount and cost-reduction strategies. Our gross profit (loss) would be reduced if our production volume increased and certain costs remained fixed or increased 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.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist of employee-related expenses, including salaries, benefits and stock-based compensation expense. Other SG&A expenses include professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses and facility-related expenses. We expect continued legal costs associated with ongoing litigation and the government investigation.

Research and Development Expenses

Research and development, or R&D, expenses include the following:

- 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 R&D 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 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.

Results of Continuing Operations

The following table sets forth our results of continuing operations for the periods presented (in thousands):

	Year Ended December 31,		
	2021	2020	Change
Net revenues	$ 22	$ 259	$ (237)
Cost of revenues	1,560	2,172	(612)
Selling, general and administrative expenses	15,475	24,533	(9,058)
Research and development expenses	12,253	8,955	3,298
Other income (expense), net	2,009	88	1,921

Comparison of Years Ended December 31, 2021 and 2020

Net Revenues

The decrease of approximately $0.2 million in net revenues for the year ended December 31, 2021 as compared to the prior year was due to decreased catheter unit sales as a result of pausing commercial sales in late 2020 while we conducted further studies on the stability of the catheter's shelf life. We have continued to supply catheters to clinical trial sites.

We expect our net revenue to be negatively impacted in the short term as we only sell catheters to support our atherectomy clinical study while we continue efforts to remedy the inconsistencies in our DABRA catheter performance and obtain an atherectomy indication.

Cost of Revenues

The decrease of approximately $0.6 million in cost of revenues for the year ended December 31, 2021 as compared to the prior year was due to a decrease in catheter unit sales, partially offset by increases in costs of repairs and maintenance on catheter manufacturing equipment. We expect our cost of revenues to decrease in the near term due to a reduction in depreciation expense as a result of an increase in the estimated useful life of our lasers included in property and equipment.

Selling, General and Administrative Expenses

The decrease of approximately $9.1 million in SG&A expenses for the year ended December 31, 2021 as compared to the prior year was due to decreases of $2.8 million in legal expenses, primarily due to the $2.7 million settlement in 2020 for the DOJ False Claims Act investigation, $1.6 million in salary, benefits and other personnel-related costs primarily due to the reduction in our sales force, $1.5 million in stock-based compensation expense, $0.9 million in insurance expense, $0.7 million in depreciation expense and $1.0 million in other expenses and an increase of $0.6 million in gain on sale of fixed assets.

Research and Development Expenses

The increase of approximately $3.3 million in R&D expenses for the year ended December 31, 2021 as compared to the prior year was primarily due to increases of $2.2 million in personnel and consulting expenses, $0.7 million in R&D supplies expense and $0.5 million in other expenses, including clinical study expenses, partially offset by a decrease of $0.1 million in stock-based compensation. These increases were due to engineering efforts on our next-generation catheters, including increased shelf life and improved deliverability, and progress on the atherectomy clinical study.

Other Income (Expense), Net

The increase of approximately $1.9 million in other income (expense), net for the year ended December 31, 2021 compared to the prior year was primarily due to the $2.0 million gain on the forgiveness of the Paycheck Protection Program, or PPP, promissory note under the Coronavirus Aid, Relief and Economic Security Act during the year ended December 31, 2021.

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 loss from continuing operations as adjusted to exclude depreciation and amortization, interest income, interest expense, income tax expense, stock-based compensation, gain on extinguishment of PPP promissory note and loss (gain) on sales and disposals of property and equipment.

The following is a reconciliation of loss from continuing operations to Adjusted EBITDA (in thousands):

	Year Ended December 31,	
	2021	2020
Loss from continuing operations	$ (27,261)	$ (35,320)
Depreciation and amortization	1,289	1,947
Interest income	(3)	(129)
Interest expense	12	41
Income tax expense	4	7
EBITDA	(25,959)	(33,454)
Stock-based compensation	2,054	3,682
Gain on extinguishment of PPP promissory note	(2,023)	—
(Gain) loss on sales and disposals of property and equipment	(550)	99
Adjusted EBITDA	$ (26,478)	$ (29,673)

The decrease in negative Adjusted EBITDA of $3.2 million for the year ended December 31, 2021 as compared to the corresponding period in the prior year was primarily due to the decrease in SG&A expenses due to lower legal expenses related to the government investigation and lower personnel and other expenses due to our continued cost saving initiatives, partially offset by an increase in R&D expenses related to efforts to improve our catheter design and costs related to our clinical study

Liquidity and Capital Resources

As of December 31, 2021, we had cash and cash equivalents of $15.0 million and an accumulated deficit of $178.3 million. Our primary sources of capital have been the net proceeds of $67.3 million from our initial public offering, $19.1 million from our 2020 public offerings, $15.2 million from our 2021 ATM offerings, $3.5 million from the sale of the Dermatology Business, $2.0 million received in the form of a PPP promissory note and, to a lesser extent, private placements of common stock and equipment financing arrangements. In addition, in February 2022, we completed the Public Offering resulting in net cash proceeds of $10.7 million.

Management expects operating losses and negative cash flows to continue for the foreseeable future with our reduced commercial footprint, and as we continue to incur costs related to our atherectomy clinical trial, engineering efforts to improve the shelf life of our catheters and develop next generation products and legal costs associated with ongoing litigation. We also expect the COVID-19 pandemic to continue to have a negative impact on the timing of enrollment our atherectomy clinical trial as well as our 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 six clinical specialists as of December 31, 2021. 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.

As a public company, we incur and will continue to incur significant legal, accounting, insurance and other expenses. We expect legal and related expenses to remain high in the near term in connection with the legal proceedings discussed in Note 16. *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 amount and timing of revenue generated by sales of our DABRA products 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 extending shelf life and reducing non-calibrations, reducing kinking, and identifying other future issues, if any;
- 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;
- following our voluntary product recall, our ability to achieve market acceptance of DABRA;
- matters arising out of our completed Audit Committee investigation and our ability to comply with the CIA;
- the cost, timing and outcomes of any litigation involving our company, products and business activities, including securities class actions and shareholder derivative lawsuits, and government investigation 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 DABRA;
- 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 DABRA 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 recently bolstered our liquidity resources, have an effective shelf registration statement and may receive additional funds from the exercise of our warrants depending on market conditions, management has 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 for a period of at least 12 months from the date of issuance of the financial statements. We plan to address this uncertainty by raising additional funds, if necessary, through public or private equity or debt financings as well as by engaging in regular and ongoing reviews of our business model and strategic options to help ensure that we are focusing our cash resources on advancing our key corporate initiatives. 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.

Further, SEC regulations limit the amount of funds we can raise during any 12-month period pursuant to our shelf registration statement on Form S-3. We are currently subject to the Baby Shelf Rule and the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates. We are currently limited by the Baby Shelf Rule as of the filing of this Annual Report, until such time as our public float exceeds $75 million.

