Filed pursuant to Rule 424(b)(4)
Registration No. 333-237701

Ra Medical Systems, Inc.

20,725,190 Units, Each Unit Consisting of One Share of Common Stock and One Warrant to Purchase One Share of Common Stock

1,497,032 Pre-funded Units, Each Pre-funded Unit Consisting of One Pre-funded Warrant to Purchase One Share of Common Stock and One Warrant to Purchase One Share of Common Stock

We are offering 20,725,190 units (each unit consisting of one share of common stock and one warrant to purchase one share of common stock). Each warrant included in a unit has an exercise price of $0.45 per share. The warrants included in the units will be immediately exercisable and will expire five years from the date of issuance. The offering price of the units is $0.45 per unit.

We are also offering to those purchasers, if any, whose purchase of units in this offering would otherwise result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, 1,497,032 pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of common stock and one warrant to purchase one share of common stock), in lieu of units that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock. The purchase price of each pre-funded unit will be equal to the price per unit being sold to the public in this offering, minus $0.0001, and the exercise price of each pre-funded warrant included in the pre-funded units will be $0.0001 per share. The pre-funded warrants included in the pre-funded units will be certificated and will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full.

The units and the pre-funded units will not be issued or certificated. The shares of common stock or pre-funded warrants, as the case may be, and the warrants included in the units or the pre-funded units can only be purchased together in this offering, but the securities contained in the units or pre-funded units will be immediately separable upon issuance and will be issued separately. The shares of common stock issuable from time to time upon exercise of the warrants and the pre-funded warrants are also being offered by this prospectus.

Our shares of common stock are listed on the New York Stock Exchange under the symbol "RMED." The last reported sales price of our shares of common stock on May 19, 2020 was $0.6601 per share. There is no established public trading market for the warrants or the pre-funded warrants, and we do not expect such a market to develop. In addition, we do not intend to apply for a listing of the warrants or the pre-funded warrants on any national securities exchange or other nationally recognized trading system.

We have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent in connection with the securities offered by this prospectus. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The placement agent is not purchasing or selling any of the securities we are offering and the placement agent is not required to arrange the purchase or sale of any specific number of securities or dollar amount. We have agreed to pay to the placement agent the placement agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. See "Plan of Distribution" on page 78 of this prospectus for more information regarding these arrangements. There is no minimum number of securities or amount of proceeds that is a condition of closing of this offering. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund if we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus. In addition, we have not specified a minimum offering amount and we have not established an escrow account in connection with this offering. Because there is no escrow account and no minimum offering amount, investors could be in a position where they have invested in us, but we have not raised sufficient proceeds in this offering to adequately fund the intended uses of the proceeds as described in this prospectus.

We are a "smaller reporting company" and an "emerging growth company" as defined under the federal securities laws and, as such, we may continue to elect to comply with certain reduced public company reporting requirements in future reports.

Investing in our securities involves a high degree of risk. See " Risk Factors" beginning on page 7 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Unit	Per Pre-Funded Unit(2)	Total
Public offering price	$ 0.45000	$ 0.44990	$ 9,999,850.20
Placement agent fees(1)	$ 0.03375	$ 0.03375	$ 749,999.99
Proceeds, before expenses, to us	$ 0.41625	$ 0.41615	$ 9,249,850.20

(1) In addition, we have agreed to pay the placement agent a management fee equal to 1.0% of the gross proceeds raised in this offering and to reimburse the placement agent for its non-accountable expenses in the amount of $40,000, its legal fees and expenses and other out-of-pocket expenses in an amount up to $100,000 and its clearing expenses in the amount of $12,900. In addition, we have agreed to issue the placement agent or its designees warrants to purchase a number of shares of common stock equal to 7.0% of the aggregate number of shares of common stock, including shares of common stock underlying the pre-funded warrants, sold in this offering with an exercise price of $0.5625 per share, or 125% of the public offering price per share. See "Plan of Distribution" for a description of the compensation to be received by the placement agent.

(2) Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. For more information, see "Plan of Distribution."

Delivery of the securities offered hereby is expected to be made on or about May 22, 2020, subject to satisfaction of certain customary closing conditions.

H.C. Wainwright & Co.

Prospectus dated May 20, 2020

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Neither we nor the placement agent have authorized anyone to provide you with any information or to make any representations other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we nor the placement agent are making an offer to sell securities in any jurisdiction in which the offer or sale is not permitted. The information in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our shares of common stock and the information in any free writing prospectus that we may provide to you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and prospects may have changed since those dates.

For investors outside the United States: We have not and the placement agent has not, done anything that would permit this offering, or possession or distribution of this prospectus, in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

Unless the context clearly indicates otherwise, references in this prospectus to “we,” “our,” “ours,” “us,” “the Company” and “Ra Medical” refer to Ra Medical Systems, Inc.

SUMMARY

This summary is not complete and does not contain all of the information that you should consider before investing in the securities offered by this prospectus. You should read this summary together with the entire prospectus carefully, including "Risk Factors" and our financial statements and the related notes incorporated by reference into this prospectus, before making an investment decision. See "Risk Factors" for a discussion of the risks involved in investing in our securities.

Overview

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

The DABRA laser is based on the same core technology and utilizes a similar excimer laser as Pharos, a medical device that we have marketed as a tool for the treatment of proliferative skin conditions since October 2004. Pharos is designed for use in the treatment of inflammatory skin conditions and is FDA cleared as a tool used in the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. Our dermatology business strategy is focused on continuing to service our existing accounts while we evaluate opportunities to grow revenue by expanding our sales footprint in the US as well as by adding international distribution partners. Because DABRA and Pharos are both based on our core excimer laser technology platform and deploy similar mechanisms of action, we benefit from economies of scale in product development, manufacturing, quality assurance and distribution.

Our vascular business strategy is focused on continuing to service our core U.S. accounts while we complete initiatives that are key to relaunching DABRA for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease to the broader market. Key components of our DABRA relaunch strategy include:

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

We are also exploring the development of a larger diameter catheter to facilitate treatment of larger vessels more commonly seen in above-the-knee procedures.

Each of these initiatives will require FDA clearance. We currently expect to complete enrollment in the atherectomy indication clinical study in the first half of 2021. We also currently expect that our engineering efforts to develop a strategy for extending the shelf life of the catheter will be completed by the end of 2020. With that strategy in place, we expect to complete the engineering work and obtain FDA clearance for the braided overjacket and the rapid exchange platform during 2021. We intend to begin expanding our vascular sales force to prepare for a commercial relaunch as some or all of these initiatives are completed.

Recent Developments

COVID-19

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

In May 2020, we entered into a $2.0 million Paycheck Protection Program Promissory Note and Agreement, or the Promissory Note, with a commercial bank under the Coronavirus Aid, Relief, and Economic Security Act. The Promissory Note bears interest at 1.0% per annum. Payments are due monthly beginning November 1, 2020. The principal amount of the Promissory Note along with any unpaid interest is due on May 3, 2022. The principal and interest may be forgiven if the proceeds are used for forgivable purposes as defined by the terms in the Promissory Note.

Securities and Shareholder Litigation Update

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

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

Government Investigations

As previously disclosed, the Audit Committee of our board of directors conducted an internal investigation regarding certain allegations made by a former employee. In connection with the Audit Committee investigation, we voluntarily contacted the Enforcement Division of the SEC. We publicly announced the results of the Audit Committee investigation on October 31, 2019.

In October 2019, the U.S. Department of Justice, or DOJ, served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. We believe 17 states are participating in the DOJ's False Claims Act investigation. In November 2019, we learned that the DOJ opened a criminal investigation relating to us and that the SEC was conducting an investigation. On March 11, 2020, the SEC served us with document subpoenas. We have been, and intend to continue, cooperating in these active and ongoing investigations.

If one or more government agencies, including those conducting the active and ongoing investigations identified above, commences legal action and we are found to have violated state or federal laws or regulations, we may be subject to civil or criminal damages, penalties, fines, disgorgement, injunctions, cease and desist orders, other equitable remedies, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which would have a material adverse effect on our business, financial condition, and results of operations for years. Regardless of whether actions are commenced, if we were to settle with one or more government agencies or state governments, including those conducting the active and ongoing investigations identified above, such settlements could include an agreement to pay civil or criminal damages, including future payments triggered by the achievement of periodic financial metrics, with interest or otherwise, a lump sum payment upon a change in control of the company or the sale of significant assets, or a pre-agreed uncontested claim if the company files for bankruptcy or liquidation, penalties, fines, disgorgement, injunctions, cease and desist orders, corporate integrity agreements, deferred prosecution agreements, or other equitable remedies, exclusion form governmental health care programs, and the curtailment or restructuring of our operations, any of which would have a material adverse effect on our business, financial condition and result s of operations for years after any settlement is reached. In light of the active and ongoing nature of the investigations, whether actions will be commenced, whether these investigations can be settled before or after actions are commenced, and the terms on which these investigations can be resolved is not certain.

