

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-K

- ☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Fiscal Year Ended December 31, 2022
OR
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period From _____ to _____
Commission file number: 001-38677

Ra Medical Systems, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
1670 Highway 160 West, Suite 205
Fort Mill, South Carolina
(Address of principal executive offices)

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

29708
(Zip Code)

(973) 691-2000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

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

Trading Symbol
RMED

Name of the exchange on which registered
NYSE American

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

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

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

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

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

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

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of a share of common stock on June 30, 2022 as reported by the NYSE American on such date was approximately \$9.9 million. Shares of the registrant's common stock held by each executive officer, director and other persons who may be deemed an affiliate of the registrant have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 23, 2023, the registrant has 4,984,093 shares of common stock, par value \$0.0001, outstanding.

RA MEDICAL SYSTEMS, INC.

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RA MEDICAL SYSTEMS, INC.

PART I

Forward-Looking Statements

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

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

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

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

ITEM 1. BUSINESS

Overview

Ra Medical Systems, Inc., or Ra Medical, was incorporated in Delaware in July 2018. Ra Medical was initially formed to develop, commercialize and market its advanced excimer laser-based platform for use in the treatment of vascular and dermatological immune-mediated inflammatory diseases.

On January 9, 2023, Ra Medical entered into the Amended and Restated Agreement and Plan of Merger, or the Merger Agreement, with Catheter Precision, Inc., or Catheter, a privately-held Delaware corporation. Under the terms of the Merger Agreement, Catheter became a wholly owned subsidiary of Ra Medical, together referred to as the Company, in a stock-for-stock merger transaction, or the Merger.

Prior to the Merger, Ra Medical developed an advanced excimer laser-based platform for use in the treatment of vascular immune-mediated inflammatory diseases. The Destruction of Arteriosclerotic Blockages by laser Radiation Ablation (DABRA) laser and single-use catheter, together referred to as DABRA, was developed as a tool in the treatment of Peripheral Artery Disease which commonly occurs in the legs. We have ceased marketing DABRA. In addition, as previously disclosed, Ra Medical completed the sale of its Pharos laser business, or Dermatology Business, to STRATA Skin Sciences, Inc. on August 16, 2021.

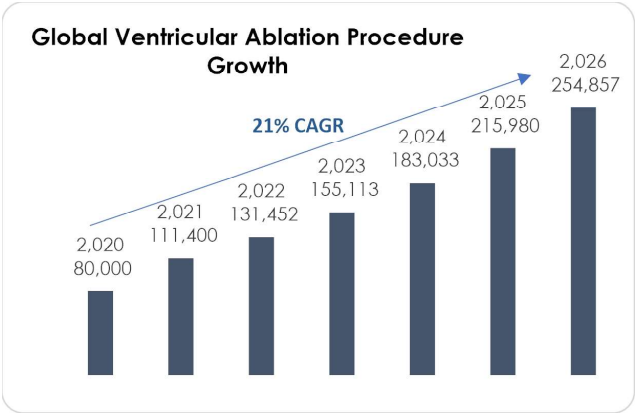
After the Merger and looking forward, we do not expect to use our legacy DABRA-related assets or continue Ra Medical's legacy lines of business, but instead expect to shift the focus of our operations to Catheter's product lines. Accordingly, our current activities primarily relate to Catheter's historical business which comprises the design, manufacture and sale of new and innovative medical technologies focused in the field of cardiac electrophysiology, or EP.

Our primary product is the View into Ventricular Onset System or VIVO™ System ("VIVO" or "VIVO System") which is a non-invasive imaging system that offers 3D cardiac mapping to help with localizing the sites of origin of idiopathic ventricular arrhythmias in patients with structurally normal hearts prior to EP procedures.

Electrophysiology Market Overview

EP is one of healthcare's largest sectors and rapidly growing. The EP market includes well known medical devices such as pacemakers, electrocardiogram, or ECG, systems and cardiac catheters, but also laboratory equipment such as intracardiac mapping systems and fluoroscopy systems (similar to x-ray in real time). The EP market includes large medical device companies such as Medtronic, Plc., Abbott Laboratories, Biosense-Webster (J&J) and Boston Scientific Corp. and is estimated to be \$11.6 billion by 2027 (CAGR of 9.4%). Population growth, increasing rates of heart disease and the rising cost of healthcare are driving growth in the EP markets.

Within the EP market, we focus our products on the catheter ablation market. The catheter ablation market was \$3.2 billion in 2020 and estimated to grow to \$6.4 billion in 2026. The catheter ablation market is growing at a faster rate (12.4% CAGR) than the EP market as a whole.



Within the last 10 years, ventricular ablation has become a fast-growing treatment option. Currently, there are about 80,000 ventricular ablations annually and VT ablations represent approximately 16% of ablations in the U.S. Currently, the market is underserved, and this number is expected to increase to over 250,000 procedures by 2026. The ventricular ablation market is expected to grow at a 21% CAGR through 2026, which is a faster rate than the global EP market and the catheter ablation market as a whole. The growth in the ventricular ablation market is driven by an aging population, advances in EP technology as well as updated physician guidelines. The Heart Rhythm Society, or HRS, Expert Consensus Statement on Catheter Ablation of Ventricular Arrhythmias, published in May 2019 recommends catheter ablation in preference to anti arrhythmic drugs or in the situation where anti arrhythmic therapy has failed or is not tolerated. The guidelines also recommend ablation for reducing recurrent VT and implantable cardioverter-defibrillator shocks.

Existing Treatments and Methods for Catheter Ablations

Traditionally, the first line of treatment for cardiac arrhythmias is medication. Unfortunately, this is not a permanent fix and most patients eventually need a catheter ablation.

Catheter Ablation Procedure Overview

An electrophysiologist stands next to the patient’s bed near the patient’s groin. A catheter or catheters are inserted into the femoral vein (located at the groin) and navigated into the right side of the heart. Depending on the type of arrhythmia, the catheter is inserted into the atrium or the ventricle. Once inserted, a diagnostic catheter is used in conjunction with an invasive (traditional) mapping system to create a map of the patient’s heart. This allows the physician to see the individual patient’s cardiac structures and size. Once the map is created, the physician begins to “pace map.” This process requires the physician to move the catheter from spot to spot to determine the electrical conduction at different areas to determine if the tissue in that area is responsible for the arrhythmia. Once the area is located, the physician will provide a form of energy (radiofrequency, cryo, etc.) to ablate the tissue in that spot.

Treatment Challenges for Ventricular Arrhythmias

Treatment of ventricular ablations with cardiac ablations is a relatively new treatment option. As a result, we believe that the patient population is underserved and is not as well understood, and the available techniques and technologies are limited when compared to the atrial ablation options.

Ablation locations within the ventricle are very difficult to identify. Often, patients are highly symptomatic (dizzy, breathing difficulties, etc.) but the arrhythmia is infrequent. When this happens, it is hard to predict when the patient will be having an “active” arrhythmia. Because of this, the physician may not be able to identify the location even when using medication to induce the arrhythmia. Without confirmation during invasive mapping, the patient is removed from the electrophysiology lab without the ablation procedure being performed and the patient is required to return at a later date and try again for a successful outcome.

Even when a patient has frequent ventricular arrhythmias, the process of pace-mapping often takes 4 – 5 hours to identify the location for ablation, which can increase the likelihood of patient complications due to the extended time under anesthesia.

Lastly, many patients with untreated ventricular arrhythmias cannot tolerate anesthesia well, thus invasive mapping that takes a long time is not an option for them.

Treatment Challenges for Atrial Arrhythmias

Catheter ablation for atrial arrhythmias is more standardized and “advanced” than for ventricular ablations, thus less pace mapping is required. Instead, a procedure called Pulmonary Vein Isolation (“PVI”) is performed for atrial fibrillation, and a single line is ablated for atrial flutter. In pulmonary vein isolation, tiny scars are created in the left upper chamber of the heart in the area where the four lung (pulmonary) veins connect.

Despite steady improvement in the tools available to perform effective procedures, there is clear study evidence that catheter based atrial fibrillation treatment technology can become more effective. According to a study entitled “*Long Term Outcomes of Catheter Ablation of Atrial Fibrillation: A Systematic Review and Meta-Analysis*” published in the *Journal of American Heart Association* on March 18, 2013, which looked at multiple individual studies covering over 6,000 patients, “single procedure freedom from atrial fibrillation at long term follow up was 53.1%.” The same study found “with multiple procedures performed, the long-term success rate was 79.8%.” Ineffective treatment may result in patients undergoing two or more EP procedures to achieve relief from atrial fibrillation at an estimated cost in the range of \$20,000 or more per procedure.

Specific reasons have not been proven for the lower success rate of initial ablation procedures. However, there is growing evidence that better results occur if the treating EP physician is able to make better lesions by maintaining stable contact force of the catheter against the heart wall, thereby reliably delivering the energy required to eliminate the abnormal rhythms. Variation in catheter contact force occurs as the physician attempts to manually position and hold the catheter tip in a stable position during cases lasting 2 to 3 hours in order to perform typically over 100 ablations of the cardiac anatomy.

Large multi-national medical device companies, such as Medtronic, Inc., Boston Scientific Corp., Abbott Laboratories, St. Jude Medical, Inc. and the Biosense Webster division of Johnson & Johnson, among others, continue to invest heavily to develop and introduce new devices and technologies to improve patient outcomes. Included among these are force-sensing catheters, including the Biosense SmartTouch TM catheter, which provide a continuous readout of the contact force between the catheter and the heart wall. Our business is focused on the controlled delivery of these catheter technologies to enhance both the performance of ablation procedures and the ease and safety for the physicians who perform them.

A recent peer-reviewed multicenter study sponsored by Biosense Webster, entitled “Paroxysmal AF Catheter Ablation with a Contact Force Sensing Catheter” published in 2014 found that catheter ablation success rates can be as high as 80% when the physician is able to maintain stable contact force within investigator selected working ranges. “When the CF (contact force) employed was between investigator selected working ranges > 80% of the time during therapy, outcomes were 4.25 times more likely to be successful.” Further, “stable CF during radiofrequency application increases the likelihood of twelve-month success.” However, it should be noted that, using manually controlled methods, the physicians in the study could only maintain optimal tissue contact in less than 30% of the patients studied.

In addition, another study, sponsored by St. Jude Medical, Inc. and published in 2015 showed similar findings using their recently FDA-approved contact-force sensing catheter, TOCCASTAR. In the TOCCASTAR study,

85.5% of ablation procedure patients were free of atrial fibrillation at one year after the procedure when optimal catheter tip contact force was maintained, versus only 67.7% when non-optimal contact force was achieved.

VIVO Clinical Use and Studies

To date, VIVO has been used in more than 850 procedures, by more than 30 physicians in 7 countries. Initial clinical work was completed with the first-generation software, which resulted in FDA 510(k) Clearance in June 2019.

The U.S. multi-center study enrolled 51 patients from 5 centers. Of note, the Principal Investigator and center to have the highest enrollment was Johns Hopkins University in Baltimore, Maryland. This study was conducted to evaluate the accuracy of VIVO as compared to invasive mapping systems (current prevailing method for determining arrhythmia origins). VIVO met all study endpoints and correctly matched the predicted arrhythmia origin in 44/44 patients (100%; primary endpoint) and correctly matched paced sites in 225/226 locations (99.56%; secondary endpoint). In some instances, this study showed that VIVO has better predictability for arrhythmia origin than a physician's manual review of a 12 lead ECG.

While conducting the initial clinical study for FDA submission, we developed generation 2 in parallel with a goal to have this version complete and ready to submit upon 510(k) clearance of generation 1. We successfully achieved this goal and received CE Mark and FDA 510(k) Clearance for generation 2 in 2020.

Additional clinical work has occurred with generation 2. Until recently, this data has been single center, physician-initiated research and has resulted in peer reviewed clinical science at electrophysiology conferences and in journals.

Three physicians, at different centers, in the UK conducted a feasibility study for Stereotactic Ablative Radiotherapy, or SABR, and published their data on nine patients. SABR is an ablation technique utilizing non-invasive methods akin to proton therapy for cancer treatment. To do a complete non-invasive ablation, accurately predicting the ablation location non-invasively is key to procedural success, and VIVO was utilized for this purpose. Non-invasive ablation is a new technique and requires additional data, but it is showing promise and has generated excitement within the EP community. If accepted for wide-spread treatment, this would allow for previously un-ablatable patients to receive lifesaving treatments.

In February 2023, a study from the Royal Brompton Hospital was published. This study enrolled 24 patients and VIVO accurately identified the outflow tract VT and premature ventricular contractions, or PVCs, origin in 23/24 (96%) and sub-localized in 100% of subjects. Acute success was achieved in 100% of cases. Standard ECG algorithms, conducted by 3 physicians in blind trials, only identified the correct chamber in 50-88% of the patients and sub-localized within the right ventricular outflow tract (septum v free wall) in 37 – 58% of subjects. Of note, six patients had previously attended for nine attempted ablations collectively, which were either unsuccessful or aborted owing to lack of spontaneously occurring clinical PVCs. One patient had previously reported for four separate attempts without PVCs and ablations were aborted, but collection of a single beat allowed VIVO to create an analysis map and provide the physician with information to complete the ablation for all these patients. In addition, this study showed a 27% reduction in procedure time when using VIVO as compared to a historical cohort. This study concluded that VIVO can accurately identify arrhythmia origin with an accuracy that is superior to that of established ECG algorithms.

In April 2022, one physician from the Netherlands presented an abstract at EHRA (European Heart Rhythm Association), focused on using VIVO as a way to screen patients prior to the ablation procedure. This study of 15 patients concludes that using VIVO pre-procedurally may enable the physician to determine procedure success rates and prevent unnecessary ablation procedures. This data will need to be further studied in larger numbers but determining success in advance of the procedure would improve ablation therapy, which has a high failure rate and thus requires additional ablation procedures.

In October 2021 the first patient was enrolled in the VIVO EU Registry. This registry aims to gather data about how VIVO is used in real-world settings, outside of a rigorous clinical study. The registry will enroll 125 patients across Europe and the UK and collect information about different workflows and applications for VIVO. To

date, 80 patients have been enrolled and enrollment is targeted to be complete in Q2 2023. This data serves multiple purposes including fulfilling European regulatory requirements for on-going data collection, publication of multi-center data, and future development of studies and improvements to the VIVO technology.

Our Products

VIVO™ System

Our lead product, VIVO, is an FDA-cleared and CE marked product that utilizes non-invasive inputs to locate the origin of ventricular arrhythmias. VIVO has been used in more than 850 procedures in leading U.S. and European hospitals under a limited commercial launch that commenced in the third quarter of 2021. A full commercial launch commenced in the first quarter of 2023 and is currently underway.

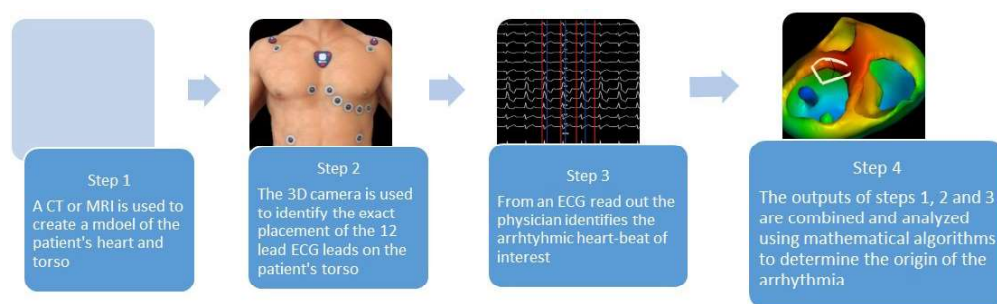
VIVO is a non-invasive imaging system that offers 3D cardiac mapping to help with localizing the sites of origin of idiopathic ventricular arrhythmias in patients with structurally normal hearts prior to electrophysiology procedures. The VIVO system has achieved a CE Mark allowing it to be commercialized in the European Union and has been placed at several hospitals in Europe. FDA 510(k) Clearance in the United States was received in June 2019.

The VIVO software is provided on an off the shelf laptop, and the system includes a 3D camera. In addition, the system can only be used with a disposable component, the VIVO Positioning Patches, which are required for each procedure.



The VIVO software contains proprietary algorithms that are based on standard EP principles. However, the accuracy of the algorithms is improved because it does not use generalized assumptions and instead, uses patient specific information. VIVO uses standard clinical inputs such as a CT or MRI and a 12 lead ECG, both of which are routinely gathered for most EP procedures, allowing VIVO to seamlessly integrate into the workflow. A 3D photograph is obtained of the patient’s torso after the ECG leads are in place and all of these clinical inputs are combined to generate a 3D map of the patient’s heart with a location of the earliest onset of the ventricular arrhythmia.

VIVO Workflow



LockeT

LockeT, a suture retention device, is a sterile, Class I product that was registered with the FDA in February 2023, at which time we began initial shipments to distributors. We believe LockeT is indicated for wound healing by distributing suture tension over a larger area in the patient in conjunction with a figure of eight suture closure and is intended to temporarily secure sutures and aid clinicians in locating and removing sutures efficiently.

Clinical studies for LockeT are planned to begin during 2023. These studies are planned to show the product's effectiveness and benefits, including faster wound closure, earlier ambulation, potentially leading to early hospital discharge, and cost analysis. This data is intended to provide crucial data for marketing and to expand our indications for use with the FDA. See *License and Other Agreements* below.

Amigo® Remote Catheter System

Our product portfolio also includes the Amigo® Remote Catheter System, or Amigo, a robotic arm that serves as a catheter control device. Prior to 2018, we marketed Amigo. We own the intellectual property related to Amigo, and this product is under consideration for future research and development of a generation 2 product.

Our Previously Marketed DABRA Product

Prior to the Merger, we manufactured and marketed DABRA, a portable excimer laser console with proprietary, single-use catheters for the minimally invasive endovascular treatment of vascular blockages resulting from lower extremity vascular disease in both above and below the knee lesions.

The DABRA catheter transmitted energy from the laser to the vascular blockage. The laser energy traveled through the catheter and ablated the blockage, reducing it to chemicals that were found naturally in the bloodstream. The catheters were specifically designed for use with our excimer laser. The DABRA catheter used a liquid-filled plastic tubing allowing for the efficient and precise delivery of the laser energy.

After the Merger, we are no longer manufacturing and marketing DABRA.

Our Solution

Adoption of our VIVO System by electrophysiologists is expected to enhance their ability to diagnose and treat cardiac arrhythmias.

Non-invasive mapping prior to the ablation procedure provides a solution for patients that could not be ablated previously. First, many patients with VT do not tolerate anesthesia well. By providing a non-invasive solution to determine the ablation location, physicians are better able to understand where the arrhythmia originates and how easily one can access the ablation location, minimizing the amount of time that the patient may need to be anesthetized, and allowing many patients the ability to have an ablation that otherwise could not. Second, many patients are highly symptomatic, but do not have PVCs often. In these situations, the patients are often brought in for

ablation procedures only to have no arrhythmia and sent home time and time again. In these instances, the physicians can monitor the patient prior to hospitalization and obtain information about the arrhythmia. In this way, the patient can still proceed to an ablation procedure without having PVCs on the day of surgery.

Non-invasive mapping also enables planning prior to the start of the procedure. This enables the physicians to better understand where they are targeting, which enables them to make advanced decisions about where they are navigating the catheter and which catheter(s) they are using, reducing both procedure time and cost.

Surgery patients who are offered the LockeT device are expected to benefit from faster wound closure and earlier ambulation, potentially leading to early hospital discharge and lower costs.

Our Strategy

Our goal is to become a leading medical imaging company in the field of cardiac electrophysiology, and we are dedicated to developing and delivering electrophysiology products to provide patients, hospitals, and physicians with novel technologies and solutions to improve the lives of patients with cardiac arrhythmias. We aim to establish VIVO as an integral tool used by cardiac electrophysiologists during ablation treatment of ventricular arrhythmias by reducing procedure time and patient complications and increasing procedural success.

Customers

For the years ended December 31, 2022 and 2021, Ra Medical had four and three individual customers, respectively, that represented more than 10% of its total revenues.