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

The following information reflects cash flows for continuing operations and discontinued operations for the periods presented (in thousands):

	Year Ended December 31,	
	2021	**2020**
Net cash (used in) provided by:		
Operating activities	$ (27,625)	$ (28,304)
Investing activities	3,802	15,933
Financing activities	14,962	21,693
Net change in cash and cash equivalents	$ (8,861)	$ 9,322

Net Cash Used in Operating Activities

During the year ended December 31, 2021, net cash used in operating activities of $27.6 million consisted of a net loss of $25.1 million, gains of $6.0 million consisting of the gains on the sale of the Dermatology Business of $3.5 million, extinguishment of the PPP promissory note of $2.0 million and sale of fixed assets of $0.5 million, partially offset by non-cash expenses of $3.8 million consisting primarily of stock-based compensation and depreciation and amortization of $2.2 million and $1.6 million, respectively, and a decrease in operating assets and liabilities of $0.3 million.

During the year ended December 31, 2020, net cash used in operating activities of $28.3 million consisted of a net loss of $36.0 million, partially offset by non-cash expenses of $6.7 million, consisting primarily of stock-based compensation and depreciation and amortization of $4.1 million and $2.4 million, respectively, and an increase in operating assets and liabilities of $1.0 million.

Net Cash Provided by Investing Activities

During the year ended December 31, 2021, net cash provided by investing activities of $3.8 millionconsisted primarily of the net proceeds of $3.5 million from the sale of the Dermatology Business and $0.6 million in proceeds from the sales of equipment, partially offset by purchases of equipment of $0.3 million.

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

Net Cash Provided by Financing Activities

During the year ended December 31, 2021, net cash provided by financing activities of $15.0 million consisted primarily of net proceeds of $15.2 million from our ATM offerings, partially offset by payments of $0.3 million on our financed equipment.

During the year ended December 31, 2020, net cash provided by financing activities of $21.7 million primarily consisted of net proceeds of $19.1 million received from our 2020 public offerings, $2.0 million from the PPP promissory note and $0.8 million from the exercise of warrants, partially offset by payments of $0.3 million on our financed equipment.

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.

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.

Accounting for Long-Lived Assets—Useful Lives

We are required to make subjective assessments as to the useful lives of our property and equipment for purposes of determining depreciation expense that, if incorrectly estimated, could be material to our financial statements. Depreciation expense for our property and equipment is computed using the straight-line method over the estimated useful lives of our various assets of property and equipment. The most significant portion of our property and equipment represents the cost of our lasers which historically have been depreciated over an estimated useful life of 5 years. We review the expected useful lives of our assets on an ongoing basis and adjust, if necessary. See Note 2 to the financial statements for further discussion regarding depreciation of our lasers.

Research and Development Expenses

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual accordingly. Services related to research and development projects are expensed as research and development costs at the time such costs are incurred.

Clinical Trial Costs and Accruals

We accrue clinical trial costs based on work performed. In determining the amount to accrue, we rely on estimates of total costs incurred based on enrollment, the completion of clinical trials and other events. We follow this method because we believe reasonable dependable estimates of the costs applicable to various stages of a clinical trial can be made. However, the actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending on a number of factors. Differences between the actual clinical trial costs and the estimated clinical trial costs that we have accrued in any prior period are recognized in the subsequent period in which the actual costs become known. Historically, our estimated accrued expenses have approximated actual expenses incurred; however, material differences could occur in the future.

Stock-Based Compensation

We calculate the cost of awards of equity instruments based on the grant date fair value of the awards issued to employees, members of our board of directors and nonemployee consultants using the Black-Scholes option pricing valuation model, or Black-Scholes model, which incorporates various assumptions including volatility, expected term and risk-free interest rate. The expected term of the options is the estimated period of time until exercise and was determined using the SEC's safe harbor rules, using an average of vesting and contractual terms, as we did not have sufficient historical experience of similar awards. Expected stock price volatility is based on historical volatilities of certain "guideline" companies, as the Company does not have sufficient historical stock price data. The risk-free interest rate is based on the implied yield available on U.S. Treasury zero-coupon issues with an equivalent term. The estimated fair value of stock-based compensation awards is amortized on a straight-line basis over the relevant vesting period, adjusted for actual forfeitures at the time they occur.

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 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Sensitivity

We had cash and cash equivalents of $15.0 million as of December 31, 2021. 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.

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.

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, 2021. 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, 2021, 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, 2021 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, 2021 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, Haskell & White LLP, is not required to and has not issued an attestation report as of December 31, 2021 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

We previously filed a summary compensation table for our named executive officers in the Registration Statement. On March 18, 2022, our board of directors granted year-end bonus awards to our named executive officers for services provided during the year ended December 31, 2021. As a result, we are including an updated summary compensation statement in this Annual Report on Form 10-K to update that disclosure.

Summary Compensation Table

The following table provides information regarding the compensation of our chief executive officer and each of the next two most highly compensated executive officers during 2021, together referred to as our "Named Executive Officers," for 2021 and 2020, as applicable.

Name and Principal Position	Year	Salary	Bonus (1)	Stock Awards (2)	Option Awards (3)	Non-Equity Incentive Plan Compensation		All Other Compensation (4)	Total
Jonathan Will McGuire(5)	2021	$ 495,192	—	—	—	$ 375,000	(6)	$ 40,933	$ 911,125
Chief Executive Officer	2020	378,846	$ 50,000	$ 609,153	$ 248,355	329,063	(7)	41,568	1,656,985
Andrew Jackson(8)	2021	366,709	—	—	—	138,851	(6)	15,141	520,701
Chief Financial Officer	2020	385,923	134,415	162,975	—	173,564	(7)	17,754	874,631
Daniel Horwood	2021	224,578	—	—	—	166,829	(9)	13,234	404,641
Former General Counsel and Secretary(10)	2020	328,004	78,678	90,510	—	153,542	(7)	16,964	667,698

(1) Amounts in this column relate to: (i) for Mr. McGuire in 2020, a signing bonus of $50,000; (ii) for Mr. Jackson in 2020, retention bonus payments of $134,415 and (iii) for Mr. Horwood in 2020, retention bonus payments of $78,678.

(2) This column reflects the aggregate grant date fair value of restricted stock units and restricted stock awards granted to the named individuals during the corresponding year, computed in accordance with the provisions of ASC Topic 718. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of restricted stock units. The actual value that may be realized is also subject to time-based vesting restrictions that require the named executive officer to continue to provide services to us.

(3) This column reflects the aggregate grant date fair value of stock options granted to the named individuals during the corresponding year computed in accordance with the provisions of ASC Topic 718. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options. The actual value that may be realized is also subject to time-based vesting restrictions that require the named executive officer to continue to provide services to us.

(4) Amounts reflect Company matching contributions to the Named Executive Officers' 401(k) plans. In addition, for Mr. McGuire, this column includes $19,848 paid for a supplemental health insurance plan.

(5) Mr. McGuire was hired as our Chief Executive Officer effective March 30, 2020.

(6) Amounts shown represent performance bonuses earned in 2021, which were paid in cash in March 2022.

(7) Amounts shown represent performance bonuses earned in 2020, which were paid in cash in March 2021.

(8) Mr. Jackson also served as our Interim Chief Executive Officer from August 11, 2019 through March 29, 2020.

(9) Amount represents severance pay that Mr. Horwood received upon his resignation on July 30, 2021.

(10) Mr. Horwood served as our General Counsel and Secretary until July 31, 2021.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

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 2022 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, 2021.

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 2022 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, 2021.

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 2022 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, 2021.

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 2022 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, 2021.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Our independent registered public accounting firm is Haskell & White LLP, Irvine, CA. Auditor ID200.

The information required by this item is incorporated by reference to our Proxy Statement relating to our 2022 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, 2021.