Corporate Information

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

You may find on our website at www.ramed.com electronic copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. Such filings are placed on our website as soon as reasonably possible after they are filed with the SEC.

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

The Offering

Units offered by us	20,725,190 units, each unit consisting of one share of common stock and one warrant to purchase one share of common stock, at a price of $0.45 per unit.
Pre-funded units offered by us	We are also offering to those purchasers, if any, whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock immediately following the consummation of this offering, the opportunity to purchase, if such purchasers so choose, 1,497,032 pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of common stock and one warrant to purchase one share of common stock), in lieu of units that would otherwise result in any such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock. The purchase price of each pre-funded warrant will equal the public offering price at which shares are being sold to the public in this offering, minus $0.0001.
Warrants offered by us	22,222,222 warrants to purchase an aggregate of 22,222,222 shares of common stock. Each unit and pre-funded unit includes one warrant to purchase one share of common stock. Each warrant will have an exercise price of $0.45 per share, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants.
Pre-funded warrants offered by us	1,497,032 pre-funded warrants to purchase an aggregate of 1,497,032 shares of common stock. Each pre-funded unit includes one pre-funded warrant to purchase one share of common stock. Each pre-funded warrant will have an exercise price of $0.0001 per share, will be immediately exercisable and may be exercisable at any time until all of the pre-funded warrants are exercised in full. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the pre-funded warrants.
Shares of common stock to be outstanding after this offering	36,117,571 shares of common stock (assuming the sale of all units and pre-funded units covered by this prospectus, the exercise in full of all pre-funded warrants included in the pre-funded units, and no exercise of any warrants included in the units or pre-funded units, and based on 13,895,349 shares outstanding as of March 31, 2020).

Use of proceeds	We intend to use the net proceeds from this offering forgeneral corporate purposes, including working capital, our atherectomy indication trial, engineering efforts, and supporting our commercial relaunch strategy. 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 be required to apply a portion of the net proceeds for litigation expenses and to settle 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 and Shareholder Litigation Update" and "—Government Investigations." Because this is a best efforts offering with no minimum amount as a condition to closing, we may not sell all or any of the securities offered hereby. As a result, we may receive significantly less in net proceeds than we currently estimate. See "Use of Proceeds" in this prospectus.
Dividend policy	We have never declared or paid any cash dividends on our shares of common stock. We do not anticipate paying any cash dividends in the foreseeable future.
Risk factors	You should carefully consider the risk factors described in the section of this prospectus entitled "Risk Factors," together with all of the other information included in this prospectus, before deciding to purchase our shares of common stock.
New York Stock Exchange symbol	Our shares of common stock are listed on the New York Stock Exchange under the symbol "RMED." We do not intend to list the warrants or the pre-funded warrants on any securities exchange or nationally recognized trading system.

Assumptions Used Throughout This Prospectus

Unless otherwise stated in this prospectus, the total number of shares of common stock outstanding as of the date of this prospectus and after this offering is based on 13,895,349 shares outstanding as of March 31, 2020, and excludes the following other securities as of March 31, 2020:

- 5,727,801 shares of common stock reserved for issuance under our equity incentive plans, of which there were (i) outstanding options to purchase 3,722,397 shares of common stock at a weighted average exercise price of $12.40 per share, (ii) 297,626 shares of common stock underlying unvested restricted share units, or RSUs, and (iii) 1,707,778 shares of common stock available for future grant;
- 22,222,222 shares of common stock issuable upon exercise of the warrants included in this offering, at an exercise price of $0.45 per share; and
- 1,555,555 shares of common stock issuable upon the exercise of the placement agent's warrants with an exercise price of $0.5625 to be issued to the placement agent or its designees in connection with this offering.

Except as otherwise noted, all information in this prospectus reflects and assumes (i) no exercise of outstanding options issued under our equity incentive plans and (ii) no exercise of the warrants included in the units or pre-funded units.

Summary Financial Data

The following tables summarize our financial data for the periods and as of the dates indicated. We derived the statements of operations data for the years ended December 31, 2018 and 2019 from our audited financial statements incorporated by reference into this prospectus. We derived the balance sheet data as of March 31, 2020 from our unaudited financial statements incorporated by reference into this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future, and the results of operations for the three months ended March 31, 2020 are not necessarily indicative of results for the full year. You should read the following summary financial data in conjunction with our financial statements and the related notes, which are incorporated by reference into this prospectus.

	Year Ended December 31,		Three Months Ended March 31,	
	2018	2019	2019	2020
	(in thousands)		(in thousands)	
Statements of Operations Data:				
Net revenue				
Product sales	$ 3,159	$ 3,859	$ 894	$ 586
Service and other	3,098	3,340	854	788
Total net revenue	6,257	7,199	1,748	1,374
Cost of revenue				
Product sales	2,652	5,856	1,395	964
Service and other	1,554	2,994	547	620
Total cost of revenue	4,206	8,850	1,942	1,584
Gross profit (loss)	2,051	(1,651)	(194)	(210)
Operating expenses:				
Selling, general and administrative	30,435	51,549	13,229	6,285
Research and development	2,776	4,530	1,531	1,295
Total operating expenses	33,211	56,079	14,760	7,580
Operating loss	(31,160)	(57,730)	(14,954)	(7,790)
Other income, net	338	788	280	89
Loss before income taxes	(30,822)	(56,942)	(14,674)	(7,701)
Income tax expense	10	15	—	—
Net loss	$ (30,832)	$ (56,957)	$ (14,674)	$ (7,701)

	As of March 31, 2020	
	Actual	As Adjusted(1)
	(in thousands)	
Balance Sheet Data		
Cash, cash equivalents and short-term investments	$ 23,440	$ 32,172
Working capital (2)	22,667	31,399
Total assets	36,300	45,032
Total liabilities	9,826	9,826
Accumulated deficit	(124,858)	(124,858)
Total stockholders' equity	26,474	35,206

(1) The as-adjusted balance sheet data gives effect to the sale by us of 20,725,190 units in this offering at a public offering price of $0.45 per unit and 1,497,032 pre-funded units in this offering at a public offering price of $0.4499 per unit, after deducting the estimated placement agent fees and estimated offering expenses.

(2) We define working capital as current assets less current liabilities.

RISK FACTORS

An investment in our securities involves a high degree of risk. Our business, financial condition or results of operations could be materially and adversely affected by any of these risks. If any of these risks occur, the value of our shares of common stock and our other securities may decline. Before making your investment decision, you should carefully consider the risk factors provided below and the risk factors set forth under the caption "Risk Factors" in any other filing we make with the SEC subsequent to the effective date of the registration statement in which this prospectus is contained.

Risks Related to Our Business and Products

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

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

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

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

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

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

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

The current COVID-19 pandemic and the DABRA catheter performance limitations may impact our ability to complete our atherectomy study in a timely manner. For example, enrollment in our atherectomy clinical trial may be delayed or slowed, as patients elect, or are asked, to postpone voluntary treatments and physicians' offices are either closed or only performing procedures on patients with more advanced disease state that do 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 rapid exchange version of our DABRA catheter designed to allow physicians to use a guidewire, may limit the number of cases in which th e DABRA catheter will be used during the 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 may face additional issues associated with the voluntary recall of our DABRA catheters if we are unable to show that we initiated a timely recall and improved calibration rates in the use of our DABRA catheters.

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

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

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

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

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

The research, development, marketing and sale of our current products and any potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. At the same time, companies in the medical device industry are under continued scrutiny by the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and the Department of Justice, or DOJ, for improper relationships with physicians. In October 2019, the DOJ served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. In November 2019, we learned that the DOJ opened a criminal investigation relating to us. We have been, and intend to continue, cooperating with these active and ongoing DOJ investigations. Our failure to comply with requirements governing the industry's relationships with physicians, including the reporting of certain payments to physicians under the National Physician Payment Transparency Program (Open Payments) or an investigation into our compliance by the OIG or the DOJ, could impact physicians' willingness to conduct business with us, which would have a material adverse effect on our business, financial condition, and results of operations.

We are experiencing inconsistencies in our DABRA catheter performance. This and any other development or manufacturing problems or delays 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, which we believe will significantly reduce the number of catheters that fail to calibrate. If our DABRA catheters are unable to consistently calibrate in the field, DABRA sales may continue to be adversely impacted and we will continue to incur additional costs.

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

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

Additionally, since our products are manufactured at our sole manufacturing facility in Carlsbad, 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 will require additional capital to finance our operations, which may not be available to us on acceptable terms or at all.