After the Merger, our primary customers are hospitals providing cardiac electrophysiology lab procedures. We believe there are 2,000 to 3,000 EP labs in the U.S. and a similar number of labs outside of the U.S. performing approximately 600,000 ablation procedures annually.

Sales and Marketing

Today, we use a mix of distribution partners (Europe), independent sales agents (U.S.) specializing in EP products, and direct employees providing clinical support and product specialization. In the U.S., the VIVO System and patches are currently sold by independent sales agents who call on electrophysiologists, lab staff and hospital administrators. This sales team qualifies appropriate prospective customers, and with support from our direct clinical specialists they conduct product demonstrations, and support customer training and case usage. In Europe, our products are sold through distributors, supported by three full time contracted employees.

In addition, in both the U.S. and Europe, we have entered into a co-marketing agreement with Stereotaxis, or STX. The goal is to leverage the compatibility of VIVO with their robotic system. STX customers are the same customers for VIVO, and VIVO provides their customers with an added tool to reduce procedure time. Pursuant to the agreement, STX can perform promotional activity at any hospital globally that has a Stereotaxis Robotic Magnetic Navigation System, referred to herein as a robotic hospital, and where VIVO has appropriate regulatory clearances. In addition, STX will act as a spot distributor for us at mutually agreed upon hospitals where the VIVO System is included as a line item within an STX quote. In exchange for its marketing, distribution and support activity, Stereotaxis receives a payment equal to 45% of the revenue generated from VIVO at robotic hospitals. After the initial sale of VIVO products to customers by Stereotaxis, we will be responsible for selling additional VIVO-related products to the customers but will continue to owe the 45% payment to Stereotaxis with respect to any such sales. The agreement has a term that runs through December 31, 2023, provided however, that the agreement will automatically extend for successive two-year terms unless either party provides the other written notice of termination at least one year prior to the next-scheduled termination date. Stereotaxis will continue to be entitled to receive the 45% payments described above for a period of six months following termination of the agreement.

We have begun to hire additional clinical support and direct sales representation to support the full VIVO product launch in 2023. They are experienced in the electrophysiology field and will identify and target prospective customers to educate, and demonstrate our products, leading to adoption and purchase of our technology. We will continue to use direct clinical specialists to provide training and ongoing clinical support.

In the future, we intend to market our products in the U.S. and certain international markets using a combination of a direct sales force and independent distributors. This may require us to make a significant investment building our U.S. commercial infrastructure and sales force and in recruiting and training our sales representatives and clinical specialists for U.S. commercialization of VIVO. This is a lengthy process that requires recruiting appropriate sales representatives, establishing a commercial infrastructure in the United States, and training our sales representatives, and will require significant ongoing investment by us. Following initial training, our sales representatives typically require lead time in the field to grow their network of accounts, coordinate their sales efforts with each hospital's capital budgeting and acquisition cycle and produce sales results. Successfully recruiting and training a sufficient number of productive sales representatives is required to achieve growth at the rate we desire.

Marketing and market development activities will target increasing our product usage and expanding the applications of VIVO into the physician clinic and not just hospitals by employing a reimbursement specialist to provide reimbursement for VIVO in different settings.

Outside the U.S., we will continue to foster additional key partner relationships with distributors who will market, sell and support its products.

In addition, we believe there are opportunities to offer additional complementary products through our sales and marketing channels that would enhance the productivity of our sales force and provide additional scale to revenue, better covering fixed operating costs.

Manufacturing

VIVO manufacturing, inventory and product fulfillment is housed in our approximate 2,000 square feet facility in Fort Mill, South Carolina. This facility currently has one full-time employee who oversees manufacturing, quality objectives, and order fulfillment.

Competition

The medical device industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other activities of industry participants. We face potential competition from major medical device companies worldwide, many of which have longer, more established operating histories, and significantly greater financial, technical, marketing, sales, distribution, and other resources. Our overall competitive position is dependent upon a number of factors, including product performance and reliability, manufacturing cost, and customer support. Our primary competitors in the cardiac electrophysiology space include known medical devices such as pacemakers, electrocardiogram, or ECG, systems and cardiac catheters, but also laboratory equipment such as intracardiac mapping systems and fluoroscopy systems (similar to x-ray in real time). The EP market includes large medical device companies such as Medtronic, Plc., Abbott Laboratories, Biosense-Webster (J&J) and Boston Scientific Corp.

Reimbursement

At this time, there is no reimbursement for VIVO. Ablation procedures are reimbursed using one current procedural technology, or CPT, code, which varies depending on the type and complexity of the procedure. The range of reimbursement for ablations varies within regions but can be as much as \$20,000 or more.

We currently intend, in the future, to hire a reimbursement specialist to guide us through the process of obtaining a CPT code specifically for VIVO.

Research and Development

The major focus of our research and development team is to leverage our existing technology platform for new applications and improvements to our existing applications, including multiple engineering efforts to improve our current products. Future research and development efforts will involve continued enhancements to and cost reductions for VIVO and LockeT. We will also explore the development of other products that can be derived from our core technology platform and intellectual property. Our research and development team works together with our

commercial team to set development priorities based on communicated customer needs. The feedback received from our customers is reviewed and evaluated for incorporation into new products.

In the future we intend to develop a generation 3 of VIVO. This version would have expanded indications to include ischemic heart disease and improve usability by the hospital staff and contain more automaticity, potentially reducing our need for clinical support.

Resources Material to Our Business

Patents and Proprietary Technology

Patents

We have a number of patents covering its intellectual property, both in the U.S., as well in a number of international countries. We consider the U.S. to be the most important market for its products, and hence, the most important country for the filing of patents. Any foreign filings are merely replicates of the U.S. filings. For the U.S., we have the following patent positions for the different product areas:

- **VIVO** – We have two U.S. patents granted on the original VIVO concept, which have been licensed from a third party. We consider the primary component to be the ideas around utilizing a 3D camera to identify the exact location of the body surface electrodes. These two patents expire in 2038. An additional two applications have been published, which disclosed ideas around merging of the heart models to other heart images. An additional application has been published covering the idea of determining the thickness of the wall of the ventricle (filed 2021), and another filing from 2021 has been published covering the concept of the rendering of a heart model. Two additional applications have been filed and not yet published.
- **AMIGO** – We have twenty issued U.S. patents. The first patent, filed in 2006 and expiring in 2031, covers the basic idea, with a three way motor, a remote control, a sled device, and a docking station for a catheter. The more detailed ideas behind the original concept were covered in three patents filed between 2011 and 2013 and expiring in 2026. Additional concepts and methods were filed with six patents between 2010 and 2013, with expirations between 2029 and 2031. We consider the most relevant of the intellectual property to be the guiding track with opposing flexible guides to hold the catheter stable as it is advanced, the form and function of the controller handle, and the introducer interface of the arm to the introducer. An additional ten patents, filed between 2013 and 2017, and expiring in 2034 to 2037, are patents covering ideas not used in the original commercial device, but potential ideas for future embodiments.
- **LockeT – Suture Retention Device** - We filed four U.S. patent applications in 2022, and have two more in the process of writing. These cover the basic concept, methods of use and the design of the conceived device.

License and Other Agreements

PEACS, NV Software and Technology License Agreement

On May 1, 2016, we entered into a certain Software and Technology License Agreement with PEACS, NV, a Netherlands company, or the License Agreement, for the exclusive worldwide license of the underlying technology to its VIVO product, including intellectual property rights and patent applications pertaining thereto. The license was for use of the technology for the field of use defined as “the localization of the origin of cardiac activation for the electrophysiology treatment and/or detection of cardiac arrhythmias.” The License Agreement called for us to pay for the prosecution and maintenance of patents to protect the technology.

In May, 2021, the License Agreement was modified to modify the field of use specifically exclude the use of clinical applications for the implanting of atrial or ventricular pacemakers, including bi-ventricular pacemakers.

LockeT Royalty Agreement

In February 2022, we agreed to an assignment and royalty agreement, or the Royalty Agreement, for the LockeT device which is under development. Pursuant to the Royalty Agreement, we agreed to pay a royalty fee of

5% on net sales up to \$1 million. Thereafter, if a patent for the LockeT device is obtained from the U.S. Patent and Trademark Office, we will pay a royalty fee of 2% of net sales up to a total of \$10 million in royalties. In addition, at the time of the Merger, additional royalty rights with respect to LockeT device were granted to certain holders, or the Noteholders, of Catheter's outstanding convertible promissory notes in exchange for forgiveness of the interest that had accrued under those notes but remained unpaid, pursuant to the terms of certain Debt Settlement Agreements. The Debt Settlement Agreements provided for the Noteholders to receive, in the aggregate, approximately 12% of the net sales, if any, of the LockeT device, commencing upon the first commercial sale through December 31, 2035.

Trademarks

We own or have rights to trademarks that it uses in connection with the operation of its business. We own or have rights to trademarks for Ra Medical Systems and Catheter Precision and their logos, as well as other trademarks such as AMIGO.

Trade Secrets

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

Government Regulations

Governmental authorities in the U.S. (at the federal, state, and local levels) and abroad extensively regulate, among other things, the research and development, testing, manufacture, quality control, clinical research, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of products such as those we market and are developing. See *Item 1.A. Risk Factors—Risks Related to Government Regulation*.

United States Medical Device Regulation

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

The FDCA classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Class II devices provide intermediate levels of risk. They are subject to general controls and must also comply with special controls. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices must typically be approved by the FDA before they are marketed. LockeT is a sterile, Class I product and was registered with the FDA in February of 2023. VIVO is an FDA-cleared Class II product.

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

The FDA conducts market surveillance and periodic visits, both announced and unannounced, to inspect or re-inspect equipment, facilities, laboratories and processes to confirm regulatory compliance. These inspections may include the manufacturing facilities of subcontractors. Following an inspection, the FDA may issue a report, known as a Form 483, listing instances where the manufacturer has failed to comply with applicable regulations

and/or procedures or, if observed violations are severe and urgent, a warning letter. If the manufacturer does not adequately respond to a Form 483 or warning letter, the FDA make take enforcement action against the manufacturer or impose other sanctions or consequences, which may include:

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

Pre-Market Authorization and Notification

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

510(k) Notification

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

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

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

VIVO was cleared by the FDA via a traditional 510(k) with supporting clinical data. This data was collected via a clinical study enrolling 51 subjects and took approximately 12 months to gather. It is expected that future generations of VIVO will require similar data collection and 510(k) submission to receive FDA clearance.

Because the LockeT device is a Class I product, it did not require clinical data or a formal submission process. After completing validation testing and compiling a Device History File, LockeT was added to our listing of registered devices. The regulatory pathway for future LockeT devices will depend on the intended use and desired labeling claims and the requirements for clinical data.

De Novo Classification

Devices of a new type that the FDA has not previously classified based on risk are automatically classified into Class III by operation of section 513(f) (1) of the FDCA, regardless of the level of risk they pose. To avoid requiring PMA review of low- to moderate-risk devices classified in Class III by operation of law, Congress enacted section 513(f)(2) of the FDCA. This provision allows the FDA to classify a low- to moderate-risk device not previously classified into Class I or II through the de novo classification pathway. The FDA evaluates the safety and effectiveness of devices submitted for review under the de novo classification pathway and devices determined to be Class II through this pathway can serve as predicate devices for future 510(k) applicants. The de novo classification pathway can require clinical data and is generally more burdensome than the 510(k) pathway and less burdensome than the PMA pathway. According to the most recent FDA performance review goals, applicable to requests received during fiscal year 2022, the agency would attempt to issue a decision within 150 days of receipt on 70% of de novo classification requests.

Pre-Market Approval

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

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

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

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

Clinical Trials

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

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

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

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

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

Post-Market Requirements

After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, the medical device reporting regulations (which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and reports of corrections and removals regulations (which require manufacturers to report recalls or removals and field corrections to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA). Failure to properly identify reportable events or to file timely reports, as well as failure to address observations to FDA's satisfaction, can subject us to warning letters, recalls, or other sanctions and penalties.

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

Manufacturers of medical devices are permitted to promote products solely for the uses and indications set forth in the approved or cleared product labeling. A number of enforcement actions have been taken against

manufacturers that promote products for “off-label” uses (i.e., uses that are not described in the approved or cleared labeling), including actions alleging that claims submitted to government healthcare programs for reimbursement of products that were promoted for “off-label” uses are fraudulent in violation of the Federal False Claims Act or other federal and state statutes and that the submission of those claims was caused by off-label promotion. The failure to comply with prohibitions on “off-label” promotion can result in significant monetary penalties, revocation or suspension of a company’s business license, suspension of sales of certain products, product recalls, civil or criminal sanctions, exclusion from participating in federal healthcare programs, or other enforcement actions. In the United States, allegations of such wrongful conduct could also result in a corporate integrity agreement with the U.S. government that imposes significant administrative obligations and costs, as has occurred in the past with respect to our legacy products that we no longer market.

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

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

For a PMA or Class II 510(k) or de novo devices, the FDA also may require post-marketing testing, surveillance, or other measures to monitor the effects of an approved or cleared product. The FDA may place conditions on a PMA-approved device that could restrict the distribution or use of the product. In addition, quality-control, manufacture, packaging, and labeling procedures must continue to conform to QSRs and other applicable regulatory requirements after approval and clearance, and manufacturers are subject to periodic inspections by the FDA. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with QSRs. If the FDA believes we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements and patients are being subjected to serious risks, the agency can shut down our manufacturing operations, require recalls of our medical device products, refuse to approve new marketing applications, initiate legal proceedings to detain or seize products, enjoin future violations, or assess civil and criminal penalties against us or our officers or other employees.

European Economic Area (EEA) Regulation

The EEA recognizes a single medical device approval (the CE Mark) which allows for distribution of an approved product throughout the EEA without additional general applications in each country. Individual EEA members, however, reserve the right to require additional labeling or information to address particular patient safety issues prior to allowing marketing. Third parties called “Notified Bodies” award the CE Mark. These Notified Bodies are approved and subject to review by the “Competent Authorities” of their respective countries. Our Notified Bodies perform periodic on-site inspections to independently review our compliance with systems and regulatory requirements. A number of countries outside of the EEA accept the CE Mark in lieu of marketing submissions as an addendum to that country’s application process. We have a CE Mark for the VIVO System. Beginning July 1, 2023, the United Kingdom will require its own medical device approval (UKCA). VIVO is currently registered with MHRA (UK governing body) to market the VIVO system in the UK. As of July 1, 2023, VIVO will bear the UKCA symbol as required by the UK MDR 2022 to continue UK distributions. MDR requirements now include on-going collection of clinical data to include in annual reports to ensure state of the art technology and safety requirements are met. We are currently collecting data via a multi-center (and country) European Registry. This registry plans to enroll 125 patients with 12-month follow-up. The first patient was enrolled in October 2021 and there are currently 65 patients enrolled.

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Persons and entities can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the health care fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- in addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH Act, and its implementing regulations, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;
- the U.S. Physician Payments Sunshine Act, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other “transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), non-physician healthcare professionals (defined to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives) and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by the patients themselves; state laws that require pharmaceutical and device companies to comply with the industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise

restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

Because of the breadth of these laws and the narrow scope of the statutory or regulatory exceptions and safe harbors available, our business activities could be challenged under one or more of these laws. Relationships between medical product manufacturers and health care providers are an area of heightened scrutiny by the government.

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

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

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

Foreign Corrupt Practices Act

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

There is no assurance that our internal control policies and procedures will protect us from acts committed by our employees or agents. If we are found to be liable for FCPA or other violations (either due to our own acts or our inadvertence, or due to the acts or inadvertence of others), we could suffer from civil and criminal penalties or other sanctions, including contract cancellations or debarment, and loss of reputation, any of which could have a material adverse impact on our business, financial condition, and results of operations.

Privacy and Data Protection Laws

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

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

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

Environmental Regulation

We are subject to federal, state and local regulations governing the storage, use and disposal of waste materials and products. Although we believe that our safety procedures for storing, handling and disposing of these materials and products comply with the standards prescribed by law and regulation, we cannot eliminate the risk of accidental contamination or injury from those hazardous materials. Federal regulations promulgated by the Occupational Safety and Health Administration impose additional requirements on us, including those protecting employees from exposure to elements such as blood-borne pathogens. We cannot predict the frequency of compliance, monitoring, or enforcement actions to which we may be subject as those regulations are being implemented, which could adversely affect our operations.

Segment Information

We operate our business as one segment which includes all activities related to the marketing, sales and development of medical technologies focused in the field of cardiac EP. The chief operating decision-maker reviews the operating results on an aggregate basis and manages the operations as a single operating segment.

Employees

As of March 23, 2023, we had 14 full-time employees which includes finance and administrative, sales and marketing and clinical professionals. We are planning to increase our sales force in support of product launches but currently have no other plans to increase our staff.

Corporate Information

Our principal executive offices are located at 1670 Highway 160 West, Suite 205, Fort Mill, South Carolina 29708. Our telephone number is (973) 691-2000. Our corporate website address is www.ramed.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this document, and you should not consider information on our website to be part of this document.

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

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

Risk Factor Summary**Risks Related to Our Financial Position and Need for Additional Capital**

- We may be required to raise additional funds to finance our operations and remain a going concern; We may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us.
- Our business has a history of losses and will incur additional losses, and we may never achieve profitability.

Risks Related to Our Business and Products

- We will not be able to reach profitability unless we are able to achieve our product expansion and growth goals.
- Our research and development and commercialization efforts may depend on entering into agreements with corporate collaborators.
- We have entered into joint marketing agreements with respect to our products, and may enter into additional joint marketing agreements, that will reduce our revenues from product sales.
- Royalty agreements with respect to our surgical vessel closing pressure device in development will reduce any future profits from this product.
- If we experience significant disruptions in our information technology systems, our business may be adversely affected.
- Litigation and other legal proceedings may adversely affect our business.
- If we make acquisitions or divestitures, we could encounter difficulties that harm our business.
- Failure to attract and retain sufficient qualified personnel could also impede our growth.
- 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.
- Our revenues may depend on our customers' receipt of adequate reimbursement from private insurers and government sponsored healthcare programs.
- We may be unable to compete successfully with companies in our highly competitive industry, many of whom have substantially greater resources than we do.
- Our future operating results depend upon our ability to obtain components in sufficient quantities on commercially reasonable terms or according to schedules, prices, quality and volumes that are acceptable to us, and suppliers may fail to deliver components, or we may be unable to manage these components effectively or obtain these components on such terms.
- If hospitals, physicians and patients do not accept our current and future products or if the market for indications for which any product candidate is approved is smaller than expected, we may be unable to generate significant revenue, if any.

- The recent coronavirus outbreak (“COVID-19”) adversely affected our financial condition and results of operations and we cannot provide any certainty as to whether there will be future impacts from COVID-19 or another pandemic.

Risks Related to Government Regulation and our Industry

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

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.

Risks Related to Ownership of Our Common Stock

- The price of our stock has been and may continue to 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.
- The ownership of our common stock is highly concentrated, and may become more so in the near future, which may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the company stock price to decline.

Risks Related to Our Financial Position and Need for Additional Capital

We may be required to raise additional funds to finance our operations and remain a going concern; We may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us.

We are no longer pursuing Ra Med’s historical lines of business and have instead determined to move forward with Catheter’s products following our acquisition of Catheter. Catheter’s operations to date have consumed substantial amounts of cash and Catheter has sustained negative cash flows from Catheter’s operations for the last several years. The Catheter business may require future additional capital infusions including public or private financing, strategic partnerships or other arrangements with organizations that have capabilities and/or products that are complementary to Catheter’s own capabilities and/or products, in order to execute our strategic vision. However, there can be no assurances that we can complete any financings, strategic alliances or collaborative development agreements, and the terms of such arrangements may not be advantageous to us. In addition, any additional equity financing will be dilutive to our current stockholders, and debt financing, if available, may involve restrictive covenants. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize. Our failure to raise capital when needed could materially harm our business, financial condition, and results of operations. See “—We have entered into joint marketing agreements with respect to our products, and may enter into additional joint marketing agreements, that will reduce our revenues from product sales,” and “—Royalty agreements with respect to our surgical vessel closing pressure device in development will reduce any future revenues from this product.”