PART IV — FINANCIAL INFORMATION

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. *Financial Statements*. We have filed the following documents as part of this Annual Report:

2. *Financial Statement Schedules.*

There are no financial statement schedules provided because the information called for is either not required or is shown either in the financial statements or the notes thereto.

3. *Exhibits.*

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	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-38677	3.1	11/17/2020
3.3	Amended and Restated Bylaws of the Registrant	8-K	001-38677	3.2	10/1/2018
4.1	Specimen common stock certificate of the Registrant.	S-1	333-226191	4.1	7/16/2018
4.2*	Description of Capital Stock				
4.3	Form of warrant issued in May 2020	8-K	001-38677	4.1	5/22/2020
4.4	Form of pre-funded warrant issued in May 2020	8-K	001-38677	4.2	5/22/2020
4.5	Form of placement agent warrant issued in May 2020	8-K	001-38677	4.3	5/22/2020
4.6	Form of warrant offered in July 2020	S-1	333-239887	4.3	7/16/2020
4.7	Form of pre-funded warrant issued in July 2020	S-1	333-239887	4.4	7/16/2020
4.8	Form of placement agent warrant offered in July 2020	S-1	333-239887	4.5	7/16/2020
4.9	Form of Series A Warrant offered in February 2022	S-1/A	333-262195	4.8	2/3/2022

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
4.10	Form of Series B Warrant offered in February 2022	S-1/A	333-262195	4.9	2/3/2022
4.11	Form of pre-funded warrants offered in February 2022	S-1/A	333-262195	4.10	2/3/2022
4.12	Warrant Agency Agreement dated February 8, 2022, by and between the Registrant and American Stock & Trust Company LLC	8-K	001-38677	4.4	2/9/2022
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+	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
10.10+	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
10.11+	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
10.12	Paycheck Protection Program Promissory Note and Agreement as of May 3, 2020.	8-K	001-38677	10.1	5/7/2020
10.13	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
10.14	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
10.15	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-K	001-38677	10.19	3/17/2021
10.16	Corporate Integrity Agreement, between the Company and the Office of Inspector General of the Department of Health and Human Services, dated December 28, 2020.	10-K	001-38677	10.20	3/17/2021

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.17	Asset Purchase Agreement, dated August 16, 2021, by and between Ra Medical Systems, Inc. and Strata Skin Sciences, Inc.	8-K	001-38677	10.1	8/16/2021
10.18	Services Agreement, dated August 16, 2021, by and between Ra Medical Systems, Inc. and Strata Skin Sciences, Inc.	8-K	001-38677	10.2	8/16/2021
10.19	Trademark Assignment Agreement, dated August 16, 2021, by and between Ra Medical Systems, Inc. and Strata Skin Sciences, Inc.	8-K	001-38677	10.3	8/16/2021
23.1*	Consent of Haskell & White LLP, Independent Registered Public Accounting Firm.				
23.2*	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.				

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
101.INS*	Inline XBRL Instance Document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data File (formatted as Inline XBRL)				

* 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.

Date: March 23, 2022

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

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

Signature	Title	Date
/s/ Jonathan Will McGuire Jonathan Will McGuire	Director and Chief Executive Officer (Principal Executive Officer)	March 23, 2022
/s/ Andrew Jackson Andrew Jackson	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 23, 2022
/s/ Martin Colombatto Martin Colombatto	Chairman of the Board of Directors	March 23, 2022
/s/ Richard Mejia, Jr. Richard Mejia, Jr.	Director	March 23, 2022
/s/ Susanne Meline Susanne Meline	Director	March 23, 2022
/s/ Joan Stafslien Joan Stafslien	Director	March 23, 2022

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 sheet of Ra Medical Systems, Inc. (the "Company") as of December 31, 2021, the related statements of operations, comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2021 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, 2021, and the results of its operations and its cash flows for the year ended December 31, 2021, 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 limited liquid resources and 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 audit. 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 audit 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ HASKELL & WHITE LLP

We have served as the Company's auditor since 2021.

Irvine, California
March 23, 2022

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 (January 14, 2022 as to the effects of the discontinued operations as described in Note 3)

We have served as the Company's auditor since 2018. In 2021, we became the predecessor auditor.

RA MEDICAL SYSTEMS, INC.

Balance Sheets
(in thousands, except par value data)

	December 31, 2021	December 31, 2020
ASSETS		
Current Assets		
Cash and cash equivalents	$ 15,045	$ 23,906
Accounts receivable, net	21	24
Inventories	986	877
Prepaid expenses and other current assets	1,037	1,100
Current assets of discontinued operations	—	1,713
Total current assets	17,089	27,620
Property and equipment, net	1,809	2,527
Operating lease right-of-use assets	2,110	2,484
Other non-current assets	36	45
Long-term assets of discontinued operations	—	762
TOTAL ASSETS	$ 21,044	$ 33,438
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 988	$ 471
Accrued expenses	4,119	4,147
Current portion of operating lease liabilities	283	356
Current portion of PPP promissory note	—	421
Current portion of equipment financing	—	265
Current liabilities of discontinued operations	—	2,102
Total current liabilities	5,390	7,762
Operating lease liabilities	1,981	2,264
PPP promissory note	—	1,579
Long-term liabilities of discontinued operations	—	686
Total liabilities	7,371	12,291
Commitments and contingencies (Note 16)		
Stockholders' Equity		
Preferred stock, $0.0001 par value, 10,000 shares authorized; no shares issued	—	—
Common stock, $0.0001 par value, 300,000 shares authorized; 7,010 and 3,189 shares issued and outstanding at December 31, 2021 and 2020, respectively	8	7
Additional paid-in capital	191,937	174,342
Accumulated deficit	(178,272)	(153,202)
Total stockholders' equity	13,673	21,147
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 21,044	$ 33,438

See accompanying notes to financial statements and reports of independent registered public accounting firms.

RA MEDICAL SYSTEMS, INC.

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

	Year Ended December 31,	
	2021	**2020**
Net revenues		
Product sales	$ 22	$ 254
Service and other	—	5
Total net revenues	22	259
Cost of revenues		
Product sales	832	1,369
Service and other	728	803
Total cost of revenues	1,560	2,172
Gross loss	(1,538)	(1,913)
Operating expenses		
Selling, general and administrative	15,475	24,533
Research and development	12,253	8,955
Total operating expenses	27,728	33,488
Operating loss	(29,266)	(35,401)
Other income (expense), net		
Other income (expense), net	(14)	88
Gain on extinguishment of PPP promissory note (Note 9)	2,023	—
Total other income (expense), net	2,009	88
Loss from continuing operations before income taxes	(27,257)	(35,313)
Income taxes	4	7
Loss from continuing operations	(27,261)	(35,320)
Discontinued operations (Note 3)		
Income (loss) from discontinued operations (including gain on sale of $3,500 in 2021) before income taxes	2,191	(725)
Income taxes	—	—
Income (loss) from discontinued operations	2,191	(725)
Net loss	$ (25,070)	$ (36,045)
Net income (loss) per share, basic and diluted		
Continuing operations	$ (5.39)	$ (20.79)
Discontinued operations	0.43	(0.43)
Total net loss per share, basic and diluted	$ (4.96)	$ (21.22)
Weighted average common shares used in computing net income (loss) per share, basic and diluted	5,055	1,699

See accompanying notes to financial statements and reports of independent registered public accounting firms.