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development and commercialization efforts. As of March 31, 2020, we had cash and cash equivalents and short-term investments of $23.4 million and an accumulated deficit of $124.9 million. In the full year 2019 and the first quarter 2020, we used $33.2 million and $7.0 million for operating activities, respectively. We have experienced recurring net losses from operations, negative cash flows from operating activities, and a significant accumulated deficit and expect to continue to incur net losses into the foreseeable future. As a result, our financial statements include explanatory disclosures expressing substantial doubt about our ability to continue as a going concern.

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

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

- whether we are able to successfully and timely remedy the inconsistencies in our DABRA catheter performance, including extended shelf life and reduced non-calibrations;
- whether we are able to further enhance our DABRA catheter performance with a braided overjacket designed to reduce kinking and develop a rapid exchange version of our DABRA catheter designed to allow physicians to use more standard techniques, including a guidewire, to navigate the vasculature more easily;
- our ability to develop a larger diameter catheter to facilitate treatment of larger vessels more commonly seen in above-the-knee procedures;
- the timing of enrollment in our clinical trial for an atherectomy indication for use;
- our ability to achieve sufficient market acceptance, the ability for our customers to get coverage and adequate reimbursement from third-party payors and our ability to achieve acceptable market share for DABRA and Pharos;
- our ability to improve and extend the shelf life of our DABRA catheters and obtain FDA clearance for the extended shelf life;
- the cost to establish, maintain, expand, and defend the scope of our intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights;
- the emergence of competing technologies and other adverse market developments;
- the costs associated with manufacturing, selling, and marketing DABRA and Pharos for their cleared or approved indications or any other indications for which we receive regulatory clearance or approval, including the cost and timing of expanding our manufacturing capabilities, as well as establishing our sales and marketing capabilities;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the timing, receipt, and amount of license fees and sales of, or royalties on, our future products or future improvements on our existing products, if any; and
- the time and cost necessary to complete post-marketing studies that could be required by regulatory authorities or other studies required to obtain clearance for additional indications.

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

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

We incurred net losses of $57.0 million and $30.8 million for the years ended December 31, 2019 and 2018, respectively. As of March 31, 2020, we had an accumulated deficit of $124.9 million. We expect to continue to incur significant manufacturing, product development, regulatory and other expenses as we continue to remedy the inconsistencies in our DABRA catheter performance, to obtain regulatory clearances or approvals for our products in additional jurisdictions and for additional indications, to develop new products or add new features to our existing products, and to defend, cooperate and resolve pending lawsuits and government investigations, as applicable. In addition, our general and administrative expenses have increased following our initial public offering and we expect these costs to continue due to the additional costs associated with being a public company. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenue in order to achieve and sustain profitability and, even if we achieve profitability, we cannot be sure that we will remain profitable for an extended period of time. Our failure to achieve or maintain profitability would have a material adverse effect on our business, financial condition, and results of operations and could negatively impact the value of our common stock.

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

As previously disclosed in our public filings, the Audit Committee completed its internal investigation. In connection with the Audit Committee investigation, we voluntarily contacted the Enforcement Division of the SEC in August 2019 to advise them of the investigation of certain allegations made by a former employee. In October 2019, the DOJ served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. We believe 17 states are participating in the DOJ's False Claims Act investigation. We publicly announced the Audit Committee's findings on October 31, 2019. In November 2019, we learned that the DOJ opened a criminal investigation relating to us. On November 13, 2019, the SEC notified us that it is conducting an investigation. On March 11, 2020, the SEC served us with document subpoenas. We have been, and intend to continue, cooperating in these active and ongoing investigations.

If one or more government agencies, including those conducting the active and ongoing investigations identified above, commences legal action and we are found to have violated state or federal laws or regulations, we may be subject to civil or criminal damages, penalties, fines, disgorgement, injunctions, cease and desist orders, other equitable remedies, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which would have a material adverse effect on our business, fin ancial condition, and results of operations for years. Regardless of whether actions are commenced, if we were to settle with one or more government agencies or state governments, including those conducting the active and ongoing investigations identified above, such settlements could include an agreement to pay civil or criminal damages, including future payments triggered by the achievement of periodic financial metrics, with interest or otherwise, a lump sum payment upon a change in control of the company or the sale of significant

assets, or a pre-agreed uncontested claim if the company files for bankruptcy or liquidation, penalties, fines, disgorgement, injunctions, cease and desist orders, corporate integrity agreements, deferred prosecution agreements, or other equitable remedies, exclusion form governmental health care programs, and the curtailment or restructuring of our operations, any of which would have a material adverse effect on our business, financial condition and results of operations for years after any settlement is reached. In light of the active and ongoing nature of the investigations, whether actions will be commenced, whether these investigations can be settled before or after actions are commenced, and the terms on which these investigations can be resolved is not certain.

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

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

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

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

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

If a disaster such as a pandemic, epidemic, outbreak of an infectious disease or other public health crisis were to occur in an area in which we operate, our operations could be adversely affected. For example, COVID-19 has now been characterized as a global pandemic and how long and how extensive the economic effects will last, has not been determined. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain it or treat its impact, among others. A further spread of the pandemic could cause include the temporary closure of our manufacturing facilities and those used in our supply chain processes, restrictions on the export or shipment of our products, business closures in impacted areas, and further restrictions on our employees' and consultants' ability to travel and to meet with customers. The pandemic could also cause delays in enrollment in our atherectomy indication trial as well as delays in the completion of our critical engineering efforts, as well as 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 11, "Commitments and Contingencies," in the notes to the condensed financial statements for the three months ended March 31, 2020, incorporated by reference into this prospectus.

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

As a result of the delayed filing of some of our periodic reports with the SEC, we are not currently eligible to register the offer and sale of our securities using a registration statement on Form S-3. To regain eligibility to use Form S-3, we must be timely and current in our public reporting for a period of 12 months preceding our intended S-3 filing. Should we wish to register the offer and sale of our securities to the public prior to the time we are eligible to use Form S-3, both our transaction costs and the amount of time required to complete the transaction could increase, making it more difficult to execute any such transaction successfully and potentially harming our financial condition.

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

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

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

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

- decreased demand for our products;
- harm to our reputation;
- initiation of investigations by regulators;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We market and sell DABRA for use as a tool in the treatment of vascular blockages resulting from lower extremity vascular disease and Pharos for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma. Although physicians, in the practice of medicine, may prescribe or use marketed products for uncleared or unapproved indications, manufacturers may promote their products only for the cleared or approved indications and in accordance with the provisions of the cleared or approved label. However, one of our strategies in the future is to pursue additional vascular indications for DABRA and additional dermatological indications for Pharos. Submitting the required applications for additional indications may require substantial additional funding beyond our cash and cash equivalents and short-term investments as of March 31, 2020. We cannot assure you that we will be able to successfully obtain clearance or approval for any of these additional product indications through the application process or that a premarket FDA submission may not be necessary.

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

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

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

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

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

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

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

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

Our promotional materials and training methods must comply with FDA regulations and other applicable laws, including restraints and prohibitions on the promotion of off-label, or uncleared use, of our products. Physicians may use our products for off-label use without regard to these prohibitions, as FDA regulations do not restrict or regulate a physician's choice of treatment within the practice of medicine. Although our policy is to follow published FDA guidance in order to avoid promoting our products improperly, the FDA or other regulatory agencies or third parties could disagree and conclude that we have engaged in off-label promotion. For example, our DABRA Laser System has been cleared by the FDA for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease and has an intended use for ablating a channel in occlusive peripheral vascular disease. We have not received FDA clearance or approval to market DABRA for an atherectomy indication, and we may not promote DABRA for an atherectomy indication. As previously disclosed, the DOJ served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning, among other things, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs. Our pivotal clinical study of the DABRA Laser System would not be sufficient to expand our FDA-cleared indication for use to an atherectomy indication for use, which the FDA currently defines to include a prespecified improvement in luminal patency, or prespecified increase in the openness of the artery at a pre-defined time point, such as six months following a DABRA procedure, using a consistent assessment tool.

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

The False Claims Act, prohibits, among other things, making a fraudulent claim for payment of federal funds, causing such a fraudulent claim to be made, or making a false statement to get a false claim paid. The government may assert that a claim resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim under the False Claims Act. Many companies have faced government investigations or lawsuits by whistleblowers who bring a *qui tam* action under the False Claims Act on behalf of themselves and the government for a variety of alleged improper marketing activities, including providing free product to customers expecting that the customers would bill federal programs for the product, providing consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company's products, and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs. In addition, the government and private whistleblowers have pursued False Claims Act cases against medical device companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses. Medical device and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs. If we are found to have improperly promoted off-label uses, we may be subject to significant liability, including civil fines, criminal fines and penalties, civil damages, exclusion from federal funded healthcare programs and potential liability under the federal False Claims Act and any applicable state

false claims act. Due to the Civil Investigative Demand seeking information with respect to the False Claims Act, we could incur substantial legal costs, including settlement costs, and business disruption responding to such investigation or suit, regardless of the outcome. If we are found to have violated the False Claims Act, it may result in significant financial penalties, on a per claim or statement basis, treble damages and exclusion from participation in federal health care programs.In addition, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials, which could negatively impact our marketing and decrease demand for our products. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers, competitors, or other persons claiming to be harmed by such conduct.