Our business has a history of losses and will incur additional losses, and we may never achieve profitability.

Our only current business is conducted through Catheter, our wholly owned subsidiary, which currently derives revenues from the View into Ventricular Onset System or VIVO™ System (“VIVO” or “VIVO System”). In the past, Catheter generated revenue from the sales of the Amigo® Remote Catheter System (“Amigo”), the business line of which Catheter discontinued in 2017. VIVO is currently in the research and development phase for a generation 2 product. While Catheter does generate revenue, Catheter is still operating at a loss, and there is no guarantee that Catheter will be able to grow the revenues enough to offset Catheter’s costs to realize profitability. To date, Catheter has not been profitable, and Catheter’s accumulated deficit was approximately \$116.9 million and \$110.5 million at December 31, 2022 and December 31, 2021, respectively. Catheter’s losses have resulted principally from costs incurred in research and development, and from general and administrative costs associated with Catheter’s operations. In order to commercialize Catheter’s assets, we will need to conduct substantial additional research, development and clinical trials. Catheter will also need to receive necessary regulatory clearances in the United States and obtain meaningful patent protection for and establish freedom to commercialize Catheter’s product candidates. We must also complete further clinical trials and seek regulatory approvals for any new product candidates Catheter discovers, licenses or acquires. We cannot be sure whether and when we will obtain required regulatory approvals, or successfully research, develop, commercialize, manufacture and market any other product candidates. We expect that these activities, together with future general and administrative activities, will result in significant expenses for the foreseeable future. We may never achieve profitability.

Risks Related to Our Business and Products

We will not be able to reach profitability unless we are able to achieve our product expansion and growth goals.

Our goal to achieve profitability is dependent upon establishing VIVO as an integral tool used by cardiac electrophysiologists during ablation treatment of ventricular arrhythmias, as well as upon developing and marketing new products, such as our wound closure product that is under development. In today’s healthcare environment, the process for new technologies to be adopted and penetrate market share has become more complex, with the need to win over multiple stakeholders within clinical, administrative and support teams in hospitals, and increasingly we must target the administrators in integrated delivery networks. To accomplish this, we will need to:

- Develop initial users that demonstrate clinical and economic benefits and support studies which provide evidence of tangible benefits to prospective customers, such as procedural success, patient complications and reduced procedure times.
- Collaborate with clinical thought leaders to establish clinical techniques, evolve our product features and demonstrate enhanced capabilities to broaden the appeal of VIVO.
- Expand our FDA clearance to market our products for additional procedure types. In Europe, VIVO is cleared for pre-procedural planning in all types of hearts and procedures. In the U.S., we will seek clearance for ischemic hearts to broaden the indications for use of our products, which can expand clinical demand.
- Enhance the design, user utility and clinical capability of VIVO through further product development and collaboration with clinical users.
- Seek to engage collaboration with larger market participants and their larger sales force coverage to integrate the prospecting, sale and support of our products in conjunction with other products used in electrophysiology procedures.
- Opportunistically identify acquisitions to enhance our enterprise scale, sales synergy and fixed cost coverage.
- Seek to obtain codes for reimbursement from Medicare to broaden the appeal of using VIVO in the physician’s clinic.
- If we are unable to accomplish one or more of the foregoing, we may be unable to achieve our product expansion and growth goals, and may be unable to achieve profitability.

Our research and development and commercialization efforts may depend on entering into agreements with corporate collaborators.

We may need seek out additional collaborations in order to commercialize Catheter's products. We will continue to seek research collaborations, co-development and marketing agreements, and licensing deals for Catheter's products in development; however, there is no guarantee that we will be successful in our efforts. Any collaborator with whom we may enter into such collaboration agreements may not support fully our research and commercial interests since our program may compete for time, attention and resources with such collaborator's internal programs. Therefore, these future collaborators may not commit sufficient resources to our program to move it forward effectively, or the program may not advance as rapidly as it might if we had retained complete control of all research, development, regulatory and commercialization decisions.

We have entered into joint marketing agreements with respect to our products, and may enter into additional joint marketing agreements, that will reduce our revenues from product sales.

Catheter entered into a Joint Marketing Agreement with Stereotaxis, Inc. in January 2021, as subsequently amended in January 2022 and May 2022, pursuant to which Stereotaxis agrees to promote our VIVO System to customers who may benefit from the use of VIVO in robotic or non-robotic electrophysiology procedures. Pursuant to the agreement, Stereotaxis can perform promotional activity at any hospital globally that has a Stereotaxis Robotic Magnetic Navigation System, referred to herein as a robotic hospital, and where VIVO has appropriate regulatory clearances. In addition, Stereotaxis will act as a spot distributor for us at mutually agreed upon hospitals where the VIVO System is included as a line item within a Stereotaxis quote. In exchange for its marketing, distribution and support activity, Stereotaxis receives a payment equal to 45% of the revenue generated from VIVO at robotic hospitals. After the initial sale of VIVO products to customers by Stereotaxis, Catheter will be responsible for selling additional VIVO-related products to the customers but will continue to owe the 45% payment to Stereotaxis with respect to any such sales. The agreement has a term that runs through December 31, 2023, provided however, that the agreement will automatically extend for successive two-year terms unless either party provides the other written notice of termination at least one year prior to the next-scheduled termination date. Stereotaxis will continue to be entitled to receive the 45% payments described above for a period of six months following termination of the agreement. Although we believe that this agreement is in the best interest of our business and our stockholders, it will material reduce the revenues that we receive from VIVO products that are sold by Stereotaxis, and any similar agreements entered into in the future may have the same impact.

Royalty agreements with respect to our surgical vessel closing pressure device in development will reduce any future profits from this product.

In February 2022, Catheter agreed to an assignment and royalty agreement for the Surgical Vessel Closing Pressure Device, which is under development. Pursuant to the agreement, Catheter agreed to pay a royalty fee of 5% on net sales up to \$1 million. Thereafter, if a patent for the Surgical Vessel Closing Pressure Device is obtained from the U.S. Patent and Trademark Office, Catheter will pay a royalty fee of 2% of net sales up to a total of \$10 million in royalties. In addition, at the time of our merger with Catheter, additional royalty rights with respect to the Surgical Vessel Closing Pressure Device were granted to certain holders (the "Noteholders") of Catheter's outstanding convertible promissory notes in exchange for forgiveness of the interest that had accrued under those notes but remained unpaid, pursuant to the terms of certain Debt Settlement Agreements. The agreements provide for the Noteholders to receive, in the aggregate, approximately 12% of the net sales, if any, of the Surgical Vessel Closing Pressure Device, commencing upon the first commercial sale through December 31, 2035. As a result, even if the Surgical Vessel Closing Pressure Device is successfully developed and marketed, our revenues from this device will be reduced by the amount of these royalties.

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, 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.

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 have previously been a party to securities class action and shareholder derivative litigation and other litigation as set forth in 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.

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

We may acquire companies, products or technologies that we believe to be complementary to the present or future direction of our business, or may be of a strategic nature with a focus on a new direction focused on the combined company and the business that we may acquire. 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.

Failure to attract and retain sufficient qualified personnel could also impede our growth.

Our current Chief Financial Officer, Brian Conn, is currently only working for us on a part-time interim basis. As a result, we will need to hire a new, full-time Chief Financial Officer soon. In addition, as has been previously disclosed, Will McGuire, our Chief Executive Officer, has been diagnosed with a serious illness not caused by COVID-19 and has been undergoing treatment for his illness. Discussions are ongoing with Mr. McGuire, but we anticipate that we may also need to seek a replacement Chief Executive Officer in the near future. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees,

including our Executive Chairman, David A. Jenkins. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition, and results of operations. We face intense competition for executive-level talent from a variety of sources, including from current and potential competitors in the medical device and healthcare industries, and there is no guarantee that we can locate suitable replacements when they are needed.

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

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

As previously disclosed, in 2019, we identified material weaknesses in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to the aggregation of control deficiencies in our control environment, in particular an inappropriate “tone at the top” set by certain members of senior management, a failure to promote adherence to our Code of Ethics and Conduct, and the lack of sufficient competent resources in key roles at the organization.

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

Our revenues may depend on our customers' receipt of adequate reimbursement from private insurers and government sponsored healthcare programs.

Political, economic, and regulatory influences continue to change the healthcare industry in the United States. The ability of hospitals to pay fees for our products will partially depend on the extent to which reimbursement for the costs of such materials and related treatments will continue to be available from private health coverage insurers and other similar organizations. We may have difficulty gaining market acceptance for the products we sell if third-party payers do not provide adequate coverage and reimbursement to hospitals.

Major third-party payers of hospitals, such as private healthcare insurers, periodically revise their payment methodologies based, in part, upon changes in government sponsored healthcare programs. We cannot predict these periodic revisions with certainty, and such revisions may result in stricter standards for reimbursement of hospital charges for certain specified products, potentially adversely impacting our business, results of operations, and financial conditions when we start receiving reimbursement from third party payers.

The sales of our products and services will depend in part on the availability of reimbursement by third-party payers, such as government health administration authorities, private health insurers and other organizations. Third-party payers often challenge the price and cost-effectiveness of medical treatments and services. Governmental approval of health care products does not guarantee that these third-party payers will pay for the products. Even if third-party payers do accept our products and services, the amounts they pay may not be adequate to enable us to realize a profit. Legislation and regulations affecting the pricing of therapies may change before our products and services are approved for marketing, and any such changes could further limit reimbursement, if any.

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 the indications for 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 in the cardiac electrophysiology, or EP, space include known medical devices such as pacemakers, electrocardiogram, or ECG, systems and cardiac catheters, but also laboratory equipment such as intracardiac mapping systems and fluoroscopy systems (similar to x-ray in real time). The EP market includes large medical device companies such as Medtronic, Plc., Abbott Laboratories, Biosense-Webster (J&J) and Boston Scientific Corp.

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.

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

Because we have historically obtained certain components globally, some of which are uniquely customized, from limited sources, we are subject to significant supply and pricing risks and exposed to multiple potential sources of component shortages. Many components, including those that are available from multiple sources, are at times subject to industry-wide shortages and significant commodity pricing fluctuations that could materially adversely affect our financial condition and operating results. We may source alternative parts to mitigate the challenges caused by these shortages, but there is no guarantee we may be able to continually do so as we scale production to meet our growth targets. The unavailability of any component or supplier could result in production delays, idle manufacturing facilities, product design changes and loss of access to important technology and tools for producing and supporting our products, as well as impact our capacity production. Our suppliers may not be willing or able to sustainably meet our timelines or our cost, quality and volume needs, or to do so may cost us more, which may require us to replace them with other sources. If our supply of components for a new or existing product continues to be delayed or constrained for any reason, including if an outsourcing partner delayed shipments of completed products to us or additional time is required to obtain sufficient quantities from the original source, or if we have to identify and obtain sufficient quantities from an alternative source, then our financial condition and operating results could be materially adversely affected. In addition, the continued availability of these components at acceptable prices, or at all, can be affected for any number of reasons, including if suppliers decide to concentrate on the production of common components or components for other customers instead of components customized to meet our requirements. While we have entered into agreements for the supply of many components, there can be no assurance that we will be able to extend or renew these agreements on similar terms, or at all. Component suppliers may suffer from poor financial conditions, which can lead to business failure for the supplier or consolidation within a particular industry, further limiting our ability to obtain sufficient quantities of components on commercially reasonable terms. While we believe that we will be able to secure additional or alternate sources or develop our own replacements for most of our components, there is no assurance that we will be able to do so quickly or at all.

Additionally, we may be unsuccessful in our continuous efforts to negotiate with existing suppliers to obtain cost reductions and avoid unfavorable changes to terms, source less expensive suppliers for certain parts and redesign certain parts to make them less expensive to produce. Any of these occurrences may harm our business, prospects, financial condition and operating results.

If hospitals, physicians and patients do not accept our current and future products or if the market for indications for which any product candidate is approved is smaller than expected, we may be unable to generate significant revenue, if any.

Even when any of our product candidates obtain regulatory approval, they may not gain market acceptance among hospitals, physicians, patients, and third-party payers. Physicians may decide not to recommend our treatments for a variety of reasons including:

- timing of market introduction of competitive products;
- demonstration of clinical safety and efficacy compared to other products;
- cost-effectiveness;
- limited or no coverage by third-party payers;
- convenience and ease of administration;

- prevalence and severity of adverse side effects;
- restrictions in the label of the drug;
- other potential advantages of alternative treatment methods; and
- ineffective marketing and distribution support of our products.

If any of our product candidates are approved but fail to achieve market acceptance or such market is smaller than anticipated, we may not be able to generate significant revenue and our business would suffer.

The recent coronavirus, or COVID-19, outbreak adversely affected our financial condition and results of operations and we cannot provide any certainty as to whether there will be future impacts from COVID-19 or another pandemic.

The COVID-19 outbreak adversely affected our financial condition and results of operations. The impact of the outbreak of COVID-19 on the businesses and the economy in the United States and the rest of the world was significant. The extent to which the COVID-19 outbreak will continue to impact business and the economy is highly uncertain and cannot be predicted, and there can be no guarantee that a future pandemic will not have similar or worse impacts. Accordingly, we cannot predict the extent to which our financial condition and results of operation will be affected.

In addition, we are uncertain of the full effect the pandemic will have on us for the longer term since the scope and duration of the pandemic is unknown, and evolving factors such as the level and timing of the distribution of efficacious vaccines across the world and the extent of any resurgences of the virus or emergence of new variants of the virus, such as the Delta variant and the Omicron variant, will impact the stability of economic recovery and growth. We may experience long-term disruptions to our operations resulting from changes in government policy or guidance; quarantines of employees, customers and suppliers in areas affected by the pandemic; and closures of businesses or manufacturing facilities critical to its business.

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 products 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 U.S., Europe, China and elsewhere; and
- business interruptions resulting from geo-political actions, including war and terrorism.

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

The impact of the military action in Ukraine, and the actions that have been and could be taken by other countries, including new and stricter sanctions and actions taken in response to such sanctions, have affected, and may continue to affect, our business and results of operations, including our supply chain.

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

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

If the third parties on which we rely for the conduct of our clinical trials and results do not perform our clinical trial activities in accordance with good clinical practices and related regulatory requirements, we may be unable to obtain regulatory approval for or commercialize our product candidates.

We may use independent clinical investigators and other third-party service providers to conduct and/or oversee the clinical trials of our product candidates.

FDA requires us and our clinical investigators to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate, and that the trial participants are adequately protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the respective trial plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of our product candidates or result in enforcement actions against us.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements.

We are exposed to potential product liability risks inherent in the design, manufacturing, and marketing of our products. These matters are subject to many uncertainties, and outcomes are not predictable. In addition, we may incur significant legal expenses regardless of whether we are found to be liable.

While we maintain product liability insurance, there can be no assurance that such coverage is sufficient to cover all product liabilities that we may incur. We are not currently subject to any product liability proceedings, and we have no reserves for product liability disbursements. However, we may incur material liabilities relating to

product liability claims in the future, including product liability claims arising out of the usage and delivery of our products. Should we incur product-related liabilities exceeding our insurance coverage, we would be required to use available cash or raise additional cash to cover such liabilities.

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

As of December 31, 2022, we had net operating loss carryforwards, or NOLs, of approximately \$54.5 million for federal income tax purposes and \$47.8 million for state income tax purposes. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. These NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or IRC, 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 completed an IRC Section 382 analysis regarding the limitation of net operating losses through December 31, 2020 and determined that ownership changes occurred in May 2020. Management believes further ownership changes occurred during each of the years ended December 31, 2022 and 2021. Accordingly, utilization of our NOLs is subject to an annual limitation for federal tax purposes under IRC Section 382. Due to the changes in control, we estimated that all of our \$54.5 million federal NOLs are effectively eliminated, according to IRC Section 382. In addition, \$40.8 million of our \$47.8 million in state NOLs were also eliminated. As a result of these eliminations, our federal and state NOLs were reduced to zero and \$6.9 million, respectively, before taking into consideration the valuation allowance.

Risks Related to Government Regulation and our Industry

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

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

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

We have entered into a Settlement Agreement with the Department of Justice, or DOJ, and agreements with the participating states, resolving a DOJ civil investigation concerning certain Covered Conduct (as defined in the Settlement Agreement), and the Office of Inspector General, or OIG, has agreed, conditioned upon our full payment of amounts owed in the Settlement Agreement, and in consideration of our obligations under a Corporate Integrity Agreement, to release our permissive exclusion rights and refrain from instituting any administrative action seeking to exclude us from participating in Medicare, Medicaid, or other federal health care programs as a result of the Covered Conduct. The Corporate Integrity Agreement has a five-year term and imposes monitoring, reporting, certification, documentation, oversight, screening, and training obligations on us, including the hiring of a compliance officer and independent review organization; however, the OIG has agreed that we are not subject to the terms of the Corporate Integrity Agreement for so long as we do not carry on the legacy Ra Medical business or use the related business assets post our merger with Catheter.

Some devices known as “510(k)-exempt” devices can be marketed without prior marketing clearance or approval from the FDA. In addition to the “general controls,” Class II medical devices are also subject to “special controls,” including, in many cases, adherence to a particular guidance document and compliance with the performance standard. As a Class II, 510(k)-cleared device, our VIVO product is 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 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. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearances or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which may have a material adverse effect on our business, financial condition, and results of operations.

The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices, and product quality management. For example, as discussed above, on December 28, 2020, we entered into a Settlement Agreement with the DOJ to resolve a civil False Claims Act investigation and related civil action, and in connection with the Settlement Agreement, we also have reached agreements that resolve previously disclosed related investigations conducted by certain state attorneys general. Under the Settlement Agreement, and the agreements with the participating states, we were required to make an initial payment of \$2.5 million, of which we paid \$2.4 million in December 2020 and \$0.1 million in April 2021. We also were required to make a payment of \$5.0 million as a result of the January 2023 merger with Catheter in January 2023, which we made in February 2023. We may be required to make additional payments in the future upon the achievement of revenue targets.

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. On December 28, 2020, we entered into the Settlement Agreement with the DOJ relating to claims under the civil False Claims Act investigation concerning, among other things, whether we marketed and promoted DABRA devices, which we are no longer marketing, for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute. Effective January 2022, we are also required to collect and report information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which may also impact our business and which could have a material adverse effect on our business, financial condition, and results of operations for years after any resolution of these investigations and any resulting claims are resolved.

We may have to make milestone payments under the Settlement Agreement we entered into with the DOJ.

Pursuant to our Settlement Agreement with the DOJ, if during fiscal 2023 or 2024 our revenues exceed \$10 million, we have agreed to pay the United States and certain Medicaid participating states, \$1.0 million for 2023,

and \$1.25 million for 2024, for each corresponding fiscal year where our revenue exceeds \$10 million. Payment must be made within 90 days after the end of the fiscal year.

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 could be impacted by a resurgence of the COVID-19 outbreak or another pandemic, as many patients would be likely to elect or would likely be asked to delay procedures at such a 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 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 VIVO product in the U.S. and certain non-U.S. jurisdictions, it will remain subject to extensive regulatory scrutiny.

Although our VIVO product has received regulatory clearance in the U.S. and certain non-U.S. jurisdictions, it 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.

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

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

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

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

In addition, violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. As disclosed previously, we settled a DOJ civil False Claims Act investigation concerning, among other things, whether we marketed and promoted our DABRA devices for unapproved uses that were not covered by federal healthcare programs. We are no longer marketing DABRA devices.

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 conducted four recent recalls related to our previously marketed DABRA product. We no longer market DABRA, but any government-mandated recall or additional voluntary recall by us of VIVO or another product we market in the future 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, related to our previously marketed DABRA product, that schedules for the adjustment, cleaning, and other maintenance of equipment have not been adequately established, a device master record index was not current, and document control procedures have not been fully established. We responded to the FDA with the corrective measures we are taking and to address the issued identified in the Form 483 and based on this information, the FDA issued to us an Establishment Inspection Report, or EIR, closing out the inspection. All actions are complete, and the final Form 483 report was sent to the FDA on September 25, 2020. We are no longer operating this facility, but the FDA could conduct inspections of our current facilities.