RA MEDICAL SYSTEMS, INC.

Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,	
	2021	**2020**
Net loss	$ (25,070)	$ (36,045)
Other comprehensive loss:		
Unrealized losses on short-term investments	—	(26)
Comprehensive loss	$ (25,070)	$ (36,071)

See accompanying notes to financial statements and reports of independent registered public accounting firms.

RA MEDICAL SYSTEMS, INC.

Statements of Stockholders' Equity
(in thousands)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balances at January 1, 2020	551	$ 1	$ 150,280	$ 26	$ (117,157)	$ 33,150
Common stock issued, net	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 purchases under employee stock purchase plan	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
Common stock issued, net	3,901	1	15,152	—	—	15,153
Warrant issued	—	—	132	—	—	132
Restricted stock awards cancelled	(113)	—	—	—	—	—
Common stock issued pursuant to the vesting of restricted stock units and purchases under employee stock purchase plan	33	—	74	—	—	74
Stock-based compensation	—	—	2,237	—	—	2,237
Net loss	—	—	—	—	(25,070)	(25,070)
Balances at December 31, 2021	7,010	$ 8	$ 191,937	$ —	$ (178,272)	$ 13,673

See accompanying notes to financial statements and reports of independent registered public accounting firms.

RA MEDICAL SYSTEMS, INC.

Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (25,070)	$ (36,045)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of discontinued operations	(3,473)	
Gain on extinguishment of PPP promissory note	(2,023)	
Stock-based compensation	2,237	4,082
Depreciation and amortization	1,565	2,365
(Gain) loss on sales and disposals of property and equipment	(550)	99
Provision for credit losses	47	180
Changes in operating assets and liabilities:		
Accounts receivable, net	42	368
Inventories	(197)	352
Prepaid expenses and other assets	150	642
Accounts payable	627	(961)
Accrued expenses	(390)	1,706
Deferred revenue	(234)	(774)
Other liabilities	(356)	(318)
Net cash used in operating activities	(27,625)	(28,304)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of discontinued operations	3,700	—
Payment of fees related to sale of discontinued operations	(227)	—
Proceeds from sales of property and equipment	594	—
Purchases of property and equipment	(265)	(67)
Proceeds from maturities of available-for-sale securities	—	16,000
Net cash provided by investing activities	3,802	15,933
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and warrants, net of placement agent fees	15,528	19,887
Payment of offering costs related to the issuance of common stock and warrants	(375)	(770)
Repayment of equipment financing	(265)	(293)
Proceeds from purchases under employee stock purchase plan	74	42
Proceeds from PPP promissory note	—	2,000
Proceeds from issuance of common stock in connection with the exercise of warrants	—	827
Net cash provided by financing activities	14,962	21,693
NET CHANGE IN CASH AND CASH EQUIVALENTS	(8,861)	9,322
CASH AND CASH EQUIVALENTS, beginning of year	23,906	14,584
CASH AND CASH EQUIVALENTS, end of year	$ 15,045	$ 23,906
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unpaid property and equipment	$ 17	$ —
Transfer of lasers from inventories to property and equipment	$ —	$ 207
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for interest	$ 2	$ 28
Cash payments for income taxes	$ 2	$ —

See accompanying notes to financial statements and reports of independent registered public accounting firms.

Note 1. Organization and Nature of Operations

The Company

Ra Medical Systems, Inc. (the "Company") is a medical device company leveraging its advanced excimer laser-based platform for use in the treatment of vascular immune-mediated inflammatory diseases. Its excimer laser and single-use catheter system, together referred to as "DABRA", is used as a tool in the treatment of peripheral artery disease ("PAD"). The Company was formed on September 4, 2002 in the state of California and reincorporated in Delaware on July 14, 2018.

On August 16, 2021, the Company completed the sale of its Pharos dermatology business (the "Dermatology Business"). Accordingly, the financial information and operating results of the Dermatology Business has been presented as discontinued operations in the financial statements for all periods presented. Unless otherwise noted, discussion within these notes to financial statements relates to continuing operations. See Note 3. *Discontinued Operations* for additional information.

Effects of COVID-19 and Market Conditions

The global effects of the novel coronavirus ("COVID-19") have created significant volatility, uncertainty and economic disruption. Although the number of reported cases of COVID-19 has recently decreased, the ultimate effects of the COVID-19 on the Company's business, operations and financial condition are unknown at this time. The Company expects that enrollment in its atherectomy clinical trial will continue to be affected by the uncertainly relating to COVID-19, as patients may continue to elect to postpone voluntary treatments and physicians' offices are either remaining closed, operating at a reduced capacity or are in the process of reopening or returning to full capacity. The Company's manufacturing facility located in Carlsbad, California is currently operational. The Company has experienced delays in receiving shipments of parts which has had an impact on the timing of its key engineering efforts but has not affected its ability to support its atherectomy clinical study. 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.

The Company, like many companies, is also experiencing increased difficulty in attracting and retaining key personnel due to a tight labor market.

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 $178.3 million at December 31, 2021. For the year ended December 31, 2021, the Company used $27.6 million in cash for operating activities for continuing and discontinued operations. As of December 31, 2021, the Company had cash and cash equivalents of $15.0 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 as further discussed in Note 16. *Commitments and Contingencies.* In September 2020, the Company paused commercial sales of DABRA catheters not being used for the atherectomy clinical trial while it conducted further studies on the stability of its shelf life. The Company submitted additional test data in March 2021, which was cleared by the U.S. Food and Drug Administration in July 2021. Although eligible, the Company has not resumed commercial sales and is evaluating its commercial catheter strategy. The Company also expects the COVID-19 pandemic to have a continued negative impact on 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.

Management believes that, based on the Company's liquidity resources, there is substantial doubt about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of the financial statements.

Although the Company bolstered its liquidity resources in 2021 and 2020, completed an equity financing in February 2022, resulting in net proceeds of $0.7 million, has an effective shelf registration statement 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 accompanying 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. Summary of Significant Accounting Policies

Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation as further described in Note 3 *Discontinued Operations.*

Use of Estimates

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting 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 credit losses, evaluation of impairment of assets, valuation of long-lived assets and their associated estimated useful lives, reserves for warranty costs, including product recalls, evaluation of probable loss contingencies and fair value of equity awards granted.

Segment Reporting

After the sale of the Dermatology Business in August 2021, the Company began operating its business in one segment which includes all activities related to the research, development and manufacture of the DABRA system. The chief operating decision-maker reviews the operating results on an aggregate basis and manages the operations as a single operating segment.

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.

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.

Fair Value of Financial Instruments

Cash equivalents, trade accounts receivable and accounts payable are reported on the balance sheets at carrying value which approximates fair value due to the short-term maturities of these instruments.

Accounts Receivable

Trade accounts receivable are presented net of allowances for credit losses. The Company sells its catheters directly to distributors or physicians and maintains an allowance for credit losses for balances that appear to have specific collection issues. The collection process is based on the age of the invoice and requires attempted contacts with the customer at specified intervals. Delinquent accounts receivable are charged against the allowance for credit losses 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 activity in the allowance for credit losses for the periods presented (in thousands):

	Year Ended December 31,	
	2021	**2020**
Balance at beginning of year	$ 84	$ 305
Provision for credit losses	47	42
Deductions	—	(263)
Balance at end of year	$ 131	$ 84

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. Although inventories are classified as current assets in the accompanying balance sheets, the Company anticipates that such inventories will be utilized beyond twelve months from December 31, 2021.