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 or state governments, including those conducting the active and ongoing investigations identified above, such settlements could include an agreement to pay civil or criminal damages, including future payments triggered by the achievement of periodic financial metrics, with interest or otherwise, a lump sum payment upon a change in control of the company or the sale of significant assets, or a pre-agreed uncontested claim if the company files for bankruptcy or liquidation, penalties, fines, disgorgement, injunctions, cease and desist orders, corporate integrity agreements, deferred prosecution agreements, or other equitable remedies, exclusion form governmental health care programs, and the curtailment or restructuring of our operations, any of which would have a material adverse effect on our business, financial condition and results of operations for years after any settlement is reached. In light of the active and ongoing nature of the investigations, whether actions will be commenced, whether these investigations can be settled before or after actions are commenced, and the terms on which these investigations can be resolved is not certain.

Litigation and other legal proceedings may adversely affect our business.

From time to time we are involved in and may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action, and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. For example, we are currently a party to securities litigation and other litigation as set forth in the sections of our Quarterly Report on Form 10-Q for the three months ended March 31, 2020 and our Annual Report on Form 10-K for the year ended December 31, 2019 captioned Part II, Item 1 “Legal Proceedings.”

Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition, and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers’ confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

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

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

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

In October 2019, the DOJ served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. We believe 17 states are participating in the DOJ's False Claims Act investigation. In November 2019, we learned that the DOJ opened a criminal investigation relating to us. We have been, and intend to continue, cooperating with the DOJ in its active and ongoing investigations described above.

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

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

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

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

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

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

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

- differing regulatory requirements in foreign countries;
- differing reimbursement regimes in foreign countries, including price controls and lower payment;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- product shortages resulting from any events affecting raw material or finished good supply or distribution or manufacturing capabilities abroad;

- the impact of the current situation relating to trade with China and tariffs and other trade barriers that may be implemented by governmental authorities;
- the impact of public health epidemics on the global economy, such as the new coronavirus currently impacting the United States, Europe, China and elsewhere; and
- business interruptions resulting from geo-political actions, including war and terrorism.

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

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

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

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

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

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

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

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

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

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

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

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

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

We were required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report filed on Form 10-K for the year ended December 31, 2019. As an "emerging growth company," we will avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an "emerging growth company" unless at that time we are still a "smaller reporting company." When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us

in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the U.S. Securities and Exchange Commission, or SEC, or other regulatory authorities, which would require additional financial and management resources.

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

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

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

At March 31, 2020, we had 86 full-time employees. In the third quarter of 2019, we began implementing certain operational efficiency and cost savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives include targeted workforce reductions of our sales and marketing teams. We reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to five clinical specialists as of December 31, 2019.

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

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

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

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

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

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

Risks Related to Regulatory Approval and our Industry

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

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

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

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

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

Medical devices regulated by the FDA are subject to "general controls" which include:

- registration with the FDA; listing commercially distributed products with the FDA;
- complying with cGMPs under the Quality System Regulations, or QSR;
- filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation;
- assuring that device labeling complies with device labeling requirements;
- reporting recalls and certain device field removals and corrections to the FDA;
- and obtaining premarket notification 510(k) clearance for devices prior to marketing.

As previously disclosed, the Audit Committee found, among other things, that we, out of a concern for the DABRA catheters' performance, engaged in efforts to replace product held by customers, which constituted product recalls, but were not documented as such. In October 2019, the DOJ served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning, among other things, whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA. In November 2019, we learned that the DOJ opened a criminal investigation relating to us.

Some devices known as "510(k)-exempt" devices can be marketed without prior marketing clearance or approval from the FDA. In addition to the "general controls," some Class II medical devices are also subject to "special controls," including adherence to a particular guidance document and compliance with the performance standard. As Class II, 510(k)-cleared devices, our products are subject to both general and special controls. Instead of obtaining 510(k) clearance, most Class III devices are subject to premarket approval, or PMA. We do not believe any of our current products are Class III devices, but future products could be, which would subject them to the PMA process.

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

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

The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices, and product quality management. For example, as discussed above, the DOJ is currently conducting civil and criminal investigations regarding us, including a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. We believe 17 states are participating in the DOJ's False Claims Act investigation. Such reviews and investigations may result in the civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of our products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies, and result in our incurring substantial unanticipated costs and the diversion of key personnel and management's attention from their regular duties, any of which may have an adverse effect on our financial condition, results of operations and liquidity, and may result in greater and continuing governmental scrutiny of our business in the future.

Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, the U.S. Physician Payment Sunshine Act, now known as Open Payments, requires us to report to the Centers for Medicare & Medicaid Services, or CMS, payments and other transfers of value to all U.S. physicians and U.S. teaching hospitals, with the reported information made publicly available on a searchable website. 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 the DOJ served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning, among other things, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute. Effective January 2022, we will also be required to collect and report information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which may also impact our business and which could have a material adverse effect on our business, financial condition, and results of operations for years after any resolution of these investigations and any resulting claims are resolved.

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

Under FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received 510(k) clearance, is authorized through the de novo classification process, or is the subject of an approved PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to another legally marketed product not subject to a PMA. Sometimes, a 510(k) clearance must be supported by preclinical and clinical data. Our ability to enroll patients in clinical trials, including our atherectomy indication trial, could be impacted by the COVID-19 outbreak, as many patients are electing or being asked to delay procedures at this time.

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

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

The FDA may not approve our current or future PMA applications or supplements or clear our 510(k) applications on a timely basis or at all. For example, the COVID-19 outbreak could affect the FDA's ability to review applications or supplements. Such delays or refusals could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

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

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

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

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

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

In addition, violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. As disclosed previously, the DOJ served us with a CID seeking information with respect to a False Claims Act investigation concerning, among other things, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs.

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

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

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

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

calibrate. We submitted a request for termination to the FDA in February 2020, and as of March 31, 2020, 97% of the affected product has been returned to us. Finally, a voluntary recall of DABRA lasers was initiated in January 2020 to correct a software issue that could result in user or patient injury or may adversely impact laser performance. This field correction is ongoing and is expected to complete in August 2020. 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. We are working diligently to address the issues identified in the Form 483.

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

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

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

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

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

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

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

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

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

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

As previously disclosed, the DOJ is conducting civil and criminal investigations regarding us, including a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. We believe 17 states are participating in the DOJ's False Claims Act investigation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have adopted a code of ethics and business conduct, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. For example, the Audit Committee investigation identified certain behavior inconsistent with the Company's Code of Ethics and Conduct and related policies. 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. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

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

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

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

Our Audit Committee identified certain conduct that may implicate healthcare laws and FDA regulatory requirements, 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 previously disclosed, the DOJ is conducting civil and criminal investigation regarding us, including a CID seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b.We believe 17 states are participating in the DOJ's False Claims Act investigation, as discussed above. The SEC is also conducting its own investigation.

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

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

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

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

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

Risks Related to our Intellectual Property

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

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

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

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

or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Determining whether a product infringes a patent involves complex legal and factual issues, and the outcome of a patent litigation action is often uncertain. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. Because of the number of patents issued and patent applications filed in our technical areas, our competitors or other parties may assert that our products and the methods we employ in the use of our products are covered by U.S. or foreign patents held by them. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. There could also be existing patents that one or more of our products or parts may infringe

and of which we are unaware. As the number of competitors in the market for medical lasers and as the number of patents issued in this area grows, the possibility of patent infringement claims against us increases. In certain situations, we may determine that it is in our best interests or their best interests to voluntarily challenge a party's products or patents in litigation or other proceedings, including patent interferences or re-examinations. As a result, we may become involved in unwanted litigation that could be costly, result in diversion of management's attention, require us to pay damages and force us to discontinue selling our products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of the patents that we may own or that incorporate certain technology in our products that is in the public domain;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own now or in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to Our Reliance on Third Parties

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

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

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

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

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

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

Our common stock is listed on the New York Stock Exchange, or NYSE. We received a deficiency notice from the NYSE on December 4, 2019 that we are not in compliance with a NYSE continued listing requirement for maintaining an average market capitalization over a consecutive 30 trading-day period of not less than $50 million at the same time shareholders' equity is less than $50 million. We submitted a compliance plan on January 20, 2020, and the NYSE accepted our plan on February 28, 2020. We have 18 months to cure this deficiency. In addition, if our average market capitalization over a consecutive 30 trading-day period is less than $15 million, we will be delisted from the NYSE immediately; however, on March 19, 2020, the NYSE temporarily suspended, until June 30, 2020, the application of the average market capitalization listing requirement due to ongoing market volatility relating to the ongoing COVID-19 pandemic. As of May 19, 2020, our market capitalization was $9.2 million. There can be no assurance that we will be able to successfully implement the necessary actions to maintain or regain compliance with NYSE listing requirements or that any appeal of a decision to delist our common stock would be successful.