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.

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 our previously marketed DABRA product that we received rose to a level required to be reported to the FDA. At that time, in response, we informed the FDA that we had 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. We no longer market DABRA.

The failure by us to properly identify reportable events or to file timely reports with the FDA can subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

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

Under the FDA medical device reporting regulations, or MDR regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur.

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

In addition, the PPACA and the Medicare Access and CHIP Reauthorization Act of 2015 substantially changed the way healthcare is delivered and financed by both governmental and private insurers. These changes included the creation of demonstration programs and other value-based purchasing initiatives that provide financial incentives for physicians and hospitals to reduce costs. Under the Trump Administration, there were ongoing efforts to modify or repeal all or part of PPACA or take executive action that affects its implementation. Tax reform legislation was passed that includes provisions that impact healthcare insurance coverage and payment such as the elimination of the tax penalty for individuals who do not maintain health insurance coverage (the so-called “individual mandate”). Such actions or similar actions could have a negative effect on the utilization of our products.

On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld a lower court’s determination in *Texas v. Azar*, 4:18-cv-00167, that the individual mandate was unconstitutional and remanded the case to the lower court for further analysis as to whether PPACA as a whole is unconstitutional because the individual mandate is not severable from other provisions of the law. In June 2021, the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the PPACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the PPACA. Thus, the PPACA will remain in effect in its current form. Further, legislative and regulatory changes under the PPACA remain possible, although the federal administration under President Biden has signaled that it plans to build on the PPACA and expand the number of people who are eligible for health insurance under it. It is unclear how future litigation and healthcare measures promulgated by the Biden administration or future administrations will impact the implementation of the PPACA and our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the PPACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

Other healthcare reform legislative changes have also been proposed and adopted in the U.S. since the PPACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013, which, due to subsequent legislative amendments, will stay in effect through 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of the sequester. In January 2013, the

American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

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

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

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 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.

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

After we develop new products or seek to market our products for new approved or cleared indications, we may find limited demand for the product unless government and private third-party payors provide adequate

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

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

We are regulated by federal Anti-Kickback Statutes.

The Federal Anti-Kickback Statute is a provision of the Social Security Act of 1972 that prohibits as a felony offense the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (1) the referral of a patient for items or services for which payment may be made in whole or part under Medicare, Medicaid, or other federal healthcare programs, (2) the furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid, or other federal healthcare programs or (3) the purchase, lease, or order or arranging or recommending the purchasing, leasing or ordering of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The Patient Protection and Affordable Care Act, or PPACA, amended section 1128B of the Social Security Act to make it clear that a person need not have actual knowledge of the statute, or specific intent to violate the statute, as a predicate for a violation. The OIG, which has the authority to impose administrative sanctions for violation of the statute, has adopted as its standard for review a judicial interpretation which concludes that the statute prohibits any arrangement where even one purpose of the remuneration is to induce or reward referrals. A violation of the Anti-Kickback Statute is a felony punishable by imprisonment, criminal fines of up to \$25,000, civil fines of up to \$50,000 per violation, and three times the amount of the unlawful remuneration. A violation also can result in exclusion from Medicare, Medicaid or other federal healthcare programs. In addition, pursuant to the changes of the PPACA, a claim that includes items or services resulting from a violation of the Anti-Kickback Statute is a false claim for purposes of the False Claims Act. We cannot assure that the applicable regulatory authorities will not determine that some of our arrangements with hospitals or physicians violate the federal Anti-Kickback Statute or other applicable laws. An adverse determination could subject us to different liabilities, including criminal penalties, civil monetary penalties and exclusion from participation in Medicare, Medicaid or other health care programs, any of which could have a material adverse effect on our business, financial condition or results of operations.

We are regulated by the federal Stark Law.

The federal Stark Law, 42 U.S.C. 1395nn, also known as the physician self-referral law, generally prohibits a physician from referring Medicare and Medicaid patients to an entity (including hospitals) providing 'designated health services,' if the physician or a member of the physician's immediate family has a 'financial relationship' with the entity, unless a specific exception applies. Designated health services include, among other services, inpatient hospital services, outpatient prescription drug services, clinical laboratory services, certain imaging services (e.g., MRI, CT, ultrasound), and other services that our affiliated hospitals may order for their patients. The prohibition applies regardless of the reasons for the financial relationship and the referral. Like the Anti-Kickback Statute, the Stark Law contains statutory and regulatory exceptions intended to protect certain types of transactions and arrangements. Unlike safe harbors under the Anti-Kickback Statute with which compliance is voluntary, an arrangement must comply with every requirement of a Stark Law exception or the arrangement is in violation of the Stark Law.

Because the Stark Law and implementing regulations continue to evolve and are detailed and complex, while we attempt to structure our relationships to meet an exception to the Stark Law, there can be no assurance that the arrangements entered into by us with affiliated hospitals will be found to be in compliance with the Stark Law, as it ultimately may be implemented or interpreted. The penalties for violating the Stark Law can include the denial of payment for services ordered in violation of the statute, mandatory refunds of any sums paid for such services, and civil penalties of up to \$15,000 for each violation, double damages, and possible exclusion from future participation in the governmental healthcare programs. A person who engages in a scheme to circumvent the Stark Law's prohibitions may be fined up to \$100,000 for each applicable arrangement or scheme.

Some states have enacted statutes and regulations against self-referral arrangements similar to the federal Stark Law, but which may be applicable to the referral of patients regardless of their payer source and which may apply to different types of services. These state laws may contain statutory and regulatory exceptions that are different from those of the federal law and that may vary from state to state. An adverse determination under these state laws and/or the federal Stark Law could subject us to different liabilities, including criminal penalties, civil monetary penalties and exclusion from participation in Medicare, Medicaid or other health care programs, any of which could have a material adverse effect on our business, financial condition or results of operations.

We must comply with Health Information Privacy and Security Standards.

HIPAA and regulations thereunder contain detailed requirements concerning the use and disclosure of individually identifiable patient health information by various healthcare providers, such as medical groups. HIPAA covered entities must implement certain administrative, physical, and technical security standards to protect the integrity, confidentiality and availability of certain electronic health information received, maintained, or transmitted. HIPAA also implemented standard transaction code sets and standard identifiers that covered entities must use when submitting or receiving certain electronic healthcare transactions, including billing and claim collection activities. Violations of the HIPAA privacy and security rules may result in civil and criminal penalties, including a tiered system of civil money penalties that range from \$100 to \$50,000 per violation, with a cap of \$1.5 million per year for identical violations. A HIPAA covered entity must also promptly notify affected individuals where a breach affects more than 500 individuals and report breaches affecting fewer than 500 individuals annually. State attorneys general may bring civil actions on behalf of state residents for violations of the HIPAA privacy and security rules, obtain damages on behalf of state residents, and enjoin further violations.

Many states also have laws that protect the privacy and security of confidential, personal information, which may be similar to or even more stringent than HIPAA. Some of these state laws may impose fines and penalties on violators and may afford private rights of action to individuals who believe their personal information has been misused. We expect increased federal and state privacy and security enforcement efforts.

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

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

In addition, California has enacted the CCPA which came into effect on January 1, 2020. Pursuant to the CCPA, certain businesses are required, among other things, to make certain enhanced disclosures related to California residents regarding the use or disclosure of their personal information, allow California residents to opt-out of certain uses and disclosures of their personal information without penalty, provide Californians with other choices related to personal data in our possession, and obtain opt-in consent before engaging in certain uses of personal information relating to Californians under the age of 16. The California Attorney General may seek

substantial monetary penalties and injunctive relief in the event of our non-compliance with the CCPA. The CCPA also allows for private lawsuits from Californians in the event of certain data breaches. Aspects of the CCPA remain uncertain, and we may be required to make modifications to our policies or practices in order to comply.

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

A cyber security incident could cause a violation of HIPAA, breach of customer and patient privacy, or other negative impacts.

We rely extensively on our information technology (or IT) systems to manage scheduling and financial data, communicate with hospitals and their patients, vendors, and other third parties, and summarize and analyze operating results. In addition, we have made significant investments in technology, including the engagement of a third-party IT provider. A cyber-attack that bypasses our IT security systems could cause an IT security breach, a loss of protected health information, or other data subject to privacy laws, a loss of proprietary business information, or a material disruption of our IT business systems. This in turn could have a material adverse impact on our business and result of operations. In addition, our future results of operations, as well as our reputation, could be adversely impacted by theft, destruction, loss, or misappropriation of public health information, other confidential data, or proprietary business information.

Computer malware, viruses, and hacking and phishing attacks by third parties have become more prevalent in our industry and may occur on our systems in the future. Because techniques used to obtain unauthorized access to or sabotage systems change frequently and generally are not recognized until successfully launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. As cyber-security threats develop and grow, it may be necessary to make significant further investments to protect data and infrastructure. If an actual or perceived breach of our security occurs, (i) we could suffer severe reputational damage adversely affecting customer or investor confidence, (ii) the market perception of the effectiveness of our security measures could be harmed, (iii) we could lose potential sales and existing customers, our ability to deliver our services or operate our business may be impaired, (iv) we may be subject to litigation or regulatory investigations or orders, and (v) we may incur significant liabilities. Our insurance coverage may not be adequate to cover the potentially significant losses that may result from security breaches.

We must comply with environmental and Occupational Safety and Health Administration Regulations.

We are subject to federal, state and local regulations governing the storage, use and disposal of waste materials and products. 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. Although we believe that our safety procedures for storing, handling and disposing of these materials and products comply with the standards prescribed by law and regulation, we cannot eliminate the risk of accidental contamination or injury from those hazardous materials. In the event of an accident, we could be held liable for any damages that result and any liability could exceed the limits or fall outside the coverage of our insurance coverage,

which we may not be able to maintain on acceptable terms, or at all. We could incur significant costs and attention of our management could be diverted to comply with current or future environmental laws and regulations. Federal regulations promulgated by the Occupational Safety and Health Administration impose additional requirements on us, including those protecting employees from exposure to elements such as blood-borne pathogens. We cannot predict the frequency of compliance, monitoring, or enforcement actions to which we may be subject as those regulations are being implemented, which could adversely affect our operations.

We must comply with a range of other Federal and State Healthcare Laws.

We are also subject to other federal and state healthcare laws that could have a material adverse effect on our business, financial condition or results of operations. The Health Care Fraud Statute prohibits any person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, which can be either a government or private payer plan. Violation of this statute, even in the absence of actual knowledge of or specific intent to violate the statute, may be charged as a felony offense and may result in fines, imprisonment, or both. The Health Care False Statement Statute prohibits, in any matter involving a federal health care program, anyone from knowingly and willfully falsifying, concealing or covering up, by any trick, scheme or device, a material fact, or making any materially false, fictitious or fraudulent statement or representation, or making or using any materially false writing or document knowing that it contains a materially false or fraudulent statement. A violation of this statute may be charged as a felony offense and may result in fines, imprisonment or both. Under the Civil Monetary Penalties Law of the Social Security Act, a person (including an organization) is prohibited from knowingly presenting or causing to be presented to any United States officer, employee, agent, or department, or any state agency, a claim for payment for medical or other items or services where the person knows or should know (a) the items or services were not provided as described in the coding of the claim, (b) the claim is a false or fraudulent claim, (c) the claim is for a service furnished by an unlicensed physician, (d) the claim is for medical or other items or service furnished by a person or an entity that is in a period of exclusion from the program, or (e) the items or services are medically unnecessary items or services. Violations of the law may result in penalties of up to \$10,000 per claim, treble damages, and exclusion from federal healthcare programs.

In addition, the OIG may impose civil monetary penalties against any physician who knowingly accepts payment from a hospital (as well as against the hospital making the payment) as an inducement to reduce or limit medically necessary services provided to Medicare or Medicaid program beneficiaries. Further, except as permitted under the Civil Monetary Penalties Law, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider of Medicare or Medicaid payable items or services may be liable for civil monetary penalties of up to \$10,000 for each wrongful act.

In addition to the state laws previously described, we may also be subject to other state fraud and abuse statutes and regulations if we expand our operations nationally. Many states have adopted a form of anti-kickback law, self-referral prohibition, and false claims and insurance fraud prohibition. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Generally, state laws reach to all healthcare services and not just those covered under a governmental healthcare program. A determination of liability under any of these laws could result in fines and penalties and restrictions on our ability to operate in these states. we cannot assure that our arrangements or business practices will not be subject to government scrutiny or be found to violate applicable fraud and abuse laws.

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.

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

In addition to current and proposed economic sanctions on Russia, which may increase or continue for an indefinite period of time as a result of Russia's invasion of Ukraine, the U.S. has imposed or proposed new or higher tariffs on certain products exported by a number of U.S. trading partners, including China, Europe, Canada, and Mexico. In response, many of those trading partners, including China, have imposed or proposed new or higher tariffs on American products. Continuing changes in government trade policies create a heightened risk of further increased tariffs that impose barriers to international trade.

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

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 VIVO, 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 VIVO or any new devices that we market could have a material adverse effect on our business, financial condition, and results of operations.

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

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

license from or license to third parties and are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, and the like, although we are unaware of any such defects that we believe are of material importance. If we or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

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

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

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

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

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.

Risks Related to Ownership of Our Common Stock

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

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

- our failure to increase the sales of our products;

- the failure by our customers to obtain adequate reimbursements or reimbursement levels that would be sufficient to support product sales to our customers and pricing of our products to support revenue projections;
- unanticipated serious safety concerns related to the use of our products;
- changes in our organization;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our future growth;
- the size and growth of our target markets;
- actual or anticipated variations in quarterly operating results;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including shareholder litigation, government actions or litigation related to intellectual property;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- any delay in any regulatory filings for our future products and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such products;
- adverse regulatory decisions, including failure to receive regulatory approval of our future products, failure to maintain regulatory approval for our existing products or failure to obtain regulatory approval for additional indications for our existing products;
- changes in laws or regulations applicable to our products;
- adverse developments concerning our suppliers or distributors;
- our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices;
- our inability to establish and maintain collaborations if needed;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of large blocks of our common stock including sales by our executive officers and directors;
- trading volume of our common stock;
- limited "public float" in the hands of a small number of persons whose sales or lack of sales of our common stock could result in positive or negative pricing pressure on the market price for our common stock;
- additions or departures of key scientific or management personnel;
- changes in accounting practices;

- ineffectiveness of our internal controls;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

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

The ownership of our common stock is highly concentrated, and may become more so in the near future, which may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the company stock price to decline.

David A. Jenkins, our Executive Chairman of the Board, and his affiliates and family members, beneficially own or control, in the aggregate, approximately 24.6% of our outstanding shares of common stock. In addition, if the outstanding shares of our Series X convertible preferred stock, or Series X Preferred Stock, qualify to convert into common stock on or after July 9, 2024, which will occur if we satisfy the initial listing standards of the New York American or another securities exchange or are delisted from the NYSE American, it is possible that David A. Jenkins and affiliates and family members will beneficially own more than 50% of our outstanding common stock. Accordingly, these persons have a substantial influence, and in the future may have de facto control, over the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control, even if such a change of control would benefit the other stockholders. This significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise, and may adversely affect the liquidity of our common stock. In addition, it is possible that after July 9, 2024, we will satisfy the controlled company provisions of the NYSE American, in which case the combined company would not be required to satisfy all of the corporate governance requirements of the NYSE American, including without limitation, requirements that a majority of the Board be independent and that the combined company have independent compensation and nominating committees. See "—In the near future, we may be a "controlled company" within the meaning of NYSE American rules and, as a result, we may qualify for, and may choose to rely on, exemptions from certain corporate governance requirements".

In the future, we may be a "controlled company" within the meaning of NYSE American rules and, as a result, we may qualify for, and may choose to rely on, exemptions from certain corporate governance requirements.

If the outstanding shares of our Series X Preferred Stock qualify to convert into common stock on or after July 9, 2024, which will occur if we satisfy the initial listing standards of the New York American or another securities exchange or are delisted from the NYSE American, it is possible that David A. Jenkins and affiliates will beneficially own more than 50% of our outstanding common stock. In that case, the Company will be a "controlled company" as defined in Section 801 of the NYSE American Company Guide. Under the NYSE American rules, a company of which more than 50% of the voting power is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain NYSE American corporate governance requirements, including:

- the requirement that a majority of the Company's board of directors consists of independent directors;
- the requirement that the Company's directors must be nominated by a Nominating Committee composed by a majority of independent directors; and
- the requirement that executive compensation must be determined or recommended to the Company's board of directors for determination, by a Compensation Committee comprised of independent directors or by a majority of the independent directors on the Company's board.

Accordingly, if we qualify as a controlled company, we will likely elect to be treated as such and our stockholders will not be afforded the same protections generally as stockholders of other NYSE American-listed companies.

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, or IPO, which would mean that we would lose our emerging growth company status at the beginning of 2024, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least \$1.235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

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

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

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 20, 2023, we had 2,492,558 outstanding shares of our common stock and outstanding options to purchase up to 990 shares of our common stock. At our special meeting of stockholders held on March 21, 2023, our stockholders approved the conversion of 1,993,627 shares of our Series X Preferred Stock into 1,993,627 shares of our common stock. The remaining 12,655,965 shares of Series X Preferred Stock may be convertible into 12,655,965 shares of our common stock on or after July 9, 2024, in the event that we meet the initial listing standards of the NYSE American or another securities exchange or have been delisted from the NYSE American. Also at the special meeting, our stockholders authorized the issuance of 497,908 shares of our common stock and 7,203 shares of our convertible Series A preferred stock, which are convertible into up to 4,501,060 shares of our common stock, as well as the issuance of warrants described below.

In connection with our February 2022 equity offering, July 2022 warrant repricing and 2020 equity offerings, we issued warrants to investors and our placement agents and, in connection with the sale of the Dermatology Business in 2021, we issued a warrant to the broker. In connection with our January 2023 warrant repricing, we issued a warrant to purchase up to 331,608 shares of common stock at \$4.00 per share. Pursuant to a private

placement in January 2023, as approved by the stockholders at our March 21, 2023 special meeting of stockholders, we also issued warrants to purchase up to 9,998,186 shares of common stock at a purchase price of \$3.00 per share. We had an aggregate of 11,148,855 warrants outstanding as of March 23, 2023. We have an effective shelf registration statement and had an ATM offering thereunder until January 18, 2022 and a second effective ATM offering thereunder from September 2, 2022 through October 7, 2022. During the year ended December 31, 2022, we sold 1,071,240 shares of common stock under the second ATM offering. No shares were sold under the first ATM offering during 2022. In addition, pursuant to our 2018 Equity Incentive Plan, or 2018 Plan, equity incentive awards representing up to an aggregate of 8,552 shares of our common stock were available for issuance to our employees, directors and consultants as of December 31, 2022. The 2018 Employee Stock Purchase Plan, or ESPP, was paused after the end of the contribution period in May 2022. No shares were available for sale under the ESPP as of December 31, 2022. Both the 2018 Plan and the ESPP include an “evergreen” provision that provides for an annual increase in the number of shares available for future grant or sale each year, as applicable, as determined by our board of directors. During the first quarter of 2020, we adopted the 2020 Inducement Equity Incentive Plan, or the 2020 Plan, for the purpose of attracting, retaining and incentivizing employees in furtherance of our success. As of December 31, 2022, 181 shares were available for issuance under the 2020 Plan. We assumed options to purchase 753,694 shares in connection with the merger with Catheter. If these additional shares of common stock are issued and sold, or if it is perceived that they will be sold, in the public market, this could result in additional dilution and the trading price of our common stock could decline.

Further, SEC regulations limit the amount of funds we can raise during any 12-month period pursuant to our shelf registration statement on Form S-3. We are currently subject to General Instruction I.B.6 to Form S-3, or the Baby Shelf Rule, and the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates. We are currently limited by the Baby Shelf Rule as of the filing of this Annual Report, until such time as our public float exceeds \$75 million. If we are required to file a new registration statement on another form, we may incur additional costs and be subject to delays due to review by SEC staff.