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 revenues 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. If the sample tests are unsuccessful, the entire batch is written off, with the expense recorded in cost of revenues in the statement of operations.

Property and Equipment

Property and equipment are recorded at cost and 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	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.

The Company periodically reviews the residual values and estimated useful lives of each class of its property and equipment for ongoing reasonableness, considering long-term views on its intended use of each class of property and equipment and the planned level of improvements to maintain and enhance assets within those classes. Effective January 1, 2022, based on management's revised assessment of average laser on-time utilization, the Company changed the estimated useful life of its lasers to eight years.

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

Impairment of Long-Lived Assets

The Company periodically reviews its long-lived assets for impairment when certain events or changes in circumstances indicate that the carrying value of the long-lived assets may not be recoverable. Should the sum of the undiscounted expected future net cash flows be less than the carrying value, the Company would recognize an impairment loss at that date. There were no impairment charges for the years ended December 31, 2021 or 2020.

Product Warranty

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.

The warranty accrual is included in accrued expenses in the accompanying balance sheets. Warranty expenses are included in cost of revenues 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 generates revenue from the sales of products and services. Product sales consist of the sales of catheters for use with the DABRA laser system. The Company has paused selling commercial product and is only selling catheters for use in the atherectomy clinical trial. 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 revenues primarily consist of billable services, including fees related to DABRA laser commercial usage agreements.

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

When engaged in commercial sales, 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", which provides for specific terms of continued use of the 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 usage agreement provides the Company the exclusive rights to supply related single-use catheters to the customer which aggregate the majority of the product sales revenue. There are no specified minimum purchase commitments for the catheters.

The Company recognizes revenue associated with the usage agreements and catheter supply arrangements in accordance with Financial Accounting Standards Board "*Revenue from Contracts with Customers (Topic 606),"* ("Topic 606") since (i) the contract primarily includes variable payments, (ii) the catheters are priced at their standalone selling price, and (iii) 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.

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.

Shipping and Handling Costs

Shipping and handling charged to customers are included in net product sales. Shipping and handling costs are included in selling, general and administrative expenses in the accompanying statements of operations.

Advertising Expense

The Company expenses advertising costs as incurred.

Research and Development

Major components of research and development costs include personnel expenses, stock-based compensation, consulting, supplies 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 as selling, general and administrative expenses in the accompanying statements of operations.

Stock-Based Compensation

The Company records stock-based compensation expense associated with stock options, restricted stock awards ("RSAs") and restricted stock units ("RSUs") issued to employees, members of the Company's board of directors and consultants in accordance with the authoritative guidance for 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. The cost of an award of an equity instrument is measured at the grant date, based on the estimated fair value of the award using the Black-Scholes option pricing valuation model, or Black-Scholes model, which incorporates various assumptions including expected term, volatility and risk-free interest rate, and is recognized as expense on a straight-line basis over the requisite service period of the award. Share-based compensation for an award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized, and any previously recognized compensation expense is reversed. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur.

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 equivalent 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 upon 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.

For the years ended December 31, 2021 and 2020, we had three and four individual customers, respectively, that represented greater than 10% of total net revenues. One individual customer represented greater than 10% of accounts receivable at each of December 31, 2021 and 2020.

Significant Accounting Policies Related to Discontinued Operations

Laser Sales

The Company recognized revenue on laser sales at the point in time that control transferred to the customer. Control of the product typically transferred upon shipment.

Warranty Service Revenue

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

Contracts With Multiple Performance Obligations

Certain of the Company's contracts with customers contained multiple performance obligations. For these contracts, the Company accounted for individual products and services as separate performance obligations if they are distinct, which was 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 was allocated to the separate performance obligations on a relative standalone selling price basis. The Company determined 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 was a difference between the cash selling price and the consideration in the contract and a significant amount of time between the payment, which was due up-front, and delivery of the services (greater than one year), the Company recorded an adjustment for significant financing to reflect the time value of money. The Company recognized revenue associated with the cash selling price and interest expense using the effective interest method as the Company satisfied its performance obligation(s). The amount of interest expense the Company recognized over the contract term was based on the contract liability balance, which increased for the accrual of interest and decreased as services are provided.

For services contracts that had an original duration of one year or less, the Company used the practical expedient applicable to such contracts and did 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 capitalized costs to obtain contracts that were considered incremental and recoverable, such as sales commissions. The capitalized costs were amortized to selling, general and administrative expense over the estimated period of benefit of the asset, which was the contract term. The Company elected to use the practical expedient to expense the costs to obtain a contract when the amortization period was less than one year.

Rental Income

The Company also derived income pursuant to product operating lease agreements for its Pharos laser systems, prior to the sale of the Dermatology Business. Consequently, the Company retained title to the equipment. Depreciation expense on these leased lasers was recorded to cost of revenues on a straight-line basis. The costs to maintain these leased lasers were charged to cost of revenues as incurred.

These lease arrangements contained 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 accounted for the combined lease component as an operating lease and recognized lease income on a straight-line basis over the lease term.

Recent 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.

Note 3. Discontinued Operations

Consistent with the Company's continued focus on the PAD market, the Company completed the sale of its Dermatology Business to STRATA Skin Sciences, Inc. ("Strata") on August 16, 2021, for cash proceeds of $3.7 million. The Company paid broker and legal fees of approximately $0.2 million related to the sale of the Dermatology Business. In addition, the Company issued a warrant to the broker to purchase 74,247 shares of common stock at an exercise price of $2.99 per share. The warrant is immediately exercisable and expires five years following the date of issuance. The warrant was valued at approximately $0.1 million on the grant date using the Black-Scholes option pricing model based on the following assumptions: expected volatility of 104.55%, risk-free interest rate of 0.32%, expected dividend yield of 0% and an expected term of 2.5 years.

The Dermatology Business was previously disclosed as a separate reportable segment of the Company. The sale of the Dermatology Business resulted in a gain of $3.5 million which is included as a component of income from discontinued operations in the statement of operations for the year ended December 31, 2021.

The Company has reported the results of the Dermatology Business in income (loss) from discontinued operations in the statements of operations and excluded such results from continuing operations for the years ended December 31, 2021 and 2020. The assets and liabilities of the Dermatology Business are recorded as assets of discontinued operations and liabilities of discontinued operations, respectively, in the balance sheet at December 31, 2020.

Certain overhead costs previously allocated to the Dermatology Business for segment reporting purposes did not qualify for classification as discontinued operations and have been reallocated to continuing operations for the years ended December 31, 2021 and 2020.

The following table summarizes the carrying amounts of the assets and liabilities included as discontinued operations in the balance sheet at December 31, 2020 (in thousands):

	December 31, 2020
Assets of discontinued operations	
Accounts receivable, net	$ 214
Inventories	1,341
Prepaid expenses and other current assets	158
Property and equipment, net	684
Other long-term assets	78
Total assets of discontinued operations	$ 2,475
Liabilities of discontinued operations	
Accounts payable	$ 100
Accrued expenses	201
Deferred revenue	2,487
Total liabilities of discontinued operations	$ 2,788

The assets and liabilities of discontinued operations have been classified as current and long-term, as applicable, in the balance sheet at December 31, 2020.