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

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

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

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

- any delay in any regulatory filings for our future products and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such products;
- adverse regulatory decisions, including failure to receive regulatory approval of our future products, failure to maintain regulatory approval for our existing products or failure to obtain regulatory approval for additional indications for our existing products;
- changes in laws or regulations applicable to our products;
- adverse developments concerning our suppliers or distributors;
- our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices;
- our inability to establish and maintain collaborations if needed;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of large blocks of our common stock including sales by our executive officers and directors;
- trading volume of our common stock;
- limited "public float" in the hands of a small number of persons whose sales or lack of sales of our common stock could result in positive or negative pricing pressure on the market price for our common stock;
- additions or departures of key scientific or management personnel;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

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

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

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

- increased expenses from remedying the performance of our catheters;
- the timing and cost of, and level of investment in, research and development activities relating to our current and any future products, which will change from time to time;
- the cost of manufacturing our current and any future products, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with suppliers;

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

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

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

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

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

As of December 31, 2019, we had net operating loss carryforwards, or NOLs, of approximately $63.7 million for federal income tax purposes, and $66.0 million for state income tax purposes. These federal and state NOLs begin expiring in 2029. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. These NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity

ownership by 5% stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. We have determined that we have not experienced Section 382 ownership changes in the past and therefore our NOLs are not subject to an annual limitation under Section 382. In addition, as a result of the Tax Cuts and Jobs Act of 2017, as modified by the recently enacted Coronavirus Aid, Relief, and Economic Security Act of 2020, or CARES Act, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely anddeductibility of federal NOLs generally may be limited in future years.

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

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

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

As of March 31, 2020, our executive officers, directors, and 10% stockholders owned approximately 38% of the outstanding shares of our common stock. In addition, as of March 31, 2020, our officers, directors, 10% stockholders, and their affiliates held (i) options to purchase an aggregate of 1,950,486 shares of our common stock at a weighted average exercise prices of $13.82 per share; (ii) 560,186 restricted stock units; and (iii) 125,000 restricted stock awards which would give our officers, directors, and 10% stockholders ownership of approximately 42% of our outstanding common stock if such awards are fully vested and are exercised in full. Therefore, these stockh olders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, certain financing transactions or other major corporate transactions, and may attempt to exercise such control rights going forward. Certain stockholders affiliated with our former chief executive officer, who have represented to us that, as of December 17, 2019, they collectively held more than 50% of our common stock, have attempted to exercise such control rights in the past, and these stockholders or other of our stockholders may attempt to do so again in the future. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders, which could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

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

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

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

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

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of March 31, 2020, we had outstanding 13,895,349 shares of our common stock.

In addition, pursuant to our 2018 Equity Incentive Plan, or 2018 Plan, equity incentive awards representing up to an aggregate of 1,482,778 shares of our common stock were available for issuance to our employees, directors and consultants as of March 31, 2020. The 2018 Plan includes an annual increase in the number of shares available for future grant each year pursuant to the "evergreen" provision of our 2018 Plan. Additionally, pursuant to our 2018 Employee Stock Purchase Plan, or ESPP a total of 618,289 shares were available for sale under our ESPP as of March 31, 2020. The ESPP also includes an annual increase in the number of shares available for sale under our ESPP each year pursuant to the "evergreen" provision of our ESPP. In addition to the increase in shares available to grant in 2020 due to the "evergreen" provisions contained in the 2018 Plan and the ESPP, in the first quarter of 2020 we adopted the 2020 Inducement Equity Incentive Plan (the "2020 Plan") for the purpose of attracting, retaining and incentivizing employees in furtherance of our success. On adoption, 800,000 shares of common stock were reserved solely for the granting of inducement stock options, restricted stock, restricted stock units and other awards and 225,000 shares were available for issuance as of March 31, 2020. If these additional shares of common stock are issued and sold, or if it is perceived that they will be sold, in the public market, this could result in additional dilution and the trading price of our common stock could decline.

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

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

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

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

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

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

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

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

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

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising under the Delaware General Corporation Law, our certificate of incorporation or our bylaws; any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our certificate of incorporation further provides that the federal district courts of the United States are 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.

Additional Risks Related to This Offering

Our management will have broad discretion as to the use of the proceeds from this offering, and may not use the proceeds effectively.

Our management will have broad discretion as to the application of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of the offering. Currently, we intend to use the net proceeds from this offering for general corporate purposes, including working capital, our atherectomy indication trial, engineering efforts, and supporting our commercial relaunch strategy. 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. purposes. See "Use of Proceeds." 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. You will not have the opportunity, as part of your investment decision, to assess whether these proceeds are being used appropriately. Our management may use the net proceeds for corporate purposes that may not improve our financial condition or market value, which could cause the price of our shares of common stock to decline.

There is no public market for the warrants or pre-funded warrants being offered in this offering.

There is no established public trading market for the warrants or the pre-funded warrants being offered in this offering, and we do not expect such a market to develop. In addition, we do not intend to apply to list the warrants or the pre-funded warrants on any securities exchange or nationally recognized trading system, including the New York Stock Exchange. Without an active market, the liquidity of the warrants and the pre-funded warrants will be limited.

Holders of warrants or pre-funded warrants purchased in this offering will have no rights as stockholders of shares of common stock until such holders exercise their warrants or pre-funded warrants and acquire our shares of common stock, except as set forth in the warrants or pre-funded warrants.

Except as set forth in the warrants and the pre-funded warrants, until holders of warrants or pre-funded warrants acquire our shares of common stock upon exercise of the warrants or the pre-funded warrants, holders of warrants or pre-funded warrants have no rights with respect to our shares of common stock underlying such warrants or pre-funded warrants exercise of the warrants or the pre-funded warrants, the holders will be entitled to exercise the rights of a stockholder of shares of common stock only as to matters for which the record date occurs after the exercise date.

The warrants and pre-funded warrants are speculative in nature.

The warrants and pre-funded warrants offered hereby do not confer any rights of share of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price. Specifically, commencing on the date of issuance, holders of the warrants may acquire the shares of common stock issuable upon exercise of such warrants at an exercise price of $0.45 per share of common stock, and holders of the pre-funded warrants may acquire the shares of common stock issuable upon exercise of such warrants at an exercise price of $0.0001 per share of common stock. Moreover, following this offering, the market value of the warrants and pre-funded warrants is uncertain and there can be no assurance that the market value of the warrants or pre-funded warrants will equal or exceed their respective public offering prices. There can be no assurance that the market price of the shares of common stock will ever equal or exceed the exercise price of the warrants or pre-funded warrants, and consequently, whether it will ever be profitable for holders of warrants to exercise the warrants or for holders of the pre-funded warrants to exercise the pre-funded warrants.

This is a best efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans.

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the units and pre-funded units in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities or amount of proceeds that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to fund for our general corporate purposes, including working capital, our atherectomy indication trial, engineering efforts, and supporting our commercial relaunch strategy. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds, which may not be available or available on terms acceptable to us.

SPEC IAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the information incorporated by reference 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 financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2019 and our Quarterly Report on Form 10-Q for the three months ended March 31, 2020. The statements contained or incorporated by reference in this prospectus 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 prospectus and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled "Risk Factors" and elsewhere in this prospectus, including the information incorporated by reference. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We qualify all of the forward-looking statements in this prospectus 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.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

This prospectus and the information incorporated by reference 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.

USE OF PROCEEDS

We estimate the net proceeds from this offering will be approximately $8.7 million, after deducting placement agent fees and estimated offering expenses payable by us as described in "Plan of Distribution" and excluding the proceeds, if any, from the exercise of the warrants or pre-funded warrants sold in this offering. However, this is a best efforts offering with no minimum number of securities or amount of proceeds as a condition to closing, and we may not sell all or any of these units or pre-funded units offered pursuant to this prospectus; as a result, we may receive significantly less in net proceeds.

We intend to use the net proceeds from this offering forgeneral corporate purposes, including working capital, our atherectomy indication trial, engineering efforts, and supporting our commercial relaunch strategy. 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 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," "Prospectus Summary—Securities and Shareholder Litigation Update" and "Prospectus Summary—Government Investigations."

Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from the sale of these securities.