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

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

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

- our board of directors is divided into three classes serving staggered three-year terms, such that not all members of the board is elected at one time, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at an annual or special meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairperson of the board of directors, the chief executive officer or president (in the absence of a chief executive officer) or a majority vote of our board of directors, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our certificate of incorporation relating to the issuance of preferred stock and management of our business or our bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt;
- the ability of our board of directors, by majority vote, to amend our bylaws, which may allow our board of directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend our bylaws to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

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

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

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

Our certificate of incorporation further provides that the federal district courts of the U.S. is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find either

exclusive forum provision in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to the continued listing requirements of the NYSE American. If we are unable to comply with such requirements, our common stock would be delisted from the NYSE American, which would limit investors' ability to effect transactions in our common stock and subject us to additional trading restrictions.

Shares of our common stock are currently listed on the NYSE American. In order to maintain our listing, we must maintain certain share prices, financial and share distribution targets, including maintaining a minimum amount of stockholders' equity and a minimum number of public stockholders. In addition to these objective standards, the NYSE American may delist the securities of any issuer if, in its opinion, the issuer's financial condition and/or operating results appear unsatisfactory; if it appears that the extent of public distribution or the aggregate market value of the security has become so reduced as to make continued listing on the NYSE American inadvisable; if the issuer sells or disposes of principal operating assets or ceases to be an operating company; if an issuer fails to comply with the NYSE American's listing requirements; if an issuer's common stock sells at what the NYSE American considers a "low selling price" (generally trading below \$0.20 per share for an extended period of time); or if any other event occurs or any condition exists which makes continued listing on the NYSE American, in its opinion, inadvisable. On August 31, 2022, we received a deficiency letter from the NYSE American indicating that we were not in compliance with Section 1003(f)(v) of the NYSE American Company Guide, because shares of our common stock have been selling for a low price per share for a substantial period time. We have since regained compliance with this Section, but there can be no guarantee that our stock price will not fall below the required levels again.

If the NYSE American delists our shares of common stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect our common stock would qualify to be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage;
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." Because our shares of common stock are listed on the NYSE American, our shares of common stock qualify as covered securities under such statute. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. If we were no longer listed on the NYSE American, our securities would not be covered securities and we would be subject to regulation in each state in which we offer our securities.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our manufacturing, inventory and order fulfillment activities are performed in our approximate 2,000 square foot headquarters facility in Fort Mill, South Carolina under a lease that expires in January 2026. We conduct administrative and accounting activities in an approximate 1,100 square foot facility in Budd Lake, New Jersey under a lease that expires in December 2024.

We believe that our existing facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

ITEM 3. LEGAL PROCEEDINGS

Securities Class Action

On June 7, 2019, a putative securities class action complaint captioned *Derr v. Ra Medical Systems, Inc., et al*, (Civil Action no. 19CV1079 LAB NLS) was filed in the U.S. District Court for the Southern District of California against the Company, certain current and former officers and directors, and certain underwriters of the Company's initial public offering. Following the appointment of a lead plaintiff and the filing of a subsequent amended complaint, the lawsuit alleges that the defendants made material misstatements or omissions in the Company's registration statement in violation of Sections 11 and 15 of the Securities Act of 1933, or the Securities Act, and between September 27, 2018 and November 27, 2019, inclusive, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, or the Exchange Act. On March 11, 2020, lead plaintiffs voluntarily dismissed the underwriter defendants without prejudice. On March 13, 2020, defendants filed a motion to dismiss the amended complaint. On March 24, 2021, the court issued an order granting defendants' motion to dismiss claims under the Securities Act in full and certain claims under the Exchange Act and denying defendants' motion to dismiss certain Exchange Act claims. Plaintiffs filed their second amended complaint on April 19, 2021, realleging the Securities Act claims and certain of the previously dismissed Exchange Act claims. On June 10, 2021, defendants moved to dismiss the second amended complaint. On November 12, 2021, following a private settlement mediation with the lead plaintiffs, the parties executed a stipulation of settlement that resolved the claims asserted in the securities class action. The settlement provides for a payment to the plaintiff class of \$10.0 million. On March 18, 2022, the Company paid approximately \$0.6 million towards the settlement to satisfy its self-insured retention/deductible. The Company's insurers paid the remainder of the settlement. The proposed settlement required both preliminary and final approval by the court. On February 11, 2022, the court granted preliminary approval of the settlement, scheduled a hearing on final approval of the settlement and denied the pending motion to dismiss without prejudice. On May 2, 2022, plaintiffs filed a motion for final approval of the settlement and plan of allocation, and lead counsel filed a motion for an award of attorneys' fees and reimbursement of litigation expenses. On September 23, 2022, the court granted final approval of the settlement, certified the settlement class, granted in part lead counsel's motion for an award of attorneys' fees and reimbursement of litigation expenses, dismissed plaintiffs' claims with prejudice, and entered final judgment.

Shareholder Derivative Litigation

On October 1, 2019, a shareholder derivative complaint captioned *Noel Borg v. Dean Irwin, et al* (Civil Action no. 1:99-cv-09999) was filed in the U.S. District Court for the District of Delaware against certain current and former officers and directors, purportedly on behalf of the Company, which is named as a nominal defendant in the action. The complaint alleges breaches of fiduciary duty, unjust enrichment, waste, and violations of Section 14(a) of the Exchange Act. On October 21, 2019, pursuant to the parties' stipulation, the court stayed the derivative lawsuit until the related class action is resolved. On November 10, 2022, the plaintiff filed a notice voluntarily dismissing the case without prejudice.

Settlement Agreements with the Department of Justice and Participating States

On December 28, 2020, the Company entered into a settlement agreement with the U.S., acting through the DOJ and on behalf of the OIG, and other settlement agreements with certain state attorneys general, collectively the Settlement Agreements, to resolve investigations and a related civil action concerning its marketing of the DABRA laser system and DABRA-related remuneration to certain physicians. Pursuant to the terms of the Settlement Agreements, (a) if the Company's revenue exceeds \$10 million in any of fiscal years 2021-2024, the Company also is required to pay for the corresponding year: \$500,000 for 2021, \$750,000 for 2022, \$1 million for 2023, and \$1.25 million for 2024; (b) if the Company is acquired or is otherwise involved in a change in control transaction before the end of 2024, the Company was required to pay an additional settlement amount of \$5 million, plus 4% of the value attributed to the Company in the transaction, so long as the attributed value is in excess of \$100 million, with the total change in control payment never to exceed \$28 million; and (c) if the Company's obligations under the Settlement Agreement are avoided by bankruptcy, the U.S. may rescind the releases and bring an action against the Company in which the Company agrees is not subject to an automatic stay, is not subject to any statute of limitations, estoppel or laches defense, and is a valid claim in the amount of \$56 million, minus any prior change in control payments. As a result of the merger with Catheter Precision, Inc., the Company made payments of \$4.7 million and \$0.3 million to the DOJ and participating states, respectively, in February 2023.

Filing of Complaint

On September 29, 2022, a purported stockholder of the Company filed a complaint captioned *David Nguyen v. Ra Medical Systems, Inc. et al.* (Civil Action no. 3:22-cv-01470-BEN-MSB) in the U.S. District Court for the Southern District of California against us and our current directors. The complaint alleges violations of Sections 14(a) and 20(a) of the Exchange Act based on alleged deficiencies in our preliminary proxy, filed with the SEC on September 23, 2022. On February 7, 2023, plaintiff filed a notice voluntarily dismissing the case without prejudice.

Other Litigation

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II — FINANCIAL INFORMATION

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

Market Information and Holders

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

On March 23, 2023, the last reported sales price of our common stock was \$1.42 and, according to our transfer agent, as of March 23, 2023, there were 57 record holders of our common stock. The actual number of stockholders is greater than the number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust or by other entities.

Dividend Policy

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

None.

Recent Repurchases of Equity Securities

None.

ITEM 6. [Reserved]

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

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including the Risk Factors contained in Item 1A, before making an investment decision. The risks and uncertainties described in this Annual Report on Form 10-K may not be the only ones we face. If any of the risks actually occur, our business, financial condition, operating results, cash flows and prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose part or all of your investment. Refer to the Current Report on Form 8-K filed on March 28, 2023 for management's discussion and analysis of financial condition and results of operations for Catheter Precision, Inc.'s historical financial results.

Overview

Ra Medical Systems, Inc., or Ra Medical, was incorporated in Delaware in July 2018. Ra Medical was initially formed to develop, commercialize and market its advanced excimer laser-based platform for use in the treatment of vascular and dermatological immune-mediated inflammatory diseases.

On January 9, 2023, Ra Medical entered into the Amended and Restated Agreement and Plan of Merger, or the Merger Agreement, with Catheter Precision, Inc., or Catheter, a privately held Delaware corporation. Under the terms of the Merger Agreement, Catheter became a wholly owned subsidiary of Ra Medical, together referred to as the Company, in a stock-for-stock merger transaction, or the Merger.

Pre-Merger Operations

Prior to the Merger, Ra Medical owned intellectual property related to an advanced excimer laser-based platform for use in the treatment of vascular immune-mediated inflammatory diseases. The Destruction of Arteriosclerotic Blockages by laser Radiation Ablation, or DABRA, laser and single-use catheter, together referred to as the DABRA Excimer Laser System or DABRA, was developed as a tool in the treatment of Peripheral Artery Disease which commonly occurs in the legs. Ra Medical also previously marketed the Pharos laser which was used to treat proliferative skin conditions. Ra Medical completed the sale of its Pharos laser business, or Dermatology Business, to STRATA Skin Sciences, Inc. on August 16, 2021. Accordingly, the financial information and results of operations of the Dermatology Business have been presented as discontinued operations for the year ended December 31, 2021.

As previously reported, the board of directors approved a reduction in force, or RIF, effective June 6, 2022, under which approximately 65% of Ra Medical's full-time employees were immediately terminated and provided one-time severance payments totaling approximately \$0.6 million. In August and September 2022, an additional 20% of Ra Medical's employees were terminated and provided one-time severance payments totaling approximately \$0.3 million. The purpose of the RIF was to preserve capital with the goal of maximizing the opportunities available to Ra Medical during the board of directors' review of strategic alternatives.

As a result of the RIF and the board of directors' review of strategic alternatives, Ra Medical paused all engineering activities in June 2022. On July 5, 2022, Ra Medical announced the receipt of FDA 510(k) clearance for the DABRA 2.0 catheter as part of the DABRA Excimer Laser System. This catheter includes a braided over jacket to make the catheter more robust and more kink-resistant when navigating tortuous anatomy. This catheter also has a six-month shelf life as a result of multiple design and manufacturing remediations implemented to address prior limitations. Ra Medical has ceased marketing the DABRA Excimer Laser System and does not intend to commercialize the DABRA 2.0 catheter.

As previously reported, Ra Medical's strategy was to pursue an atherectomy indication for use, which the FDA defines to include a prespecified improvement in luminal patency. Ra Medical received an Investigational Device Exemption, or IDE, approval in January 2020, and the study was approved for up to 10 clinical sites and 100 subjects. In February 2022, the FDA approved a protocol amendment, raising the enrollment limit from a maximum of 100 subjects to 125 subjects.

On June 6, 2022, Ra Medical ceased enrollment in the atherectomy clinical study at 108 subjects, with the intent to satisfy the FDA's data requirements to support an atherectomy indication by completing the six-month follow-up by the end of 2022 or early 2023. However, due to the Merger, Ra Medical closed all clinical sites subsequent to the Merger in January 2023, and it has no plans to pursue the atherectomy indication with the FDA.

Post-Merger Operations

Looking forward, we do not expect to use our legacy DABRA-related assets or continue Ra Medical's legacy lines of business, but instead expect to shift the focus of our operations to Catheter's product lines. Accordingly, our current activities primarily relate to Catheter's historical business, which comprises the design, manufacture and sale of new and innovative medical technologies focused in the field of cardiac electrophysiology, or EP.

Our primary product is the View into Ventricular Onset System or VIVO™ System ("VIVO" or "VIVO System"). We are focused on the design, market development and usage adoption of our VIVO System by cardiac electrophysiologists to enhance their ability to diagnose and treat cardiac arrhythmias. We have completed development, received regulatory clearance, and initiated sales of the VIVO System in the U.S. and Europe.

Our business strategy is to become the leading medical imaging company in the field of cardiac electrophysiology, and we are dedicated to developing and delivering electrophysiology products to provide patients, hospitals, and physicians with novel technologies and solutions to improve the lives of patients with cardiac arrhythmias. We aim to establish VIVO as an integral tool used by cardiac electrophysiologists during ablation treatment of ventricular arrhythmias by reducing procedure time and patient complications and increasing procedural success.

We have been cleared to label the VIVO System with the CE Mark in the EU and certain other countries. The CE Mark designation, which affirms the product's conformity with European health, safety, and environmental protection standards, allows us to market that product in countries that are members of the EU and the European Free Trade Association. Catheter has commenced limited sales of the VIVO System in Europe and the UK through independent distributors. Catheter's international distributors are supported by two EU based full time and one part time employee.

We have received United States Food and Drug Administration, or FDA, clearance to market and promote the VIVO System in the United States as a pre-procedure planning tool for patients with structurally normal hearts undergoing ablation treatment for idiopathic ventricular arrhythmias. VIVO allows for the acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician. We began a limited commercial launch of VIVO in 2021 and to date, VIVO has been utilized in more than 850 procedures in the U.S. and EU by over 30 physicians, with no reported device-related complications.

LockeT, a suture retention device, is a sterile, Class I product that was registered with the FDA in February 2023, at which time we began initial shipments to distributors. LockeT is indicated for wound healing by distributing suture tension over a larger area in the patient in conjunction with a figure of eight suture closure, and it is intended to temporarily secure sutures and aid clinicians in locating and removing sutures efficiently.

Clinical studies for LockeT are planned to begin during 2023. These studies are planned to show the product's effectiveness and benefits, including faster wound closure, earlier ambulation, potentially leading to early hospital discharge, and cost analysis. This data is intended to provide crucial data for marketing and to expand our indications for use with the FDA.

Prior to 2018, Catheter marketed the Amigo® Remote Catheter System, or the Amigo or Amigo System, which provides for accurate positioning, manipulation, and stable control of catheters for use by electrophysiologists in the diagnosis and treatment of abnormal heart rhythms known as cardiac arrhythmias. Amigo was designed for use during the ablation procedure, to allow the physician to remotely navigate standard commercially available catheters, with stability and precision, and maintains catheter locations within the heart while decreasing radiation exposure and avoiding long periods standing bedside in heavy protective lead aprons. Amigo was used in over 2,000 procedures in the U.S. and Europe and was well received by leading experts in the field of EP. We own the intellectual property related to Amigo, and this product is under consideration for future research and development of a generation 2 product.

Recent Developments

Conversion of Series X Preferred Stock

On March 21, 2023, we held a special meeting of stockholders, or Stockholders' Meeting, at which the stockholders approved, among other things, the issuance of 1,993,627 shares of our common stock upon the conversion of 1,993,627 of our Series X Preferred Stock which were issued upon the closing of the Merger. The remaining 12,655,965 shares of Series X Preferred Stock are expected to remain outstanding until at least July 9, 2024, and will convert thereafter into up to 12,655,965 shares of common stock, only if we meet the initial listing standards of the NYSE American or another national securities exchange or are delisted from the NYSE American.

Warrant Inducement Offer

On January 9, 2023, we reduced the exercise price of certain existing warrants, or the Existing Warrants, exercisable for 331,608 shares of Ra Medical common stock held by a certain investor, or the Investor, with exercise prices ranging from \$14.00 to \$526.50 per share to \$4.00 per share, or the Warrant Repricing. In connection with the Warrant Repricing, we entered into a warrant inducement offer letter, or the Inducement Letter, with the Investor pursuant to which it exercised all of the 331,608 Existing Warrants, or the Inducement Offer. In consideration for exercising the Existing Warrants pursuant to the terms of the Inducement Letter, we received approximately \$1.3 million in gross proceeds. We paid the placement agent aggregate cash fees of approximately \$0.2 million related to the Inducement Offer which represented 8.0% of the gross proceeds received from the Inducement Offer plus other offering costs. In consideration for exercising the Existing Warrants pursuant to the terms of the Inducement Letter, we issued the Investor a new Series E common stock purchase warrant, or Series E Warrant, to purchase 331,608 shares of common stock at an exercise price of \$4.00 per share. The Series E Warrant is exercisable for five years from the date of stockholder approval. Exercise of the Series E Warrant in full was approved by Ra Medical's stockholders at the Stockholders' Meeting.

Securities Purchase Agreement

On January 9, 2023, we entered into a Securities Purchase Agreement, or the Securities Purchase Agreement, for a private placement, or the Private Placement, with the Investor. Pursuant to the Securities Purchase Agreement, the Investor agreed to purchase, for an aggregate purchase price of approximately \$8.0 million, (a) Class A Units at a price that is the lower of \$3.00 per unit and 90% of the 5 day volume weighted average price of our common stock immediately prior to obtainment of the approval of the Company's stockholders of conversion of the PIPE Preferred Stock and PIPE Warrants (as each are defined below), each consisting of one share of common stock, one Series F Common Stock Purchase Warrant, or Series F Warrant, and one Series G Common Stock Purchase Warrant, or Series G Warrant, and together with the Series F Warrants the PIPE Warrants, and (b) Class B Units at a price of \$1,000 per unit, each consisting of one share of a new series of the Company's preferred stock, designated as Series A Convertible Preferred Stock, par value \$0.0001, or the PIPE Preferred Stock, and one Series F Warrant and one Series G Warrant for each share of the Company's common stock underlying the PIPE Preferred Stock, each share of which is convertible into a number of shares of the Company's common stock equal to \$1,000 divided by the lower of \$3.00 and 90% of the 5 day volume weighted average closing price of the Company's common stock immediately prior to the obtainment of the approval of the Company's stockholders of conversion of the PIPE Preferred Stock and PIPE Warrants, or the Preferred Conversion Rate. The closing under the Securities Purchase Agreement and the sale and issuance of the Class A Units and Class B Units (and the issuance of any underlying common stock) was approved at the Stockholders' Meeting. At the closing of the Private Placement, we issued 497,908 Class A Units for proceeds of approximately \$0.8 million and 4,501,060 Class B Units for proceeds of approximately \$7.2 million.

The PIPE Warrants are exercisable at an exercise price of \$3.00 per share, subject to adjustments as provided under the terms of the PIPE Warrants. The PIPE Warrants are exercisable at any time on or after the closing date of the Private Placement until the expiration thereof, except that the PIPE Warrants cannot be exercised if, after giving effect thereto, the purchaser would beneficially own more than 4.99%, or the Maximum Percentage, of the outstanding shares of common stock of the Company, which Maximum Percentage may be increased or decreased by the purchaser with written notice to the Company to any other percentage specified not in excess of 9.99%. The Series F Warrants have a term of two years from the date of stockholder approval, and the Series G Warrants have a

term of six years from the date of stockholder approval. Stockholder approval of the Series F Warrants and Series G Warrants was obtained at the Stockholders' Meeting.

Shares of PIPE Preferred Stock, the conversion of which was approved at the Stockholders' Meeting, convert into common stock at the option of the holder at the Preferred Conversion Rate, subject to certain ownership limitations as described below. The conversion price is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

Subject to limited exceptions, holders of shares of PIPE Preferred Stock will not have the right to convert any portion of their Preferred Stock if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or up to 9.99% at the election of the holder) of the number of shares of the Company's common stock outstanding immediately after giving effect to its conversion.