The following table summarizes the major classes of items constituting income (loss) from discontinued operations in the statements of operations for each of the periods presented (in thousands):

	Year Ended December 31,	
	2021	2020
Net revenues		
Product sales	$ 852	$ 1,154
Service and other	1,748	2,992
Total net revenues	2,600	4,146
Cost of revenues		
Product sales	1,201	1,522
Service and other	1,089	1,789
Total cost of revenues	2,290	3,311
Gross income	310	835
Operating expenses		
Selling, general and administrative	1,110	1,440
Research and development	388	54
Total operating expenses	1,498	1,494
Operating loss	(1,188)	(659)
Interest income (expense), net	(94)	(66)
Loss from discontinued operations	(1,282)	(725)
Gain on sale of the Dermatology Business	3,473	—
Income (loss) from discontinued operations	$ 2,191	$ (725)

Depreciation expense for the Dermatology Business was $0.3 million and $0.4 million for the years ended December 31, 2021 and 2020, respectively. There were no capital expenditures for the Dermatology Business during the years ended December 31, 2021 and 2020. The provision for credit losses for the Dermatology Business for the years ended December 31, 2021 and 2020 was nil and $0.1 million, respectively. Stock-based compensation expense for the Dermatology Business was approximately $18,000 and $0.2 million for the years ended December 31, 2021 and 2020, respectively. Stock-based compensation expense of approximately $0.1 million and $0.2 million was

capitalized to inventory and property and equipment for the Dermatology Business during the years ended December 31, 2021 and 2020, respectively.

Note 4. Fair Value Measurements

As of December 31, 2021 and 2020, cash equivalents of $9.4 million and $18.4 million, respectively, were comprised of money market funds which were measured at fair value on a recurring basis using Level 1 inputs.

Note 5. Inventories

Inventories consisted of the following (in thousands):

	December 31,	
	2021	2020
Raw materials	$ 911	$ 547
Work in process	70	270
Finished goods	5	60
Inventories	$ 986	$ 877

Note 6. Property and Equipment

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

	December 31,	
	2021	2020
Lasers	$ 3,085	$ 3,194
Machinery and equipment	858	834
Computer hardware and software	353	353
Construction in progress	169	51
Leasehold improvements	145	119
Furniture and fixtures	48	48
Automobiles	—	1,054
Property and equipment, gross	4,658	5,653
Accumulated depreciation	(2,849)	(3,126)
Property and equipment, net	$ 1,809	$ 2,527

Depreciation expense was $1.0 million and $1.6 million for the years ended December 31, 2021 and 2020, respectively.

Note 7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2021	2020
Compensation and related benefits	$ 2,004	$ 2,479
Accrued legal expenses	1,345	957
Accrued warranty (Note 8)	195	204
Other accrued expenses	575	507
Accrued expenses	$ 4,119	$ 4,147

Note 8. Accrued Warranty

Activity in the product warranty accrual is included in accrued expenses and consisted of the following (in thousands):

	Year Ended December 31,	
	2021	2020
Balance at beginning of year	$ 204	$ 234
Claims satisfied	(9)	(53)
Increase in warranty accrual	—	19
Change in liability for pre-existing warranties	—	4
Balance at end of year	$ 195	$ 204

The accrued warranty balances at December 31, 2021 and 2020 each included $0.1 million relating to the voluntary recall of catheters, which was initiated in September 2019.

Note 9. 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 "CARES Act"). The PPP Promissory Note bore interest at 1.0% per annum. Under the terms of the PPP Promissory Note, payments would have been due monthly beginning November 1, 2020, and the principal amount of the PPP Promissory Note, along with any unpaid interest, would have been due in May 2022. On June 5, 2020, the Paycheck Protection Program Flexibility Act of 2020 extended the deferral period for all loans to 10 months after the last day of the covered period. Under the revised terms, payments would have been due beginning August 2021, and the principal amount, along with unpaid interest, would have been due in May 2022. The principal and interest could be forgiven if the proceeds are used for forgivable purposes as defined by the terms in the PPP Promissory Note. The Company applied for full forgiveness under the provisions of the CARES Act in March 2021 and received approval by the Small Business Administration on June 24, 2021. Gain on extinguishment of the PPP Promissory Note of $2.0 million was included in other income (expense), net in the statement of operations for the year ended December 31, 2021. Interest expense on the PPP Promissory Note for the years ended December 31, 2021 and 2020 was $10,000 and $13,000, respectively.

Note 10. Operating Leases

During the years ended December 31, 2021 and 2020, the Company had two operating leases for office and manufacturing space which required it to pay base rent and certain utilities. Monthly rent expense was recognized on a straight-line basis over the terms of the leases. The office operating lease expired in December 2021 and the manufacturing operating lease expires in 2027.

At December 31, 2021, the remaining lease term for the manufacturing operating lease was six years. The manufacturing operating lease is included in the balance sheet at the present value of the lease payments at a 7% discount rate, the rate of interest that the Company estimates it would 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 lease does not provide an implicit rate.

For the years ended December 31, 2021 and 2020, operating lease expense and cash paid were each $0.5 million. 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.Operating lease right-of-use asset amortization was $0.4 million for each of the years ended December 31, 2021 and 2020. Variable costs were *de minimis* for the years ended December 31, 2021 and 2020.

The following table presents the lease liability related to the Company's operating lease as of December 31, 2021 (in thousands):

Years Ending December 31,		
2022	$	432
2023		445
2024		459
2025		472
2026		486
Thereafter		501
Total operating lease payments		2,795
Less: imputed interest		(531)
Total operating lease liability	$	2,264

Note 11. Equipment Financing

During 2018, the Company entered into four loan agreements to finance 25 automobiles. The loans matured in 2021 and bore interest at a weighted average interest rate of 6.5%. These loans were secured by the automobiles. Interest expense for the years ended December 31, 2021 and 2020 was *de minimis* and $28,000, respectively. The loans were repaid in full in March 2021.

Note 12. Net Loss per Share

The Company calculates basic net 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 include warrants, stock options and non-vested restricted stock awards and restricted stock 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, 2021 consisted of warrants of 2,419,280, stock options of 108,448, restricted stock awards of 179,334, restricted stock units of 70,025 and Employee Stock Purchase Plan ("ESPP") shares of 22,639.

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 ESPP shares of 3,200.

Note 13. Equity Offerings

In December 2021, the Company completed ATM offerings of 54,077 shares of common stock at a weighted average price of $1.79 per share. The Company received approximately $0.1 million in net proceeds, after deducting placement agent fees.

During July 2021 and August 2021, the Company completed ATM offerings of 1,139,306 shares of common stock, at a weighted average price of $4.00 per share. The Company received approximately $4.4 million in net proceeds, after deducting placement agent fees.

During May 2021 and June 2021, the Company completed ATM offerings of 2,582,019 shares of common stock at a weighted average price of $4.29 per share. The Company received approximately $10.6 million in net proceeds, after deducting placement agent fees.

In February 2021, the Company completed an ATM offering of 35,768 shares of common stock at a price of $8.39 per share. The Company received approximately $0.3 million in net proceeds, after deducting placement agent fees. The Company also incurred $0.2 million in offering fees and other expenses in association with filing the related Registration Statement on Form S-3 with the SEC.