DIVIDEND POLICY

No dividends have been declared or paid on our shares of common stock. We do not anticipate paying any cash dividends on any of our shares of common stock in the foreseeable future. We currently intend to retain any earnings to finance the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will be dependent upon then-existing conditions, including our earnings, capital requirements, results of operations, financial condition, business prospects and other factors that our board of directors considers relevant. See the section of our Quarterly Report on Form 10-Q for the three months ended March 31, 2020 captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations" for additional information regarding our financial condition.

CAPITALIZATION

The following table summarizes our cash and cash equivalents and capitalization as of March 31, 2020:

- on an actual basis;
- on an as-adjusted basis to give effect to the sale by us of 20,725,190 units in this offering at a public offering price of $0.45 per unit and 1,497,032 pre-funded units in this offering at a public offering price of $0.4499 per unit, after deducting the estimated placement agent fees and estimated offering expenses, and assuming the exercise in full of all pre-funded warrants included in the pre-funded units.

	As of March 31, 2020	
	Actual	As Adjusted
	(in thousands, except share data)	
Cash and cash equivalents and short-term investments	$ 23,440	$ 32,172
Equipment financing (including current portion)	$ 482	$ 482
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized; none issued	$ —	$ —
Common stock, $0.0001 par value, 300,000,000 shares; 13,895,349 issued and outstanding, actual; 36,117,571 shares issued and outstanding, as adjusted	1	3
Additional paid-in capital	151,327	160,057
Accumulated deficit	(124,858)	(124,858)
Accumulated other comprehensive income	4	4
Total stockholders' equity	26,474	35,206
Total capitalization	$ 26,956	$ 35,688

The number of shares of common stock to be outstanding after this offering is based on the 13,895,349 shares outstanding as of March 31, 2020, and excludes the following other securities as of March 31, 2020:

- 5,727,801 shares of common stock reserved for issuance under our equity incentive plans, of which there were (i) outstanding options to purchase 3,722,397 shares of common stock at a weighted average exercise price of $12.40 per share, (ii) 297,626 shares of common stock underlying unvested restricted share units, or RSUs, and (iii) 1,707,778 shares of common stock available for future grant;
- 22,222,222 shares of common stock issuable upon exercise of the warrants included in this offering, at an exercise price of $0.45 per share; and
- 1,555,555 shares of common stock issuable upon the exercise of the placement agent's warrants with an exercise price of $0.5625 to be issued to the placement agent in connection with this offering.

Except as otherwise noted, all information in this prospectus reflects and assumes (i) no exercise of outstanding options issued under our equity incentive plans and (ii) no exercise of the warrants included in the units or pre-funded units.

DESCRIPTION OF SECURITIES WE ARE OFFERING

The following description summarizes certain terms of our capital stock, certain provisions of our certificate of incorporation and bylaws and certain terms of the warrants and the pre-funded warrants included in this offering. This summary does not purport to be complete and is qualified in its entirety by the provisions of our certificate of incorporation and bylaws and the provisions of the warrants and the pre-funded warrants, copies of which are filed with the SEC as exhibits to the Registration Statement on Form S-1 of which this prospectus forms a part, and to the applicable provisions of Delaware law.

We are offering (i) 20,725,190 units, each unit consisting of one share of common stock and one warrant to purchase one share of common stock, and (ii) 1,497,032 pre-funded units, each pre-funded unit consisting of one share of common stock and one pre-funded warrant to purchase one share of common stock.

Each share of common stock and accompanying warrant included in each unit will be immediately separable upon issuance and will be issued separately, and each pre-funded warrant to purchase one share of common stock and the accompanying warrant included in each pre-funded unit will be immediately separable upon issuance and will be issued separately. The units and pre-funded units will not be issued or certificated. We are also registering the shares of common stock included in the units and the shares of common stock issuable from time to time upon exercise of the pre-funded warrants included in pre-funded units and warrants included in the units and the pre-funded units offered hereby.

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 May 12, 2020, there were 13,895,349 shares of common stock issued and outstanding and there were 76 holders of record of our common stock. As of May 12, 2020, there were no outstanding shares of preferred 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 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 certificate of incorporation and our 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 take over bids, coercive or otherwise , and may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. 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. These provisions could 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.

Issuance of Undesignated Preferred Stock. As discussed above under "—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 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 bylaws or remove directors without holding a meeting of stockholders called in accordance with the bylaws. In addition, our 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 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 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. 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 certificate of incorporation and bylaws contain provisions that establish specific procedures for appointing and removing members of our board of directors. Under our certificate of incorporation and 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 certificate of incorporation and 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 certificate of incorporation provides otherwise. Our certificate of incorporation and 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 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.

Choice of Forum. Our 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 certificate or our bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and (v) any action asserting a claim against us that is governed by the internal-affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. Our certificate of incorporation further provides that the federal district courts of the United States will be 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.

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.

Transfer Agent and Registrar

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

Market Listing

Our common stock is listed on the New York Stock Exchange under the symbol "RMED."

Warrants

The following description of the warrants we are offering is a summary and is qualified in its entirety by reference to the provisions of the warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Duration and Exercise Price. Each warrant offered hereby will have an initial exercise price per share equal to $0.45. The warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our shares of common stock and the exercise price.

Exercisability. The warrants will be exercisable, at the option of the holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of common stock purchased upon such exercise (except in the case of a cashless exercise, as discussed below). A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding shares of common stock immediately after exercise. However, upon notice from the holder to us, the holder may decrease or increase the holder's beneficial ownership limitation, which may not exceed 9.99% of the number of outstanding shares of common stock immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants, provided that any increase in the beneficial ownership limitation will not take effect until 61 days following notice to us. Purchasers in this offering may also elect, prior to the issuance of the warrants, to have the initial exercise limitation set at 9.99% of our outstanding shares of common stock. No fractional shares will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round down to the next whole share.

Cashless Exercise. If, at the time a holder exercises its warrants, a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not then effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the common warrants.

Transferability. Subject to applicable laws, a warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

Exchange Listing. There is no trading market available for the warrants on any securities exchange or nationally recognized trading system. We do not intend to list the warrants on any securities exchange or nationally recognized trading system.

Right as a Stockholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of our shares of common stock, the holders of the warrants do not have the rights or privileges of holders of our shares of common stock, including any voting rights, until they exercise their warrants.

Fundamental Transaction. In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our shares of common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding shares of common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding shares of common stock, the holders of the warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction.

Pre-Funded Warrants

The following description of our pre-funded warrants we are offering is a summary and is qualified in its entirety by reference to the provisions of the pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Duration and Exercise Price. Each pre-funded warrant offered hereby will have an initial exercise price per share equal to $0.0001. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our shares of common stock and the exercise price. The pre-funded warrants will be issued in certificate form.

Exercisability. The pre-funded warrants will be exercisable, at the option of the holder, in whole or in part, by delivering to us a duly-executed exercise notice accompanied by payment in full for the number of shares of common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Purchasers of the pre-funded warrants in this offering may elect to deliver their exercise notice following the pricing of the offering and prior to the issuance of the pre-funded warrants at closing to have their pre-funded warrants exercised immediately upon issuance and receive shares of common stock underlying the pre-funded warrants upon closing of this offering. A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding shares of common stock immediately after exercise. However, upon notice from the holder to us, the holder may decrease or increase the beneficial ownership limitation, which may not exceed 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants, provided that any increase in the beneficial ownership limitation will not take effect until 61 days following notice to us. No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round down to the next whole share.

Cashless Exercise. At any time, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of the shares of common stock determined according to a formula set forth in the pre-funded warrants.

Transferability. Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Exchange Listing. There is no trading market available for the pre-funded warrants on any securities exchange or nationally recognized trading system. We do not intend to list the pre-funded warrants on any securities exchange or nationally recognized trading system.

Right as a Shareholder. Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of our shares of common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our shares of common stock, including any voting rights, until they exercise their pre-funded warrants.

Fundamental Transaction. In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our shares of common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding shares of common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding shares of common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a general discussion of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) with respect to their purchase, ownership and disposition of our common stock, warrants and pre-funded warrants purchased in this offering. This discussion is for general information only, is not tax advice and does not purport to be a complete analysis of all the potential tax considerations. This discussion is based upon the provisions of the United States Internal Revenue Code of 1986, as amended, or the Code, existing and proposed Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all in effect as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. We have not sought any ruling from the Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions.

This discussion does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction or under U.S. federal gift and estate tax laws. In addition, this discussion does not address any tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies, regulated investment companies, real estate investment trusts or other financial institutions;
- persons subject to the alternative minimum tax or the Medicare contribution tax on net investment income;
- tax-exempt organizations or governmental organizations;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);
- certain former citizens or long-term residents of the United States;
- partnerships or other entities or arrangements classified as partnerships for U.S. federal income tax purposes or other pass-through entities (and investors therein);
- persons whose functional currency is not the U.S. dollar;
- persons who hold our common stock, warrants or pre-funded warrants as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction or integrated investment;
- persons who hold or receive our common stock, warrants or pre-funded warrants pursuant to the exercise of any warrant or option or otherwise as compensation;
- persons who hold or receive our common stock, warrants or pre-funded warrants pursuant to conversion rights under convertible instruments;
- persons who do not hold our common stock, warrants or pre-funded warrants as a capital asset within the meaning of Section 1221 of the Code; or
- persons deemed to sell our common stock, warrants or pre-funded warrants under the constructive sale provisions of the Code.