Holders of PIPE Preferred Stock will be entitled to receive dividends on shares of PIPE Preferred Stock equal, on an as-if-converted-to-common stock basis, and in the same form as dividends actually paid on shares of the common stock. Except as otherwise required by law, the PIPE Preferred Stock does not have voting rights. However, as long as any shares of PIPE Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the PIPE Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the PIPE Preferred Stock, (b) alter or amend the Certificate of Designation for the PIPE Preferred Stock, (c) amend its certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of PIPE Preferred Stock, (d) increase the number of authorized shares of PIPE Preferred Stock, or (e) enter into any agreement with respect to any of the foregoing. The PIPE Preferred Stock does not have a preference upon any liquidation, dissolution or winding-up of the Company. The holders of PIPE Preferred Stock shall be entitled to receive out of the assets, whether capital or surplus, of the Company the same amount that a holder of the Company's common stock would receive if the PIPE Preferred Stock were fully converted (disregarding for such purposes any conversion limitations) to the Company's common stock, which amounts will be paid pari passu with all holders of the Company's common stock.

The Company also entered into a registration rights agreement with the purchasers requiring the Company to register the resale of the shares of its common stock, the shares issuable upon exercise of the PIPE Warrants and the shares issuable upon the conversion of the PIPE Preferred Stock.

We intend to use the net proceeds from the Private Placement to advance the development and commercialization of our novel electrophysiology technologies and solutions and to support general corporate purposes.

Settlement Agreements with the Department of Justice and Participating States

On December 28, 2020, Ra Medical entered into a settlement agreement with the U.S., acting through the DOJ and on behalf of the OIG, and other settlement agreements with certain state attorneys general, collectively the Settlement Agreements, to resolve investigations and a related civil action concerning its marketing of the DABRA laser system and DABRA-related remuneration to certain physicians. Pursuant to the terms of the Settlement Agreements, if Ra Medical was acquired or was otherwise involved in a change in control transaction before the end of 2024, Ra Medical was required to pay a settlement amount of \$5.0 million. As a result of the Merger, Ra Medical made payments of \$4.7 million and \$0.3 million to the DOJ and participating states, respectively, in February 2023. Such amounts were included in accrued expenses in the balance sheet at December 31, 2022.

Components of our Results of Operations for the Years Ended December 31, 2022 and 2021

Net Revenues

Product sales revenues consisted of sales of catheters for use with the DABRA laser in our atherectomy clinical trials.

Cost of Revenues

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

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consisted of employee-related expenses, including salaries, benefits and stock-based compensation expense. Other SG&A expenses include professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses and facility-related expenses.

Research and Development Expenses

Research and development, or R&D, expenses were expensed as incurred and included the following:

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

Restructuring Costs

Restructuring costs consisted of all costs related to the RIF and the board of directors' decisions to stop enrollment in the clinical trial and cease manufacturing activities, including severance, impairment of long-term assets, inventory obsolescence, write-off of prepaid R&D supplies, and the termination of our operating lease agreement and a service contract.

Results of Operations for the Years Ended December 31, 2022 and 2021

The following table sets forth the results of Ra Medical's continuing and discontinued operations for the periods presented (in thousands):

	Year Ended December 31,				Change
	2022	14	2021	22	
Net revenues	\$		\$		\$ (8)
Cost of revenues		161		1,560	(1,399)
Selling, general and administrative expenses		16,250		15,475	775
Research and development expenses		6,392		12,253	(5,861)
Restructuring costs		4,172		—	4,172
Other income (expense), net		99		2,009	(1,910)

Net Revenues

The decrease of approximately \$8,000 in net revenues for the year ended December 31, 2022 as compared to the prior year was due to decreased catheter unit sales as a result of the discontinuation of all manufacturing activities in June 2022 while we explored strategic options.

Cost of Revenues

The decrease of approximately \$1.4 million in cost of revenues for the year ended December 31, 2022 as compared to the prior year was due to a decrease in catheter unit sales, the RIF and the discontinuation of all manufacturing activities in June 2022.

Selling, General and Administrative Expenses

The increase of approximately \$0.8 million in SG&A expenses for the year ended December 31, 2022 as compared to the prior year was due primarily to the increase in legal expenses of \$4.6 million due to the \$5.0 million settlement with the DOJ and participating states as a result of the Merger in January 2023, partially offset by decreases of \$2.5 million and \$1.4 million in personnel and consulting expenses and stock-based compensation, respectively, due to the RIF.

Research and Development Expenses

The decrease of approximately \$5.9 million in R&D expenses for the year ended December 31, 2022 as compared to the prior year was primarily due to the RIF and the board of directors' decisions to pause all engineering activities, discontinue manufacturing activities and cease enrollment in the clinical trial, resulting in decreases of \$4.0 million in personnel and consulting expenses, \$1.5 million in R&D supplies expense, \$0.2 million in stock-based compensation and \$0.2 million in other costs, primarily facility costs.

Restructuring Costs

Restructuring costs of \$4.2 million were incurred during the year ended December 31, 2022 due to the RIF and the board of directors' decisions to discontinue manufacturing activities and enrollment in the clinical trial. No such expenses were incurred in the prior year. See Note 14. *Restructuring and Impairment Charges* in the notes to financial statements for a summary of such costs.

Other Income (Expense), Net

The decrease of approximately \$1.9 million in other income (expense), net for the year ended December 31, 2022 as compared to the prior year was primarily due to the \$2.0 million gain on the forgiveness of the Paycheck Protection Program promissory note under the Coronavirus Aid, Relief and Economic Security Act during the year ended December 31, 2021.

Liquidity and Capital Resources

As of December 31, 2022, we had cash and cash equivalents of \$15.9 million and an accumulated deficit of \$205.1 million. Since Ra Medical's inception, its operations have been funded primarily through equity and debt financings. Management expects operating losses and negative cash flows to continue for the foreseeable future as we invest in our commercial capabilities. Accrued expenses of \$7.5 million at December 31, 2022 are primarily related to the Merger with Catheter. Additional costs associated with the Merger paid during the year ended December 31, 2022 have substantially depleted our cash. During the year ended December 31, 2022, we implemented the RIF and terminated the lease for our administrative and manufacturing facility in Carlsbad, California. These actions, and other measures, have reduced costs associated with Ra Medical's operations. Following the Merger with Catheter in January 2023, we further reduced staff and other costs while assuming the operating costs of Catheter. We will continue to monitor our operating costs and seek to reduce our current liabilities. Such actions may impair our ability to proceed with certain strategic activities, and we may be unsuccessful at negotiating existing liabilities to our benefit. We believe our current cash reserves will be sufficient to fund the Company's operations for the next twelve months. If expected revenues are not adequate to fund our planned expenditures, or if we are unsuccessful at raising cash through future capital transactions, we may be required to reduce our spending rate to align with revenue levels and cash reserves, although there can be no guarantee that we will be successful in doing so.

As a public company, we incur and will continue to incur significant legal, accounting, insurance and other expenses. We expect legal and related expenses to remain high in the near term in connection with the legal proceedings discussed in Note 16. *Commitments and Contingencies* in the notes to the financial statements.

In January 2023, we raised gross proceeds of \$1.3 million from the Warrant Repricing and signed the Securities Purchase Agreement for the Private Placement for \$8.0 million. In March 2023, we completed the Private Placement and raised gross proceeds of \$8.0 million. Although we have recently bolstered our liquidity resources, reduced expenses and now have revenue to mitigate our cash used in operations, we may not achieve expected

revenue growth or maintain our current level of operating expenses. Accordingly, we may be required to raise additional cash through debt or equity transactions. We may not be able to secure financing in a timely manner or on favorable terms, if at all. Furthermore, if we issue equity securities to raise additional funds, our existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of our existing stockholders.

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

Cash Flows for the Years Ended December 31, 2022 and 2021

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

	Year Ended December 31,	
	2022	2021
Net cash provided by (used in):		
Operating activities	\$ (22,568)	\$ (27,625)
Investing activities	21	3,802
Financing activities	23,361	14,962
Net change in cash and cash equivalents	\$ 814	\$ (8,861)

Net Cash Used in Operating Activities

During the year ended December 31, 2022, net cash used in operating activities of \$22.6 million consisted of a net loss of \$26.9 million, partially offset by non-cash expenses of \$3.8 million, consisting primarily of non-cash restructuring costs of \$2.9 million and stock-based compensation and depreciation and amortization each of \$0.4 million, partially offset by a non-cash gain of \$0.1 million related to the write-off of our right-of-use asset and liability due to the termination of the lease for our manufacturing and office space. In addition, there was a net change in operating assets and liabilities of \$0.5 million.

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

Net Cash Provided by Investing Activities

During the year ended December 31, 2022, net cash provided by investing activities of \$21,000 consisted of proceeds from sales of property and equipment of approximately \$38,000, partially offset by purchases of property and equipment of approximately \$17,000.

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

Net Cash Provided by Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities of \$23.4 million consisted primarily of net proceeds of \$11.5 million from the issuance of common stock and warrants in the February 2022 offering, \$7.4 million under our ATM offerings and \$5.7 million from the exercises of warrants.

partially offset by the payment of \$1.2 million in offering costs during the year ended December 31, 2021, net cash provided by financing activities of \$15.0 million consisted primarily of net proceeds of \$15.2 million from our ATM offerings, partially offset by payments of \$0.3 million on our financed equipment.

Off-Balance Sheet Arrangements

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

Ra Medical's Critical Accounting Policies and Estimates

The information set forth below relates to Ra Medical's critical accounting policies and estimates. Refer to the Current Report on Form 8-K filed on March 28, 2023 for information related to Catheter's critical accounting policies and estimates.

Management's discussion and analysis of Ra Medical's financial condition and results of operations is based on their financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We regularly evaluate estimates and assumptions related to provisions for legal contingencies, income taxes, deferred income tax, asset valuation allowances, valuation of warrant liabilities, share based compensation and revenues. Our estimates are based on current facts, historical experience and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

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

Accounting for Long-Lived Assets—Useful Lives

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

Research and Development Expenses

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

Clinical Trial Costs and Accruals

We accrue clinical trial costs based on work performed. In determining the amount to accrue, we rely on estimates of total costs incurred based on enrollment, the completion of clinical trials and other events. We follow this method because we believe reasonable dependable estimates of the costs applicable to various stages of a clinical trial can be made. However, the actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending on a number of factors. Differences between the actual clinical trial costs and the

estimated clinical trial costs that we have accrued in any prior period are recognized in the subsequent period in which the actual costs become known. Historically, our estimated accrued expenses have approximated actual expenses incurred; however, material differences could occur in the future.

Stock-Based Compensation

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

Jobs Act Accounting Election

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

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Sensitivity

We had cash and cash equivalents of \$15.9 million as of December 31, 2022. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

Inflation Risk

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

Foreign Currency Exchange Risk

We use the U.S. dollar as our functional currency, and initially measure the foreign currency denominated in assets and liabilities at the transaction date. Monetary assets and liabilities are then re-measured at exchange rates in effect at the end of each period, and property and non-monetary assets and liabilities are converted at historical rates.

To date, Catheter has incurred minor foreign currency transaction realized gains and losses related to its European activities. As Catheter's international operations grow, foreign currency exchange risk may become a factor, and Catheter will reassess its approach to managing the risks relating to fluctuations in currency rates at that time.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements and supplementary data required by this item are set forth at the pages indicated in Item 15.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer and interim Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of December 31, 2022. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives of ensuring that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and interim Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures, and is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based upon our evaluation, our Chief Executive Officer and interim Chief Financial Officer concluded that, as of December 31, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on the assessment, management has concluded that its internal control over financial reporting was effective as of December 31, 2022 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. Our independent registered public accounting firm, Haskell & White LLP, is not required to and has not issued an attestation report as of December 31, 2022 due to a transition period established by the rules of the SEC for newly public companies that have not lost their "emerging growth company" status as defined in the JOBS Act.

Inherent Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any

system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Composition of the Board

Our business and affairs are managed under the direction of our board of directors, or the Board, which currently consists of five members, four of which are “independent” under NYSE American listing standards. Our bylaws provide that the number of directors will be fixed from time to time by resolution of the Board. All directors hold office until their successors have been elected and qualified or until their earlier death, resignation, disqualification or removal. We have divided the terms of office of the directors into three classes with staggered three year terms: Class I, whose term expires at the 2025 Annual Meeting of Stockholders; Class II, whose term expires at the 2023 Annual Meeting of Stockholders; and Class III, whose term expires at the 2024 Annual Meeting of Stockholders.

Information about the Board of Directors

The following table sets forth the names, ages as of March 23, 2023, and certain other information regarding each member of the Board. The following information has been furnished to us by the directors.

Name	Class	Age	Position	Director Since	Current Term Expires
Jonathan Will McGuire	I	60	Chief Executive Officer & Director	2020	2025
David A. Jenkins	II	65	Chairman of the Board of Directors	2023	2023
Martin Colombatto	II	64	Director	2017	2023
Susanne Meline	III	55	Director	2021	2024
James Caruso	III	62	Director	2023	2024

Jonathan Will McGuire has served as the Chief Executive Officer and a director of Ra Medical since March 2020. From August 2015 through March 2020, Mr. McGuire served as President and CEO of Second Sight Medical Products (Nasdaq: EYES), a developer, manufacturer and marketer of implantable visual prosthetics to treat blindness where he remains on the board as a director and serves on the special committee for strategy. Prior to Second Sight Medical Products, Mr. McGuire held leadership positions at Volcano Corporation, including President of Americas Commercial and Senior Vice President and General Manager of Coronary Imaging, Systems and Program Management. Prior to that, Mr. McGuire served as Vice President and General Manager of Patient Monitoring at Covidien, and President and Chief Executive Officer at AtheroMed, Inc., a venture capital-backed peripheral atherectomy company. For approximately five years, Mr. McGuire served as Chief Operating Officer for Spectranetics Corporation, a publicly traded medical device company with laser-based atherectomy products for treating peripheral and coronary arterial disease. Earlier in his career, Mr. McGuire held senior management positions at Guidant Corporation, including General Manager of Latin America, Director of U.S. and Global Marketing for Vascular Intervention, and Production Manager for Coronary Stents. Mr. McGuire also held positions in Finance and Production at IVAC Medical Systems. Mr. McGuire has also served on the board of AdvaMed Accel since December 2019. Mr. McGuire received an engineering degree from the Georgia Institute of Technology, and his MBA from the Kenan-Flagler Business School at the University of North Carolina at Chapel Hill. We believe that Mr. McGuire is qualified to serve as a director because of his extensive knowledge of our industry and his prior and current experience as a senior officer of medical device companies.

David A. Jenkins has spent most of his career as an entrepreneur in the medical device industry, and has established numerous companies including Catheter, where he currently serves as the CEO and as Chairman of Catheter’s Board. He has been Chairman of the Board of Catheter since Catheter’s inception in 2006 and has served as CEO of Catheter since December 2020. His prior experience includes having served as Chairman and CEO of Arrhythmia Research and overseeing the introduction to the market of Cardiolab, the first dual monitor, 32 channel electrophysiology recording system. This technology was later acquired by General Electric and continues to be sold into the market place today. Another of Mr. Jenkins’ companies, EP MedSystems, Inc., was sold to St. Jude Medical, Inc., now part of Abbott, for approximately \$93 million in 2008. Mr. Jenkins also founded and served as the CEO of Transneuronix, Inc., a maker of implantable stimulators for the treatment of weight loss, which was later sold to Medtronic for \$267 million in 2005. Mr. Jenkins holds a degree in accounting from the University of Kansas,

and a master's degree in business from the University of Texas, Austin. He began his career in public accounting with Coopers and Lybrand. We believe that Mr. Jenkins is qualified to serve as a director because of his extensive experience in the medical device industry.

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

Susanne Meline has served as a director of Ra Medical since January 2021. Ms. Meline co-founded Francis Capital Management ("FCM"), a value-based investment advisor, where she serves as the firm's special situations advisor. She previously worked as an investment banker with Houlihan Lokey, a global investment bank serving corporations, institutions, and governments worldwide and also practiced law in the corporate group of Jones Day, an international law firm that provides legal advisory services across multiple disciplines and jurisdictions. Ms. Meline is a Certified Director through the UCLA Anderson School of Management, a Board Leadership Fellow for the National Association of Corporate Directors (the "NACD") and holds a CERT Certificate in Cybersecurity Oversight from the NACD and Carnegie Mellon University Software Engineering Institute. Ms. Meline received a B.A. from UCLA, and a J.D. from the UC Hastings College of the Law. She currently serves on the board of directors of ClearSign Technologies Corporation (NASDAQ:CLIR) where she is the Lead Independent Director and Chair of the Compensation Committee and has also served on the board of directors of Finomial Corporation and AquaMetals Corporation. We believe that Ms. Meline is qualified to serve as a director because of her extensive knowledge of capital markets, her experience in identifying business and financial opportunities, and her experience as a board member at other public companies.

James Caruso has held senior level financial positions in both public and private companies for more than 40 years, including serving as Chief Financial Officer at several publicly traded and privately held medical device companies. He has managed all financial aspects of businesses and is proficient in SEC reporting and compliance requirements. Mr. Caruso also has extensive operational experience and has led post-acquisition business integration activities on several occasions. Mr. Caruso served as Chief Financial Officer of Catheter Precision from 2010 through 2016. Mr. Caruso also served as Chief Financial Officer of EP MedSystems, Inc. (NASDAQ:EPMD), a company focused on cardiac electrophysiology that was acquired by St Jude Medical in 2008; Hi-Tronics Designs, Inc., a privately held medical device design and manufacturing company that was acquired by Advanced Neuromodulation Systems, Inc. in 2001; and Micron Products, Inc., a publicly traded medical device manufacturing company that was acquired by Arrhythmia Research Technology in 1991. Mr. Caruso spent five years in the audit practice at Deloitte (formerly Deloitte & Touche). Mr. Caruso received his Bachelor of Science in Business Administration from Rutgers University and an MBA from Fordham University and is a Certified Public Accountant. We believe that Mr. Caruso is qualified to serve as a director because of his senior level financial experience with public and private companies.

Audit Committee

The members of our Audit Committee are Susanne Meline and James Caruso. Mr. Caruso serves as the chairperson of our Audit Committee. The Board has determined that each member of the Audit Committee is an independent director under the NYSE American listing rules, satisfies the additional independence criteria for audit committee members and satisfies the requirements for financial literacy under the NYSE American listing rules and Rule 10A-3 of the Exchange Act, as applicable. The Board has also determined that Mr. Caruso qualifies as an audit committee financial expert within the meaning of the applicable rules and regulations of the SEC and satisfies the financial sophistication requirements of the NYSE American listing rules.

Corporate Governance Principles and Code of Ethics and Conduct

The Board has adopted corporate governance principles. These principles address items such as the qualifications and responsibilities of our directors and director candidates and corporate governance policies and standards applicable to us in general. In addition, the Board has adopted a written code of ethics and conduct that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of our corporate governance principles and code of ethics and conduct are available on our website, www.ramed.com, under the Investor Relations tab under “Governance”, then “Governance Documents.” If the Board makes any substantive amendments to, or grants any waivers from, the code of ethics and conduct for any officer or director, it will disclose the nature of such amendment or waiver on the Company’s website.

Director Compensation

The Board has retained Radford Aon, a national compensation consultant, to provide an analysis of market data compiled from certain comparable public companies and assistance in determining compensation of directors. In developing the current Outside Director Compensation Policy, the Compensation Committee gathered and reviewed board compensation data from the National Association of Corporate Directors, as well as for various publicly traded companies that the compensation committee believes to be similar to the Company in some respect, taking into consideration market capitalization, number of employees, amount of revenue, net cash used or generated in operations and the industries in which such companies operate. In addition, the compensation committee evaluated the Company’s resources, including the number of shares remaining in its 2018 Equity Incentive Plan in determining the appropriate form of payment of such compensation.

This Outside Director Compensation Policy currently provides that each non-employee director is entitled to receive the following cash compensation for their services, or Retainer Cash Payments, as follows:

- \$50,000 retainer per year for each non-employee director;
- \$25,000 retainer per year for service as non-employee chairman of the board of directors;
- \$25,000 retainer per year for service as lead non-employee director;
- \$20,000 retainer per year for the chairman of the audit committee or \$10,000 retainer per year for each other member of the audit committee;
- \$10,000 retainer per year for the chairman of the compensation committee or \$7,000 retainer per year for each other member of the compensation committee; and
- \$8,500 retainer per year for the chairman of the nominating and corporate governance committee or \$4,500 retainer per year for each other member of the nominating and corporate governance committee.