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 $14.06, and expire five years following the date of issuance. The Company received approximately $8.7 million in net proceeds, after deducting placement agent fees and other offering expenses of $1.3 million.

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.

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 an 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 $10.94, 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.

As of December 31, 2021, the Company had 2,186,811 and 158,222 shares of common stock reserved for issuance pursuant to the warrants and placement agent warrants, respectively, issued by the Company in the May 2020 Offering and August 2020 Offerings. In addition, the Company had 74,247 shares of common stock reserved for issuance pursuant to the warrant issued by the Company in August 2021 to the broker in the sale of the Dermatology Business.

Note 14. Stock-Based Compensation

2018 Stock Compensation Plan

In June 2018, the 2018 Stock Compensation Plan (the "Compensation Plan") was established whereby 132,000 shares of the Company's common stock were reserved for issuance. The Company's board of directors authorized 76,076 replacement stock options and 53,633 replacement restricted stock units (collectively, the "Replacement Awards") to eligible employees, directors and consultants for equity awards that had been granted under a previous plan. The Compensation Plan was terminated in September 2018 in connection with the adoption

of the Company's 2018 Equity Incentive Plan described below and, accordingly, no new awards were available for issuance under the Compensation Plan. The Replacement Awards vested at various times through January 2020.

2018 Equity Incentive Plan

In September 2018, the Company's board of directors adopted, and the Company's stockholders approved, the 2018 Equity Incentive Plan (the "2018 Plan") which provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, performance-based stock awards and other forms of equity compensation to the Company's employees, directors and consultants. Stock options granted under the 2018 Plan generally vest one-fourth 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 vest one third on the first anniversary of the vesting commencement date and one sixth every six months thereafter such that the award will be fully vested on the third anniversary of the vesting commencement date. As of December 31, 2021, 188,307 shares of common stock were reserved for future issuance pursuant to the 2018 Plan which included (1) those shares reserved but unissued under the Compensation Plan and (2) shares of common stock subject to or issued pursuant to awards granted under the Compensation Plan that expired or otherwise terminated or were forfeited. The number of shares available for issuance under the 2018 Plan also includes an annual increase on the first day of each fiscal year equal to the lesser of (1) 65,285 shares; (2) 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 the Company's board of directors may determine. On January 1, 2021, the annual increase of 65,285 additional shares of common stock were available for future grants under the 2018 Plan.

2020 Inducement Equity Incentive Plan

In March 2020, the Company adopted the 2020 Inducement Equity Incentive Plan (the "2020 Plan") for 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. The 2020 Plan is used to offer equity awards as material inducements for new employees to join the Company. Upon adoption of the 2020 Plan, 32,000 shares of common stock were reserved for the granting of inducement stock options, restricted stock awards, restricted stock units and other forms of equity awards. As of December 31, 2021, 9,000 shares of common stock were reserved for future issuance under the 2020 Plan.

Stock Options

The following is a summary of stock option activity for employees of continuing operations and discontinued operations for the year ended December 31, 2021:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020				
2018 Plan	124,171	$ 363.31		
2020 Plan	18,000	$ 25.50		
	142,171	$ 320.54		
Forfeited	(33,723)	$ 240.17		
Outstanding at December 31, 2021	108,448	$ 345.54	5.82	$ —
Exercisable at December 31, 2021	88,324	$ 422.83	5.27	$ —
Vested and expected to vest at December 31, 2021	108,448	$ 345.54	5.82	$ —

The Company did not grant any stock options during the year ended December 31, 2021. The weighted average grant date fair value of stock options granted during the year ended December 31, 2020 under the 2018 Plan and 2020 Plan was $30.69 and $25.50, respectively. The fair value of the stock options granted during the year ended December 31, 2020 under the 2018 Plan and 2020 Plan was estimated using the Black Scholes option pricing model and the weighted average assumptions set forth below:

	2018 Plan	2020 Plan
Risk-free interest rate	1.30 %	0.50 %
Volatility	58.96 %	58.33 %
Expected dividend yield	0.00 %	0.00 %
Expected life (in years)	5.8	6.3

Restricted Stock Units

The following is a summary of the restricted stock unit activity for the 2018 Plan for employees of continuing operations and discontinued operations for the year ended December 31, 2021:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2020	33,548	$ 21.93
Granted	61,259	$ 2.74
Vested	(6,974)	$ 45.12
Forfeited	(17,808)	$ 13.59
Outstanding at December 31, 2021	70,025	$ 4.37

Restricted Stock Awards

In November 2020, the Company granted 266,161 RSAs under the 2018 Plan that were subject to both time-based vesting and the achievement of specific performance goals. During the year ended December 31, 2021, the Company determined that two of the three performance goals had not been achieved. As such, 74,998 RSAs were cancelled, and the previously recognized stock-based compensation expense of approximately $27,000 was reversed.

A summary of the restricted stock award activity for employees of continuing operations and discontinued operations for the year ended December 31, 2021 is presented below:

	Restricted Stock Awards	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2020		
2018 Plan	286,161	$ 4.77
2020 Plan	4,375	$ 25.50
	290,536	$ 5.08
Granted	103,939	$ 4.82
Vested	(88,781)	$ 5.93
Cancelled	(74,998)	$ 4.81
Forfeited	(51,362)	$ 4.81
Outstanding at December 31, 2021	179,334	$ 4.71

Employee Stock Purchase Plan

In September 2018, the Company's board of directors adopted the 2018 Employee Stock Purchase Plan (the "ESPP") whichpermits eligible employees to purchase the Company's common stock at a discount through payroll deductions during defined offering periods. Eligible employees may elect to withhold up to 15% of their base earnings to purchase shares of the Company's common stock at a price equal to 85% of the fair market value on the first day of the offering period or the purchase date, whichever is lower. The number of shares of common stock reserved for issuance under the ESPP will automatically increase on January 1 of each fiscal year by the lesser of (1)11,870 shares, (2) 1.25% of the total number of shares outstanding on December 31 of the preceding fiscal year, or (3) such other amount as the Company's board of directors may determine.

For the years ended December 31, 2021 and 2020, cash received from the exercise of purchase rights under the ESPP was approximately $0.1 million and $42,000, respectively. As of December 31, 2021, the Company had issued 32,206 shares of common stock under the ESPP, and4,764 shares of common stock were reserved for future issuance.

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

	Year Ended December 31,	
	2021	2020
Selling, general and administrative	$ 1,750	$ 3,235
Research and development	304	447
Stock-based compensation expense	$ 2,054	$ 3,682

Stock-based compensation of $0.1 million and $0.2 million was capitalized to property and equipment and inventory during the years ended December 31, 2021 and 2020, respectively.