In addition, if a partnership, entity or arrangement classified as a partnership for U.S. federal income tax purposes holds our common stock, warrants or pre-funded warrants, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, entities classified as partnerships for U.S. federal income tax purposes and other pass-through entities that hold our common stock, warrants or pre-funded warrants, as well as partners or members in such entities, should consult their tax advisors.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock, warrants or pre-funded warrants arising under the U.S. federal estate or gift tax laws or under the laws of any state, local, non-U.S. or other taxing jurisdiction or under any applicable tax treaty. In addition, significant changes in U.S. federal income tax laws were recently enacted. You should consult with your tax advisor with respect to such changes in U.S. tax law as well as potentially conforming changes in state tax laws.

Non-U.S. Holder Defined

For purposes of this discussion, you are a non-U.S. holder if you are any holder of our common stock, warrants or pre-funded warrants other than a partnership (or other entity or arrangement classified as a partnership for U.S. federal income tax purposes) or:

- an individual who is a citizen or resident of the United States (for U.S. federal income tax purposes);
- a corporation or other entity taxable as a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust if it (i) is subject to the primary supervision of a U.S. court and one or more U.S. persons have the authority to control all substantial decisions of the trust or (ii) has made a valid election under applicable Treasury Regulations to be treated as a U.S. person.

General Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, a pre-funded warrant should be treated as a share of our common stock for U.S. federal income tax purposes and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of common stock as described below. You should consult your own tax advisor regarding the risks associated with the acquisition of a pre-funded warrant pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes.

Allocation of Purchase Price and Characterization of Units and Pre-Funded Units

For U.S. federal income tax purposes, each unit and pre-funded unit should be treated as an "investment unit" consisting of one share of our common stock or one pre-funded warrant, as applicable, and a warrant to acquire one share of our common stock, subject to adjustment. The purchase price for each investment unit will be allocated between these two components in proportion to their relative fair market values at the time the investment unit is purchased by each holder. This allocation of the purchase price for each investment unit will establish your initial tax basis for U.S. federal income tax purposes in the share of common stock or pre-funded warrant, as applicable, and the warrant included in each investment unit. The separation of the share of common stock or pre-funded warrant, as applicable, and the warrant included in each investment unit should not be a taxable event for U.S. federal income tax purposes. You should consult your own tax advisor regarding the allocation of the purchase price for an investment unit.

Distributions

As described in the section captioned "*Dividend policy*," we have never declared or paid cash dividends on our capital stock and do not anticipate paying any dividends on our capital stock in the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under "*—Gain on Disposition of Common Stock, Warrants or Pre-Funded Warrants*."

Subject to the discussion below on effectively connected income, backup withholding and foreign accounts, any dividend paid to you generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, you must provide us with an IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate.

Dividends received by you that are effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a permanent establishment maintained by you in the United States) are generally exempt from the withholding tax described in the previous paragraph, subject to the discussion below on backup withholding. In order to obtain this exemption, you must provide us with an IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits, subject to an applicable income tax treaty providing otherwise. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. You should consult your tax advisor regarding any applicable tax treaties that may provide for different rules.

If you hold our common stock through a financial institution or other agent acting on your behalf, you will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries. You may be eligible to obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Gain on Disposition of Common Stock, Warrants or Pre-Funded Warrants

Subject to the discussion below on backup withholding on common stock, warrants or pre-funded warrants held by or through foreign entities, you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock, warrants or pre-funded warrants unless:

- the gain is effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment maintained by you in the United States);
- you are a non-resident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or
- we are treated as a "United States real property holding corporation," or USRPHC, for U.S. federal income tax purposes within the meaning of Section 897(c)(2) of the Code at any time within the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock, warrants or pre-funded warrants.

We believe that we are not currently and will not become a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, your common stock will be treated as U.S. real property interests only if you actually or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock. Special rules may apply to the determination of the five percent threshold in the case of a holder of a warrant or pre-funded warrant. Non-U.S. holders are urged to consult their own tax advisors regarding the effect of holding our warrants or pre-funded warrants on the calculation of such five percent threshold.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be subject to tax at 30% (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S. source capital losses for the year (provided you have timely filed U.S. federal income tax returns with respect to such losses). You should consult any applicable income tax or other treaties that may provide for different rules.

Warrants and Pre-Funded Warrants

Exercise of Warrants or Pre-Funded Warrants. In general, a non-U.S. holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of a warrant or pre-funded warrant, except to the extent the non-U.S. holder receives a cash payment for any such fractional share that would otherwise have been issuable upon exercise of the warrant or pre-funded warrant, which will be treated as a sale subject to the rules described above for "*—Gain on Disposition of Common Stock, Warrants or Pre-Funded Warrants*." A non-U.S. holder's initial tax basis in the share of common stock received upon exercise of a warrant or a pre-funded warrant, as applicable, should be equal to the sum of (i) the non-U.S. holder's tax basis in the warrant or pre-funded warrant (that is, an amount equal to the portion of the purchase price of a unit or a pre-funded unit, as applicable, allocable to the warrant or pre-funded warrant, as applicable, as described above) plus (ii) the exercise price paid by the non-U.S. holder on the exercise of the warrant or pre-funded warrant. A non-U.S. holder's holding period for shares of common stock received on exercise of a warrant will commence on the date following the date of exercise of the warrant and will not include the period during which the non-U.S. holder held the warrant. A non-U.S. holder's holding period for shares of common stock received on exercise of a pre-funded warrant should include the period during which the non-U.S. holder held the pre-funded warrant.

In certain limited circumstances, a non-U.S. holder may be permitted to undertake a cashless exercise of warrants or pre-funded warrants into our common stock. The U.S. federal income tax treatment of a cashless exercise of warrants or pre-funded warrants into our common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a warrant or pre-funded warrant described in the preceding paragraph. Non-U.S. holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of warrants or pre-funded warrants.

Expiration of Warrants or Pre-Funded Warrants. Expiration of warrants or pre-funded warrants will be treated as if the non-U.S. holder sold or exchanged the warrant or pre-funded warrant, as applicable, and recognized a capital loss equal to the non-U.S. holder's tax basis in such warrant or pre-funded warrant. However, a non-U.S. holder will not be able to utilize a loss recognized upon expiration of a warrant or pre-funded warrant against the non-U.S. holder's U.S. federal income tax liability unless the loss is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a permanent establishment in the United States) or is treated as a U.S.-source loss and the non-U.S. holder is present 183 days or more in the taxable year of disposition and certain other conditions are met.

Certain Adjustments to the Warrants or Pre-Funded Warrants. Under Section 305 of the Code, an adjustment to the number of shares of common stock issued on the exercise of the warrants or pre-funded warrants, or an adjustment to the exercise price of the warrants or pre-funded warrants, may be treated as a constructive distribution to a non-U.S. holder of the warrants or pre-funded warrants, as applicable, if, and to the extent that, such adjustment has the effect of increasing such non-U.S. holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). In addition, if we were to make a distribution in cash or other property with respect to our common stock after the issuance of the warrants or pre-funded warrants, then we may, in certain circumstances, make a corresponding distribution to a warrant or pre-funded warrant holder. The taxation of a distribution received with respect to a warrant or pre-funded warrant is unclear. It is possible such a distribution would be treated as a distribution (or constructive distribution), although other treatments are possible. For more information regarding the tax considerations related to distributions, see the discussion above regarding "*—Distributions*." Non-U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to and adjustments on the warrants or pre-funded warrants.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address, and the amount of tax withheld, if any. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends or of proceeds on the disposition of stock made to you may be subject to information reporting and backup withholding at a current rate of 24% unless you establish an exemption, for example, by properly certifying your non-U.S. status on an IRS Form W-8BEN, IRS Form W-8BEN-E or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that you are a U.S. person.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock, warrants or pre-funded warrants effected by or through a U.S. office of any broker, U.S. or foreign, except that information reporting and such requirements may be avoided if the holder provides a properly executed and appropriate IRS Form W-8 or otherwise meets documentary evidence requirements for establishing non- U.S. holder status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the U.S. through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, you may be able to obtain a refund or credit from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance

The Foreign Account Tax Compliance Act and the rules and regulations promulgated thereunder, collectively FATCA, generally impose withholding tax at a rate of 30% on dividends on, and gross proceeds from the sale or other disposition of, our common stock, warrants or pre-funded warrants paid to a "foreign financial institution" (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock, warrants or pre-funded warrants paid to a "non-financial foreign entity" (as specially defined under these rules) unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. The withholding provisions under FATCA generally apply to dividends on our common stock, warrants or pre-funded warrants, and, subject to the proposed regulations described in the next sentence, will apply to gross proceeds of a sale or other disposition of our common stock, warrants and pre-funded warrants. The Treasury Department has released proposed regulations (the preamble to which specifies that taxpayers are permitted to rely on them pending finalization) which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a disposition of our common stock, warrants or pre-funded warrants. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. You should consult your tax advisors regarding the possible implications of FACTA on your investment in our common stock, warrants or pre-funded warrants.