Retainer Cash Payments will be paid in cash on or about the last day of each fiscal quarter of the Company in arrears to each outside director as well as to each former Outside Director who served for one or more days during such fiscal quarter on a prorated basis.

Notwithstanding the foregoing, the Board may elect, prior to the first day of any fiscal year, to convert Retainer Cash Payments related to services performed by outside directors during such fiscal year into equity awards, taking into consideration the Company’s available cash and equity resources under its stock compensation plans, or Retainer Award. If granted, such Retainer Awards will be granted automatically on the first trading day on or after the 5th day of the month immediately following the end of the fiscal quarter for which the corresponding Retainer Cash Payments were earned, subject to the applicable outside director remaining an outside director through such date. Each Retainer Award will be fully vested on the applicable Retainer Award grant date, and will cover a number of shares having a value (calculated in accordance with the Black-Scholes option valuation methodology, or such other methodology as our board of directors or the compensation committee may determine) equal to the dollar value of the corresponding Retainer Cash Payments earned by the applicable outside director for the fiscal quarter to which the Retainer Award relates, rounded down to the nearest whole share.

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

Compensation for our non-employee directors is not limited to the equity awards and payments set forth in our Outside Director Compensation Policy. Our non-employee directors remain eligible to receive equity awards and cash or other compensation outside of the Outside Director Compensation Policy, as may be provided from time to time at the discretion of our board of directors. No such awards or payments were made in 2022.

The Compensation Committee is currently evaluating possible amendments to the Outside Director Compensation Policy for the year ended December 31, 2023.

2022 Director Compensation Table

The following table sets forth information regarding compensation earned or paid to our non-employee directors during the year ended December 31, 2022:

	Fees Earned or Paid in Cash (S)	Stock Awards (S)(1)	Total (S)
Martin Colomatto	89,500	—	89,500
Richard Mejia, Jr.	70,000	—	70,000
Susanne Meline	57,000	—	57,000
Joan Stafslie	68,500	—	68,500

(1) No stock awards were granted to the directors during the year ended December 31, 2022.

See *Executive Compensation* for information about the compensation of Mr. McGuire, a director who is also an executive officer.

ITEM 11. EXECUTIVE COMPENSATION

Processes and Procedures for Executive Compensation

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

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

In January 2021, the Compensation Committee hired Radford Aon to serve as its compensation consultant. Radford Aon continues to serve at the discretion of the Compensation Committee. Radford Aon was engaged to assist in helping us determine the appropriate level of overall compensation for the directors and executive officers, as well as assess each separate element of compensation, with a goal of ensuring that the compensation offered to the directors and executive officers is competitive and fair. The Compensation Committee assessed the independence of Radford Aon taking into account, among other things, the enhanced independence standards and factors set forth in Exchange Act Rule 10C-1 and the applicable NYSE American listing standards and concluded that there were no conflicts of interest with respect to the work that Radford Aon performed for the Compensation Committee. In addition, the Compensation Committee gathers and reviews executive compensation data from the National Association of Corporate Directors, as well as for various publicly traded companies that the Compensation Committee believes to be similar to the Company in some respect, taking into consideration market

capitalization, number of employees, amount of revenue, net cash used or generated in operations and the industries in which such companies operate.

The named executive officers for 2022, which consist of the principal executive officer and the next two most highly compensated executive officers who were officers as of December 31, 2022, or who would have been one of our next two most highly compensated executive officers but for the fact that the individual was not serving as an executive officer as of December 31, 2022, were as follows:

- Will McGuire, Chief Executive Officer;
- Brian Conn, Interim Chief Financial Officer; and
- Andrew Jackson, former Chief Financial Officer and Secretary.

Summary Compensation Table

The following table provides information regarding the compensation of the chief executive officer, and each of the next two most highly compensated executive officers during 2022, together referred to as our “Named Executive Officers” or “NEOs”, for 2022 and 2021, as applicable:

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	All Other Compensation (\$)	Total (\$)
Jonathan Will McGuire	2022	500,000	—	—	—	—	43,953 (2)	543,953
Chief Executive Officer and Secretary	2021	495,192	—	—	—	375,000 (1)	40,933 (2)	911,125
Brian Conn(3)	2022	—	—	—	—	—	82,500 (4)	82,500
Interim Chief Financial Officer								
Andrew Jackson(5)	2022	185,847	—	—	—	185,000 (6)	16,415 (2)	387,262
Former Chief Financial Officer and Secretary	2021	366,709	—	—	—	138,851 (1)	15,141 (2)	520,701

- (1) Amounts represent performance bonuses earned in 2021 and paid in March 2022.
- (2) Amounts include Company matching contributions to the Named Executive Officers’ 401(k) plan and taxable amounts from vested stock awards. In addition, for Mr. McGuire, this column includes amounts paid for a supplemental health insurance plan.
- (3) Mr. Conn was hired as the Interim Chief Financial Officer effective July 14, 2022.
- (4) Amount represents payments made in accordance with the Consulting Agreement with Mr. Conn dated May 25, 2022, and as amended effective August 10, 2022.
- (5) Mr. Jackson served as our Chief Financial Officer and Secretary until his resignation on May 25, 2022.
- (6) Amount represents severance pay that Mr. Jackson received upon his resignation on May 25, 2022.

Executive Employment Agreements and Arrangements

Will McGuire

The Company entered into an offer letter with Mr. McGuire dated March 9, 2020 which provided for at-will employment. The offer letter provided for an initial base salary of \$500,000 and eligibility annually for a target cash bonus of 50% of his annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. Mr. McGuire is also eligible for severance benefits, as more fully described in *Executive Change in Control and Severance Agreements* below.

The Company entered into a confirmatory employment letter with Mr. Jackson dated September 12, 2018, and effective as of the closing of our initial public offering. The confirmatory employment letter had no specific term and provided for at-will employment. The confirmatory employment letter provided for an initial base salary, effective on the closing of our initial public offering, of \$348,000 and eligibility annually for a target cash bonus of 50% of his annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. Mr. Jackson was also eligible for severance benefits, as more fully described in *Executive Change in Control and Severance Agreements* below.

Executive Change in Control and Severance Agreements

Our board of directors has approved a change in control and severance agreement for certain of our executive officers, including our named executive officers, which agreements provide for certain severance and change in control benefits as described below. Each change in control and severance agreement supersedes any prior agreement or arrangement the executive officer may have had with us that provides for severance and/or change in control payments or benefits.

The Company entered into a change in control and severance agreement with Mr. McGuire on March 30, 2020, or the Agreement, which has an initial term of three years, starting on the effective date of the Agreement. On the fifth anniversary of the effective date of the agreement, the agreement will renew automatically for additional one year terms unless either party provides the other party with written notice of nonrenewal at least one year prior to the date of automatic renewal. However, if a change in control (as defined in the applicable amendment dated January 9, 2023 to the Agreement) occurs when there are fewer than 12 months remaining during the initial term or during an additional term, the term of the change in control and severance agreement will extend automatically through the date that is 24 months following the date of the change in control.

If an executive officer's employment is terminated outside the period beginning three months before a change in control and ending 24 months following a change in control, or the Change in Control Period either (1) by the Company (or any of its subsidiaries) without "cause" (excluding by reason of death or disability) or (2) by the executive officer for "good reason" (as such terms are defined in the executive officer's change in control and severance agreement), the executive officer will receive the following benefits if he or she timely signs and does not revoke a release of claims in our favor:

- a lump-sum payment equal to: (1) 18 months for Mr. McGuire and (2) 12 months for Mr. Jackson, of the executive officer's annual base salary as in effect immediately prior to such termination (or if such termination is due to a resignation for good reason based on a material reduction in base salary, then as in effect immediately prior to the reduction);
- for Mr. McGuire, a lump sum payment equal to the pro-rata amount of the executive's annual bonus for the fiscal year in which the executive terminates employment, based on actual achievement and pro-rated based on the number of days the executive was employed by the Company during such year; and
- payment of premiums for coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or COBRA, for the executive officer and the executive officer's eligible dependents, if any, for up to: (1) 18 months for Mr. McGuire and (2) 12 months for Mr. Jackson, or taxable monthly payments for the equivalent period in the event payment of the COBRA premiums would violate or be subject to an excise tax under applicable law.

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

- a lump-sum payment equal to: (1) 24 months for Mr. McGuire and (2) 12 months for Mr. Jackson of the executive officer's annual base salary as in effect immediately prior to such termination (or if such termination is due to a resignation for good reason based on a material reduction in base salary, then as in

effect immediately prior to the reduction) or if greater, at the level in effect immediately prior to the change in control);

- a lump-sum payment equal to: (1) 150% for Mr. McGuire and (2) 100% for Mr. Jackson of the executive officer's target annual bonus as in effect for the fiscal year in which such termination occurs;
- payment of premiums for coverage under COBRA for the executive officer and the named executive officer's eligible dependents, if any, for up to: (1) 24 months for Mr. McGuire and (2) 12 months for Mr. Jackson, or taxable monthly payments for the equivalent period in the event payment of the COBRA premiums would violate or be subject to an excise tax under applicable law; and
- 100% accelerated vesting and exercisability of all outstanding equity awards and, in the case of an equity award with performance-based vesting, all performance goals and other vesting criteria generally will be deemed achieved at target.

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

Pursuant to Mr. McGuire's agreement, as amended in January 2023, he is entitled to receive a payment of approximately \$1.8 million upon his ceasing to be an employee of the Company.

Severance Agreement with Mr. Jackson

On May 31, 2022, we entered into a severance agreement with Mr. Jackson under which he received a severance payment of \$185,00 in June 2022.

Outstanding Equity Awards at 2022 Fiscal Year-End

The following table sets forth certain information concerning outstanding equity awards for our named executive officers at December 31, 2022:

Name and Position	Option Awards				Stock Awards		
	Number of Securities Underlying Unexercised Options (Exercisable) (#)		Number of Securities Underlying Unexercised Options (Unexercisable) (#)	Option Exercise Price (\$/share)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(1)
Jonathan Will McGuire <i>Chief Executive Officer and Secretary</i>	254	(2)	105	\$ 1,275	3/30/2030	36 (3)	\$ 212.04
Brian Conn <i>Interim Chief Financial Officer</i>	—		—			467 (4)	\$ 2,750.63
Andrew Jackson (5) <i>Former Chief Financial Officer and Secretary</i>	—		—			—	

- (1) Market value of the unvested restricted stock awards identified in this column is based on a closing price of \$5.89 per share of the Company's common stock as of December 30, 2022. These amounts do not correspond to the actual value that may be realized by the Named Executive Officer.
- (2) One forty-eighth of the shares subject to the option vest monthly after March 30, 2020, subject to continued service.
- (3) Restricted stock award ("RSA") vests and becomes non-forfeitable in six equal installments beginning November 20, 2020 and every six months thereafter for three years with full vesting on November 20, 2023. Vesting is subject to continued service.
- (4) RSA vests and becomes non-forfeitable according to the following schedule: 50% of the shares underlying the RSA are subject to time-based vesting and vested or shall vest and become non-forfeitable as follows: one-third of the shares vested on November 20, 2021, and one-sixth of the shares vested or will vest on each May 20 and November 20 thereafter, such that 50% of the RSA will be fully vested by November 20, 2023. The remaining 50% of the shares underlying the RSA were subject to vesting based on certain performance milestones having been met by November 20, 2021. Since only one of the three performance milestones was met by November 20, 2021, only one-third of the remaining 50% of the shares vested or shall vest and become non-forfeitable as follows: one-third of the shares vested on November 20, 2021, and one-sixth of the shares vested or will vest on each May 20 and November 20 thereafter, such that the shares will be fully vested by November 20, 2023. Vesting is subject to continued service.
- (5) Mr. Jackson resigned from the Company effective May 25, 2022, at which time all of his unvested outstanding equity awards were canceled. Mr. Jackson did not exercise his exercisable options within 90 days of his separation date. As such, the exercisable options were canceled.

Perquisites, Health, Welfare and Retirement Benefits

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees.

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

401(k) Savings Plan

Prior to the Merger, Ra Medical maintained a tax-qualified retirement plan that provided eligible employees, including named executive officers, with an opportunity to save for retirement on a tax advantaged basis. All participants' interests in their deferrals were 100% vested when contributed. Pre-tax and after-tax contributions were allocated to each participant's individual account and were then invested in selected investment alternatives according to the participant's directions. Ra Medical, in its sole discretion, could make certain contributions to the plan. The 401(k) plan was intended to qualify under Sections 401(a) and 501(a) of the Internal Revenue Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions were not taxable to the employees until distributed from the 401(k) plan, and all contributions, if any, were deductible by Ra Medical when made. As a result of the Merger, the Company terminated the 401(k) Savings Plan and liquidated all assets in March 2023.

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

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 23, 2023 by:

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

The percentage ownership information shown in the table is based on an aggregate of 4,984,093 shares of our common stock outstanding as of March 23, 2023.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to: (i) the exercise of stock options that are either immediately exercisable or exercisable on or before May 22, 2023, which is 60 days after March 23, 2023 (ii) RSUs held by that person that will vest within 60 days of March 23, 2023 and (iii) outstanding warrants to purchase common stock held by that person that is either immediately exercisable or exercisable on or before May 22, 2023, which is 60 days after March 23, 2023. These shares are deemed to be outstanding and beneficially owned by the person holding those options and warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise noted below, the address of each of the individuals and entities named in the table below is c/o Ra Medical Systems, Inc., 1670 Highway 160 West, Suite 205, Fort Mill, South Carolina 29708. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

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

	Number of Shares of Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned
5% Stockholders:		
Armistice Capital Master Fund Ltd. (1)	497,908	9.99%
RFT Investment Company LLC (2)	261,553	5.25%
Directors and Named Executive Officers:		
Jonathan Will McGuire (3)	1,541	*
David A. Jenkins (4)	991,828	19.9%
Brian Conn	—	—
James J. Caruso (5)	1,779	*
Martin Colombaro (6)	690	*
Susanne Meline (7)	5,093	*
Andrew Jackson (8)	205	*
All directors and executive officers as a group (6 persons)	1,000,931	20.1%

- (1) Does not include derivative securities that are not currently exercisable due to beneficial ownership blockers.
- (2) Does not include 1,165,949 shares of Series X Preferred Stock held by RFT Investment Company LLC which are convertible into 1,165,949 shares of common stock but which are subject to certain beneficial ownership blockers and which may not be converted, at the earliest, until July 9, 2024.
- (3) Includes (i) 8 shares of common stock subject to warrants and (ii) 282 shares of common stock subject to options, in each case exercisable within 60 days of March 23, 2023.
- (4) Includes (i) 2,264 shares held by a family charitable trust of which Mr. Jenkins is the trustee; (ii) 2,264 shares held by a charitable remainder unitrust of which Mr. Jenkins' wife is the trustee; and (iii) 709,703 shares held by a partnership of which Mr. Jenkins is the managing partner. Excludes 235,320 shares held by certain adult immediate family members of Mr. Jenkins. Does not include 8,190,261 shares of Series X Preferred Stock held by Mr. Jenkins and his affiliates which are convertible into 8,190,261 shares of common stock but which are subject to certain beneficial ownership blockers and which may not be converted, at the earliest, until July 9, 2024. Also does not include 1,049,024 shares of Series X Preferred Stock held, in the aggregate, by certain adult immediate family members of Mr. Jenkins and which are convertible into 1,049,024 shares of common stock, but which are subject to certain beneficial ownership blockers and which may not be converted, at the earliest, until July 9, 2024. Also does not include exercisable options to purchase 144,169 shares of common stock held by Missiaen Huck, the non-executive chief operating officer of Catheter and Mr. Jenkins's adult daughter.
- (5) Does not include 7,932 shares of Series X Preferred Stock held by Mr. Caruso which are convertible into 7,932 shares of common stock but which are subject to certain beneficial ownership blockers and which may not be converted, at the earliest, until July 9, 2024.
- (6) Includes (i) 73 shares of common stock subject to options exercisable within 60 days of March 23, 2023, and (ii) 30 shares held of record by M. Colombaro Trust. Mr. Colombaro serves as trustee of the M. Colombaro Trust.
- (7) Includes (i) 1,548 shares of common stock subject to warrants exercisable within 60 days of March 23, 2023 held of record by Catalysis Partners (CP) and (ii) 800 shares of common stock held of record by CP. Ms. Meline has an investment interest in CP through her IRA and, together with an immediate family member, owns a controlling interest in Francis Capital Management LLC, which also has an investment interest in CP and serves as both its Managing Member and Investment Manager. Ms. Meline disclaims beneficial interest of these securities except to the extent of her pecuniary interest therein. Also includes 2,575 shares of common stock held by a retirement fund for the benefit of Ms. Meline's husband. Does not include 11,481 shares of Series X Preferred Stock held by the retirement fund for the benefit of Ms. Meline's husband which are convertible into 11,481 shares of common stock but which are subject to certain beneficial ownership blockers and which may not be converted, at the earliest, until July 9, 2024.

(8) Includes 8 shares of common stock subject to warrants exercisable within 60 days of March 23, 2023. Mr. Jackson resigned from the Company effective May 25, 2022.

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

Related Person Transactions

Pursuant to SEC rules, a “transaction” with a related party includes any transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which the Company was or is a participant and the related person had or will have a direct or indirect material interest where the amount involved exceeds the lesser of \$120,000 or one percent of the average of the Company’s total assets at year end for the last two completed fiscal years. Accordingly, the applicable threshold for us is \$120,000.

Since January 1, 2021, we have engaged in the following transactions with our executive officers, directors, promoters or beneficial owners of more than 5% of our common stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the Item 11. *Executive Compensation*. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Employment and Separation Agreements

We currently have written employment agreements with our executive officers. For information about our employment agreements with our Named Executive Officers, refer to *Executive Compensation—Agreements with Named Executive Officers* above.

In May 2022, we entered into a separation agreement with Andrew Jackson. For information about Mr. Jackson’s separation agreement, refer to *Executive Compensation—Other Features of our Executive Compensation Program—Separation Agreement with Andrew Jackson* above.

In January 2023, we entered into an oral employment agreement with David A. Jenkins, Chairman of the Board. In accordance with the terms of Mr. Jenkins’ employment agreement, he is entitled to annual compensation of \$300,000. At the same time, we also entered into an oral employment agreement with Missiaen Huck, Mr. Jenkins’ daughter. Ms. Huck serves as the non-executive chief operating officer of Catheter and is entitled to annual compensation of \$165,000.

Merger-Related Transactions

Mr. Jenkins and his affiliates held approximately \$25.1 million of Catheter’s Convertible Promissory Notes, or the Notes, that were converted in the Merger into 7,856,251 shares of Series X Preferred Stock. Upon consummation of the Merger, each such Noteholder received, in exchange for discharge of the principal of his or its Notes, a number of shares of our Series X Preferred Stock representing a potential right to convert into our common stock in an amount equal to one common share for each \$3.20 of principal amount. In consideration for forgiving the interest accrued but remaining unpaid under the Notes in an aggregate amount of approximately \$13.9 million, Mr. Jenkins and his affiliates also received royalties equal to 11.77% of the net sales, if any, of the LockeT device, commencing upon the first commercial sale and through December 31, 2035.

In addition, to the shares described above that were issued in connection with the Notes, Mr. Jenkins and his affiliates received 1,325,838 shares of Series X Preferred Stock in the Merger, and Mr. Jenkins’ adult children received 1,284,344 shares of Series X Preferred Stock in the Merger, all in exchange for their equity interests in Catheter in accordance with the Merger exchange ratio.

Additional, non-interest bearing demand loans totaling \$1,075,000 from David Jenkins to Catheter were repaid by the Company at or shortly after the closing of the Merger.

Mr. Jenkins' daughter, Missiaen Huck, received options to purchase 144,169 shares of the Company's common stock upon the closing of the Merger in exchange for her options to purchase shares of Catheter common stock, converted based on the exchange ratio in the Merger. Of the total options to purchase 144,169 shares of the Company's common stock, 140,816 options have an exercise price of \$0.59 per share, and the remaining 3,353 options have an exercise price of \$2.02 per share.