Total unrecognized estimated stock-based compensation expense by award type and the remaining weighted average recognition period over which such expense is expected to be recognized at December 31, 2021 was as follows:

	Unrecognized Expense (in thousands)	Remaining Weighted Average Recognition Period (in years)
Stock options	$ 313	1.7
Restricted stock awards	$ 622	2.2
Restricted stock units	$ 252	2.1

Note 15. Income Taxes

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

	Year Ended December 31,	
	2021	2020
Tax computed at the federal statutory rate	21.0 %	21.0 %
State income taxes, net of federal benefits	1.3	5.1
Stock-based compensation	(2.6)	(2.2)
Tax exempt income	1.7	—
Deferred tax adjustments	—	(57.0)
Nondeductible expenses	—	(0.1)
Change in valuation allowance	(21.4)	33.2
	—	—

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

	Year Ended December 31,	
	2021	2020
Current		
Federal	$ —	$ —
State	4	7
	4	7
Deferred		
Federal	—	—
State	—	—
	—	—
Income tax expense	$ 4	$ 7

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,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 9,706	$ 3,720
Operating lease liabilities	556	691
Other accruals	71	101
Accrued compensation	399	448
Reserves	169	299
Deferred revenue	—	642
Intangible assets	56	32
Stock-based compensation	4,605	4,910
Total gross deferred tax assets	15,562	10,843
Deferred tax liabilities:		
Property and equipment	(348)	(805)
Operating lease right-of-use assets	(518)	(655)
Other	—	(61)
Total gross deferred tax liabilities	(866)	(1,521)
Valuation allowance	(14,696)	(9,322)
Total deferred taxes	$ —	$ —

At December 31, 2021, the Company had available federal and state net operating loss carryforwards of approximately $39.2 million and $41.2 million, respectively, which may potentially 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 2030. 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 $20.8 million. 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. The Company has not completed the IRC Section 382 analysis regarding the limitation of net operating losses for the year ended December 31, 2021.

As of December 31, 2021, 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, 2021. The Company files U.S. federal and various states income tax returns, which are subject to examination by the taxing authorities for years 2017 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, 2021 and 2020.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") 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 provisions for the years ended December 31, 2021 and 2020. The CARES Act did not have a material impact on the income tax provisions for the years ended December 31, 2021 and 2020.

The Consolidated Appropriations Act 2021 ("CAA"), 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 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 enactment of the CAA, the deductions paid with the proceeds of a PPP loan that was forgiven were not allowed. These provisions did not have a material impact on the income tax provisions for the years ended December 31, 2021 and 2020.

Note 16. Commitments and Contingencies

Securities Class Action and Shareholder Derivative Litigation Update

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 U.S. 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 initial public offering. 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 (the "Securities Act") 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, as amended (the "Exchange Act"). 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 March 24, 2021, the court issued an order granting defendants' motion to dismiss claims under the Securities Act in full and certain claims under the Exchange Act and denying defendants' motion to dismiss certain Exchange Act claims. Plaintiffs filed their second amended complaint on April 19, 2021, realleging the Securities Act claims and certain of the previously dismissed Exchange Act claims. On June 10, 2021, defendants moved to dismiss the second amended complaint. On November 12, 2021, following a private settlement mediation with the lead plaintiffs, the parties executed a stipulation of settlement that resolved the claims asserted in the securities class action. The settlement provides for a payment to the plaintiff class of $10.0 million. On March 18, 2022, we paid approximately $0.6 million towards the settlement and are working with our insurers to determine if we must pay an additional amount, up to an additional $0.4 million (total of $1.0 million), to satisfy our self-insured retention/deductible. Our insurers will pay the remaining amount towards the settlement. The proposed settlement requires both preliminary and final approval by the court. On February 11, 2022, the court granted preliminary approval of the settlement, scheduled a hearing on final approval of the settlement for June 13, 2022, and denied the pending motion to dismiss without prejudice. Should the court not approve the proposed settlement

or if the proposed settlement otherwise does not become final, the parties will be returned to their litigation postures prior to the execution of the stipulation of settlement. 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 such determination is made.

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 U.S. 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 Exchange Act. 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.

Settlement Agreements with the Department of Justice and Participating States

As previously announced on December 28, 2020, the Company entered into a settlement agreement ("Settlement Agreement") with the U.S., acting through the Department of Justice and on behalf of the Office of Inspector General, and other settlement agreements with certain state attorneys general to resolve investigations and a related civil action concerning its marketing of the DABRA laser system and DABRA-related remuneration to certain physicians.

Pursuant to the terms of the Settlement Agreement and the agreements with the participating states, (a) if the Company's revenue exceeds $10 million in any of fiscal years 2021-2024, the Company also is required to pay for the corresponding year: $500,000 for 2021, $750,000 for 2022, $1 million for 2023, and $1.25 million for 2024; (b) if the Company is acquired or is otherwise involved in a change in control transaction before the end of 2024, the Company 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 the Company's obligations under the Settlement Agreement are avoided by bankruptcy, the U.S. 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.

Other Litigation

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.

Services Agreement

Pursuant to the terms of the Services Agreement between the Company and Strata, executed simultaneously with the sale of the Dermatology Business, the Company will continue to provide certain services to Strata, including certain support services and the sale of spare parts, through December 2022. Income earned and expenses incurred in accordance with the Services Agreement are recorded as other income (expense), net in the accompanying statement of operations for the year ended December 31, 2021.

Note 17. Employee Benefit Plan

In January 2019, the Company established a defined contribution plan under Section 401(k) of the Internal Revenue Code ("401(k) Plan"). Under the terms of the 401(k) Plan, all full-time employees are eligible to make voluntary contributions as a percentage or defined amount of compensation. The Company makes matching contributions based on 100% of each employee's contribution up to 3% and 50% of contributions between 3% and 5%, with the match-eligible contribution limited to 4% of the employee's eligible compensation. The Company's expense related to the matching contributions was $0.3 million for each of the years ended December 31, 2021 and 2020.

Note 18. Subsequent Events

On February 8, 2022, the Company closed the sale of shares under its public offering in which it sold 9,535,000 shares of common stock, 27,602,893 each of Series A and Series B warrants and 14,467,893 pre-funded warrants resulting in cash proceeds of approximately $10.2 million, net of $1.9 million of underwriting discounts and other offering expenses. In addition, the Company may incur additional offering expenses of between approximately $0.7 million and $0.9 million for a potential tail fee owed to its former placement agent. On February 10, 2022, the underwriter partially exercised its overallotment option and purchased an additional 1,245,116 shares of common stock, resulting in cash proceeds of approximately $0.5 million, net of underwriting discounts.

On January 18, 2022, H.C. Wainwright & Co. delivered written notice to the Company that it was terminating the ATM Agreement dated January 26, 2021. During the year ended December 31, 2021, the Company sold 3,811,170 shares of common stock for gross proceeds of approximately $16.0 million.

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 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-250094, 333-237096, 333-237488, 333-227696, 333-230332 and 333-254370) and the Registration Statement on Form S-3 (No. 333-252432) of Ra Medical Systems, Inc. (the "Company") of our report dated March 23, 2022, relating to our audit of the Company's financial statements as of December 31, 2021, and for the year then ended, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, which report included an explanatory paragraph expressing substantial doubt regarding the Company's ability to continue as a going concern.

/s/ HASKELL & WHITE LLP

Irvine, California
March 23, 2022

Exhibit 23.2

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, 333-230332, and 333-254370 on Form S-8 and Registration Statement No. 333-252432 on Form S-3 of our report dated March 16, 2021 (January 14, 2022 as to the effects of the discontinued operations as described in Note 3) appearing in this Annual Report on Form 10-K of Ra Medical Systems, Inc. for the year ended December 31, 2021.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
March 23, 2022 (January 14, 2022 as to the effects of the discontinued operations as described in Note 3)

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 23, 2022

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 23, 2022

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, 2021 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 23, 2022

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, 2021 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 23, 2022

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.