The preceding discussion of U.S. federal tax considerations is for general information only. It is not tax advice. Each prospective investor should consult its tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, warrants or pre-funded warrants, including the consequences of any proposed change in applicable laws.

PLAN OF DISTRIBUTION

Pursuant to an engagement agreement, dated March 26, 2020, we have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent to solicit offers to purchase the securities offered pursuant to this prospectus on a reasonable best efforts basis. The engagement agreement does not give rise to any commitment by the placement agent to purchase any of our securities, and the placement agent will have no authority to bind us by virtue of the engagement agreement. The placement agent is not purchasing or selling any of the securities offered by us under this prospectus, nor is it required to arrange for the purchase or sale of any specific number or dollar amount of securities. The placement agent has agreed to use reasonable best efforts to arrange for the sale of the securities by us. The placement agent does not guarantee that it will be able to raise new capital in any prospective offering. The placement agent may engage sub-agents or selected dealers to assist with the offering.

We will enter into a securities purchase agreement directly with institutional investors, at such investor's option, which purchase our securities in this offering. Investors which do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering. There is no minimum number of securities or amount of proceeds that is a condition to closing of this offering.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the securities being offered pursuant to this prospectus on or about May 22, 2020.

Fees and Expenses

The following table shows the per unit and per pre-funded unit and total placement agent fees we will pay in connection with the sale of the securities in this offering.

	Per Unit	Per Pre-funded Unit
Placement Agent Fees	$ 0.03375	$ 0.03375
Total	$ 699,475.16	$ 50,524.83

We have agreed to pay the placement agent a cash fee equal to 7.5% of the gross proceeds raised in this offering and a management fee equal to 1.0% of the gross proceeds raised in this offering. In addition, we have agreed to reimburse the placement agent for its non-accountable expenses in the amount of $40,000, its legal fees and expenses and other out-of-pocket expenses in an amount up to $100,000 and its clearing expenses in the amount of $12,900. We estimate the total offering expenses of this offering that will be payable by us, excluding the placement agent fees and expenses, will be approximately $265,100.

Placement Agent Warrants

In addition, we have agreed to issue to the placement agent or its designees warrants to purchase up to 1,555,555 shares of common stock (which represents 7.0% of the aggregate number of shares of shares of common stock issued in this offering and issuable upon the exercise of the pre-funded warrants issued in this offering) with an exercise price of $0.5625 per share (representing 125% of the public offering price per share) and exercisable for five years from the date of the effectiveness of this offering. The placement agent warrants are registered on the registration statement of which this prospectus is a part. The form of the placement agent warrant has been included as an exhibit to this registration statement of which this prospectus forms a part. Pursuant to FINRA Rule 5110(g), the placement agent warrants and any shares of common stock issued upon exercise of the placement agent warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in the offering and the officers or partners

thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the placement agent or related persons do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

Tail

We have also agreed to pay the placement agent a tail fee equal to the cash and warrant compensation in this offering, if any investor, who was contacted or introduced to us by the placement agent during the term of its engagement, provides us with capital in any public or private offering or other financing or capital raising transaction during the 12-month period following expiration or termination of our engagement of the placement agent.

Lock-up Agreements

We and each of our officers and directors have agreed with the placement agent to be subject to a lock-up period of 90 days following the date of closing of the offering pursuant to this prospectus. This means that, during the applicable lock-up period, we and such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any of our shares of common stock or any securities convertible into, or exercisable or exchangeable for, shares of common stock, subject to customary exceptions. The placement agent may waive the terms of these lock-up agreements in its sole discretion and without notice. In addition, we have agreed to not issue any securities that are subject to a price reset based on the trading prices of our common stock or upon a specified or contingent event in the future, or enter into any agreement to issue securities at a future determined price for a period of two years following the closing date of this offering, subject to an exception. The placement agent may waive this prohibition in its sole discretion and without notice.

Regulation M

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the securities sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent acting as principal. Under these rules and regulations, the placement agent (i) may not engage in any stabilization activity in connection with our securities and (ii) may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the placement agent may be required to make for these liabilities.

Determination of Offering Price

The actual offering price of the securities we are offering was negotiated between usand the investors in the offering based on the trading of our shares of common stock prior to the offering, among other things. Other factors considered in determining the public offering price of the securities we are offering include our history and prospects, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, the general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Electronic Offer, Sale and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by the placement agent, if any, participating in this offering and the placement agent may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus form a part, has not been approved or endorsed by us or the placement agent, and should not be relied upon by investors.

Other Relationships

The placement agent and its respective affiliates will be full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment hedging, financing and brokerage activities. The placement agent and its respective affiliates may also in the future engage in investment banking and other commercial dealings in the ordinary course of business with us or our affiliates, for which they would receive customary compensation.

Listing

Our shares of common stock are listed on the New York Stock Exchange under the symbol “RMED.”

LEGAL MATTERS

The validity of the common stock offered by this prospectus will be passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, San Diego, California. Certain legal matters in connection with the offering will be passed upon for the placement agent by Ellenoff Grossman & Schole, LLP, New York, New York.

EXPERTS

The financial statements incorporated in this prospectus by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2019 have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is incorporated by reference (which report expresses an unqualified opinion on the financial statements and includes an explanatory paragraph referring to the Company's ability to continue as a going concern). Such financial statements have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and other reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at http://www.sec.gov. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, including any amendments to those reports, and other information that we file with or furnish to the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act can also be accessed free of charge through the Internet. These filings will be available as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. You may also access these filings through our website at www.ramed.com.

We have filed with the SEC a registration statement under the Securities Act relating to the offering of these securities. The registration statement, including the attached exhibits, contains additional relevant information about us and the securities. This prospectus does not contain all of the information set forth in the registration statement. You can obtain a copy of the registration statement, at prescribed rates, from the SEC at the address listed above. The registration statement and the documents referred to below under "Incorporation of Certain Information by Reference" are also available on our Internet website, www.ramed.com. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference into this prospectus certain information we file with it, which means that we can disclose important information by referring you to those documents. The information incorporated by reference is considered to be a part of this prospectus, and information that we file later with the SEC will automatically update and supersede information contained in this prospectus. We incorporate by reference the documents listed below that we have previously filed with the SEC (excluding those portions of any Form 8-K that are not deemed "filed" pursuant to the General Instructions of Form 8-K):

- our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 11, 2020
- our Quarterly Report on Form 10-Q for the three months ended March 31, 2020, filed with the SEC on May 13, 2020
- our Current Reports on Form 8-K filed with the SEC on March 10, 2020, March 12, 2020, April 29, 2020 and May 7, 2020; and
- the description of our common stock contained in Exhibit 4.2 to our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 11, 2020, and any amendment or report filed for the purpose of updating such description.

This prospectus forms part of a registration statement on Form S-1 that we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement or the documents incorporated by reference herein and therein. For further information with respect to us and the securities that we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement and the documents incorporated by reference herein and therein. You should rely only on the information incorporated by reference or provided in this prospectus and registration statement. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus and the documents incorporated by reference herein and therein is accurate as of any date other than the respective dates thereof.

All reports and other documents we subsequently file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of this offering, including all such documents we may file with the SEC after the date of the initial registration statement and prior to the effectiveness of the registration statement, but excluding any information furnished to, rather than filed with, the SEC, will also be incorporated by reference into this prospectus and deemed to be part of this prospectus from the date of the filing of such reports and documents.

We will provide to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request, at no cost to the requester, a copy of any and all of the information that is incorporated by reference in this prospectus.

You may also access the documents incorporated by reference in this prospectus through our website at www.ir.ramed.com. Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.

Ra Medical Systems, Inc.

20,725,190 Units, Each Unit Consisting of One Share of Common Stock and One Warrant to Purchase One Share of Common Stock

1,497,032 Pre-funded Units, Each Pre-funded Unit Consisting of One Pre-funded Warrant to Purchase One Share of Common Stock and One Warrant to Purchase One Share of Common Stock

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PROSPECTUS

May 20, 2020

H.C. Wainwright & Co.