Stock Options Granted to Executive Officers and Directors

We have granted stock options to our executive officers and directors, as more fully described in *Executive Compensation—Grants of Plan-Based Awards*, *Executive Compensation—Outstanding Equity Awards at Fiscal Year End* and *Non-Employee Director Compensation* above.

Indemnification of Officers and Directors

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

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Our independent registered public accounting firm is Haskell & White LLP Auditor ID: 200.

Fees Paid to the Independent Registered Public Accounting Firms

The following table represents aggregate fees for services provided to us in the fiscal years ended December 31, 2022 and 2021 by Haskell & White:

	Fiscal Year Ended	
	2022	2021
Audit Fees (1)	\$ 216,000	\$ 208,500
Audit-Related Fees (2)	207,770	76,422
Tax Fees (3)	—	—
All Other Fees (4)	—	—
Total Fees	<u>\$ 423,770</u>	<u>\$ 284,922</u>

- (1) "Audit Fees" consist of fees billed for professional services rendered during the respective fiscal year in connection with the audit of our annual financial statements, review of our quarterly financial statements, and services that are normally provided in connection with statutory and regulatory filings or engagements for those fiscal years.
- (2) "Audit-Related Fees" consist of fees billed for professional services rendered in connection with our Forms S-1, S-3 and S-8 registration statements and proxy statements.
- (3) "Tax Fees" consist of permissible tax compliance and tax advisory service fees. Haskell & White did not bill us for any tax fees for the years ended December 31, 2022 and December 31, 2021.
- (4) "All Other Fees" consist of fees billed for services other than the services reported in Audit Fees and Tax Fees.

Auditor Independence

During the years ended December 31, 2022 and 2021, there were no other professional services provided by Haskell & White that would have required our audit committee to consider their compatibility with maintaining the independence of Haskell & White.

Pre-Approval Policy

Our audit committee's policy is to pre-approve all audit and permissible non-audit services provided by the independent accountants and the related estimated fees. These services may include audit services, audit-related services, tax services and other services. Our audit committee generally pre-approves particular services or categories of services on a case-by-case basis. The independent registered public accounting firm and management are required to periodically report to our audit committee regarding the extent of services provided by the independent registered public accounting firm in accordance with these pre-approvals, and the fees for the services performed to date. All of the services of Haskell & White for 2022 and 2021 described above were pre-approved by our audit committee.

PART IV — FINANCIAL INFORMATION

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

	Page
Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets	F-3
Statements of Operations	F-4
Statements of Stockholders' Equity	F-5
Statements of Cash Flows	F-6
Notes to Financial Statements	F-7

2. *Financial Statement Schedules.*

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

3. *Exhibits.*

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.2	Amended and Restated Agreement and Plan of Merger, dated January 9, 2023, by and among the Registrant, certain subsidiaries, and Catheter Precision, Inc.	8-K	001-38677	2.1	1/13/2023
3.1.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-38677	3.1	10/1/2018
3.1.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant. (effective 11/16/20)	8-K	001-38677	3.1	11/17/2020
3.1.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant. (effective 09/30/22)	8-K	001-38677	3.1	9/20/2022
3.1.4	Certificate of Designation of Series X Convertible Preferred Stock.	8-K	001-38677	3.1	1/13/2023
3.1.5	Certificate of Designation of Series A Preferred Stock.	8-K	001-38677	3.2	1/13/2023
3.2.1	Amended and Restated Bylaws of the Registrant.	8-K	001-38677	3.2	10/1/2018
3.2.2	Amendment to Amended and Restated Bylaws of the Registrant.	8-K	001-38677	3.1	8/17/2022
4.1	Specimen common stock certificate of the Registrant.	S-1	333-226191	4.1	7/16/2018
4.2*	Description of Capital Stock.				
4.3	Form of warrant issued in May 2020.	8-K	001-38677	4.1	5/22/2020
4.4	Form of pre-funded warrant issued in May 2020.	8-K	001-38677	4.2	5/22/2020
4.5	Form of placement agent warrant issued in May 2020.	8-K	001-38677	4.3	5/22/2020

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
4.6	Form of warrant offered in July 2020.	S-1	333-239887	4.3	7/16/2020
4.7	Form of pre-funded warrant issued in July 2020.	S-1	333-239887	4.4	7/16/2020
4.8	Form of placement agent warrant offered in July 2020.	S-1	333-239887	4.5	7/16/2020
4.9	[omitted.]				
4.10	Form of Series B Warrant offered in February 2022.	S-1/A	333-262195	4.9	2/3/2022
4.11	[omitted.]	S-1/A	333-262195	4.10	2/3/2022
4.12	Warrant Agency Agreement, dated February 8, 2022, by and between the Registrant and American Stock & Trust Company LLC.	8-K	001-38677	4.4	2/9/2022
4.12.1	Amendment No. 1, dated July 22, 2022, to February 8, 2022 Warrant Agency Agreement by and between the Company and American Stock Transfer & Trust Company, LLC.	10-Q	001-38677	4.7	8/15/2022
4.13	Form of Series E Warrant offered in January 2023.	8-K	001-38677	4.1	1/13/2023
4.14	Form of Series F Warrant issued in March 2023.	8-K	001-38677	4.2	1/13/2023
4.15	Form of Series G Warrant issued in March 2023.	8-K	001-38677	4.3	1/13/2023
10.1	[omitted.]				
10.2+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-226191	10.2	8/24/2018
10.3+	Ra Medical Systems, Inc. 2018 Stock Compensation Plan and Forms of Award Agreement thereunder.	S-1	333-226191	10.3	7/16/2018
10.4+	Ra Medical Systems, Inc. 2018 Equity Incentive Plan and Forms of Award Agreement thereunder, as amended.	8-K	001-38677	99.1	10/13/2020
10.5+	[omitted.]				
10.6+	Ra Medical Systems, Inc. Executive Incentive Compensation Plan.	S-1/A	333-226191	10.6	8/24/2018
10.7+	Ra Medical Systems, Inc. Form of At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement for executive officers.	S-1	333-226191	10.7	7/16/2018
10.8+	[omitted.]				
10.9+	[omitted.]				
10.10+	Change in Control and Severance Agreement, by and between the Registrant and Jonathan Will McGuire, dated as of March 30, 2020.	8-K	001-38677	10.11	4/16/2020

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.10.1+	Amendment to Change in Control and Severance Agreement, dated as of January 9, 2023, by and between Ra Medical Systems, Inc. and Jonathan Will McGuire.	8-K	001-38677	10.6	1/13/2023
10.11+	Employment letter by and between the Registrant and Jonathan Will McGuire, dated as of March 9, 2020.	S-1	333-237701	10.15	4/16/2020
10.12	[omitted.]				
10.13	[omitted.]				
10.14	[omitted.]				
10.15	Settlement Agreement, among the Company, among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services and the Defense Health Agency, acting on behalf of the TRICARE Program, and Robert Gruber, dated December 28, 2020.	10-K	001-38677	10.19	3/17/2021
10.16	Corporate Integrity Agreement, between the Company and the Office of Inspector General of the Department of Health and Human Services, dated December 28, 2020.	10-K	001-38677	10.20	3/17/2021
10.16.1*	Notice of Suspension of Corporate Integrity Agreement, dated January 11, 2023.				
10.17	[omitted.]				
10.18	[omitted.]				
10.19	[omitted.]				
10.20	Form of Amended and Restated Support Agreement, dated January 9, 2023, by and among the Company, Catheter Precision, Inc. and directors, officers and certain shareholders of the Company.	8-K	001-38677	10.1	1/13/2023
10.21	Form of Lock-Up Agreement, dated January 9, 2023, by and among the Company, Catheter Precision, Inc., directors, officers, and certain stockholders of the Company; and certain stockholders of Catheter.	8-K	001-38677	10.2	1/13/2023
10.22+	Consulting Agreement by and between the Company and Brian Conn, dated as of May 25, 2022.	8-K	001-38677	10.1	7/18/2022
10.22.1+	Amendment dated as of August 10, 2022 to Consulting Agreement by and between the Company and Brian Conn.	8-K	001-38677	10.1	8/12/2022
10.23	Warrant Inducement Offer Letter dated July 22, 2022.	8-K	001-38677	10.1	7/22/2022

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.24	Securities Purchase Agreement, dated January 9, 2023, by and among the Company and Armistice Master Fund Ltd. ("January 2023 SPA").	8-K	001-38677	10.4	1/13/2023
	-Ex. A to January 2023 SPA (form of Certificate of Designation of Series A Convertible Preferred Stock).	8-K	001-38677	3.2	1/13/2023
	-Ex. B to January 2023 SPA (form of Registration Rights Agreement).	8-K	001-38677	10.5	1/13/2023
	-Ex. C to January 2023 SPA (form of Series F Warrant).	8-K	001-38677	4.2	1/13/2023
	-Ex. D to January 2023 SPA (form of Series G Warrant).	8-K	001-38677	4.3	1/13/2023
10.25	Registration Rights Agreement, dated January 9, 2023.	8-K	001-38677	10.5	1/13/2023
10.26	Warrant Inducement Offer Letter, dated January 9, 2023.	8-K	001-38677	10.3	1/13/2023
10.27.1*	Debt Settlement Agreement and Release including certain royalty rights with David A. Jenkins, dated January 9, 2023.				
10.27.2*	Debt Settlement Agreement and Release including certain royalty rights with Daniel C. Stanzione, Sr. Irrevocable Trust Dated December 31, 2007, dated January 9, 2023.				
10.27.3*	Debt Settlement Agreement and Release including certain royalty rights with Fatboy Capital, L.P., dated January 9, 2023.				
10.28*	LockeT Royalty Agreement with Auston Locke.				
10.29*	Joint Marketing Agreement dated January 19, 2021 with Stereotaxis, Inc. (the "Stereotaxis Marketing Agreement").				
10.29.1*	Extension Agreement dated January 11, 2022 to the Stereotaxis Marketing Agreement.				
10.29.2*	Addendum One dated May 27, 2022 to the Stereotaxis Marketing Agreement.				
10.30.1*	Lease with respect to Fort Mill facility.				
10.30.2*	Lease with respect to Budd Lake facility.				
10.31+*	Consulting Agreement dated February 1, 2018, with Patricia Kennedy.				
10.31.1+*	Catheter Precision, Inc. Notice of Nonplan Stock Option Award to Patricia Kennedy dated March 30, 2018.				
10.32*	Software and Technology License Agreement dated May 1, 2016, with Peacs BV.				

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.32.1*	Settlement and Amendment Agreement dated May 24, 2021 with Peacs BV.				
21.1*	Subsidiaries of the Registrant.				
23.1*	Consent of Haskell & White LLP, Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (contained on signature page).				
31.1*	Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*^	Certifications of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*^	Certifications of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	Inline XBRL Instance Document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data File (formatted as Inline XBRL)				
*	Filed herewith.				
^	The information in this exhibit is furnished and deemed not filed with the Securities and Exchange Commission for purposes of section 18 of the Exchange Act of 1934, as amended (Exchange Act), and is not to be incorporated by reference into any filing of Ra Medical Systems, Inc. under the Securities Act of 1933, as amended (Securities Act), or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.				
+	Indicates a management contract or compensatory plan.				

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

RA MEDICAL SYSTEMS, INC.

Date: March 28, 2023

By: /s/ Jonathan Will McGuire

Jonathan Will McGuire

Chief Executive Officer

POWER OF ATTORNEY

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

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

Signature	Title	Date
<u>/s/ Jonathan Will McGuire</u> Jonathan Will McGuire	Director and Chief Executive Officer (Principal Executive Officer)	March 28, 2023
<u>/s/ Brian Conn</u> Brian Conn	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2023
<u>/s/ David A. Jenkins</u> David A. Jenkins	Executive Chairman of the Board of Directors	March 28, 2023
<u>/s/ James Caruso</u> James Caruso	Director	March 28, 2023
<u>/s/ Martin Colombatto</u> Martin Colombatto	Director	March 28, 2023
<u>/s/ Susanne Meline</u> Susanne Meline	Director	March 28, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Ra Medical Systems, Inc. (the "Company") as of December 31, 2022 and 2021, the related statements of operations, stockholders' equity, and cash flows for each of the years ended December 31, 2022 and 2021 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years ended December 31, 2022 and 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ HASKELL & WHITE LLP

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

Irvine, California
March 28, 2023

RA MEDICAL SYSTEMS, INC.
Balance Sheets
(in thousands, except par value data)

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 15,859	\$ 15,045
Accounts receivable, net	—	21
Inventories	—	986
Prepaid expenses and other current assets	977	1,037
Total current assets	16,836	17,089
Property and equipment, net	—	1,809
Operating lease right-of-use assets	—	2,110
Other non-current assets	—	36
TOTAL ASSETS	\$ 16,836	\$ 21,044
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	\$ 92	\$ 988
Accrued expenses	7,484	4,119
Current portion of operating lease liabilities	—	283
Total current liabilities	7,576	5,390
Operating lease liabilities	—	1,981
Total liabilities	7,576	7,371
Commitments and contingencies (Notes 16 - 18)		
Stockholders' Equity		
Preferred stock, \$0.0001 par value, 10,000 shares authorized; no shares issued	—	—
Common stock, \$0.0001 par value, 300,000 shares authorized; 2,161 and 140 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	—
Additional paid-in capital	214,397	191,945
Accumulated deficit	(205,137)	(178,272)
Total stockholders' equity	9,260	13,673
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 16,836	\$ 21,044

See accompanying notes to financial statements.

RA MEDICAL SYSTEMS, INC.
Statements of Operations
(in thousands, except per share data)

	Year Ended December 31,	
	2022	2021
Net revenues		
Product sales	\$ 14	\$ 22
Cost of revenues		
Product sales	42	832
Service and other	119	728
Total cost of revenues	161	1,560
Gross loss	(147)	(1,538)
Operating expenses		
Selling, general and administrative	16,250	15,475
Research and development	6,392	12,253
Restructuring costs	4,172	—
Total operating expenses	26,814	27,728
Operating loss	(26,961)	(29,266)
Other income (expense), net		
Other income (expense), net	99	(14)
Gain on extinguishment of promissory note	—	2,023
Total other income (expense), net	99	2,009
Loss from continuing operations before income taxes	(26,862)	(27,257)
Income taxes	3	4
Loss from continuing operations	(26,865)	(27,261)
Discontinued operations (Note 3)		
Income from discontinued operations before income taxes	—	2,191
Income taxes	—	—
Income from discontinued operations	—	2,191
Net loss	\$ (26,865)	\$ (25,070)
Net income (loss) per share, basic and diluted		
Continuing operations	\$ (25.98)	\$ (269.91)
Discontinued operations	—	21.69
Total net loss per share, basic and diluted	\$ (25.98)	\$ (248.22)
Weighted average common shares used in computing net income (loss) per share, basic and diluted	1,034	101

See accompanying notes to financial statements.

RA MEDICAL SYSTEMS, INC.
Statements of Stockholders' Equity
(in thousands)

	Common Stock		Additional	Accumulated	Total
	Shares	Amount	Paid-In Capital	Deficit	Stockholders' Equity
Balances at January 1, 2021	63	\$ —	\$ 174,349	\$ (153,202)	\$ 21,147
Common stock issued, net	78	—	15,153	—	15,153
Warrants issued	—	—	132	—	132
Restricted stock awards canceled	(2)	—	—	—	—
Common stock issued pursuant to the vesting of restricted stock units and purchases under employee stock purchase plan	1	—	74	—	74
Stock-based compensation	—	—	2,237	—	2,237
Net loss	—	—	—	(25,070)	(25,070)
Balances at December 31, 2021	140	—	191,945	(178,272)	13,673
Common stock issued, net	1,576	—	11,638	—	11,638
Warrants issued, net	—	—	4,658	—	4,658
Warrants exercised	446	—	5,704	—	5,704
Restricted stock awards canceled	(1)	—	—	—	—
Common stock issued pursuant to the vesting of restricted stock units and purchases under employee stock purchase plan	—	—	5	—	5
Stock-based compensation	—	—	447	—	447
Net loss	—	—	—	(26,865)	(26,865)
Balances at December 31, 2022	2,161	\$ —	\$ 214,397	\$ (205,137)	\$ 9,260

See accompanying notes to financial statements.

RA MEDICAL SYSTEMS, INC.

Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (26,865)	\$ (25,070)
Adjustments to reconcile net loss to net cash used in operating activities:		
Restructuring charges	2,943	—
Stock-based compensation	447	2,237
Depreciation and amortization	421	1,565
Gain on write-off of right-of-use asset and liability	(126)	—
Loss (gain) on sales and disposals of property and equipment	44	(550)
Provision for credit losses	21	47
Gain on sale of discontinued operations	—	(3,473)
Gain on extinguishment of PPP promissory note	—	(2,023)
Changes in operating assets and liabilities:		
Accounts receivable	—	42
Inventories	(14)	(197)
Prepaid expenses and other assets	(335)	150
Accounts payable	(879)	627
Accrued expenses	2,009	(390)
Deferred revenue	—	(234)
Other liabilities	(234)	(356)
Net cash used in operating activities	(22,568)	(27,625)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sales of property and equipment	38	594
Purchases of property and equipment	(17)	(265)
Proceeds from sale of discontinued operations	—	3,700
Payment of fees related to sale of discontinued operations	—	(227)
Net cash provided by investing activities	21	3,802
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and warrants, net of fees withheld	18,906	15,528
Proceeds from exercise of warrants, net of fees withheld	5,704	—
Payment of offering costs related to the issuance of common stock and warrants	(1,254)	(375)
Proceeds from purchases under employee stock purchase plan	5	74
Repayment of equipment financing	—	(265)
Net cash provided by financing activities	23,361	14,962
NET CHANGE IN CASH AND CASH EQUIVALENTS	814	(8,861)
CASH AND CASH EQUIVALENTS, beginning of year	15,045	23,906
CASH AND CASH EQUIVALENTS, end of year	\$ 15,859	\$ 15,045
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unpaid offering costs	\$ 1,356	\$ —
Unpaid property and equipment	\$ —	\$ 17
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for income taxes	\$ 3	\$ 2
Cash payments for interest	\$ —	\$ 2

See accompanying notes to financial statements.

RA MEDICAL SYSTEMS, INC.

Notes to Financial Statements

Note 1. Organization and Nature of Operations

The Company

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

Definitive Merger Agreement

On January 9, 2023, the Company completed its merger with Catheter Precision, Inc., a privately-held Delaware corporation (“Catheter”), focused on the cardiac electrophysiology market. Following the merger, the Company began focusing on the field of cardiac electrophysiology. See Note 18. *Subsequent Events*.

Reverse Stock Split

On September 20, 2022, the Company’s board of directors approved a reverse stock split ratio of 1-for-50 (the “Reverse Stock Split”). On the effective date of the Reverse Stock Split of October 3, 2022, the number of the Company’s issued and outstanding shares of common stock decreased from 68.2 million shares to 1.4 million shares. The number of authorized shares and par value per common share remained unchanged. No fractional shares were issued as a result of the Reverse Stock Split. Stockholders who would otherwise have been entitled to receive a fractional share received a cash payment in lieu thereof. The financial statements and accompanying notes to financial statements have been retrospectively adjusted to reflect the Reverse Stock Split of the Company’s common stock for all periods presented.

NYSE American

On August 31, 2022, the Company received a deficiency letter (the “Letter”) from the NYSE American LLC (“NYSE American”) indicating that it was not in compliance with NYSE American’s continued listing standards as set forth in Section 1003(f)(v) of the NYSE American Company Guide because its shares of common stock had been selling for a substantial period of time at a low price per share, which NYSE American determined to be a 30 trading day average price of less than \$0.20 per share. The Letter had no immediate effect on the listing or trading of the Company’s common stock, and the common stock continued to trade on NYSE American under the symbol “RMED.” On December 8, 2022, the Company received a letter from NYSE American stating that the Company had regained compliance with NYSE American’s continued listing standards. Specifically, the Company had resolved the continued listing deficiency with respect to its low selling price as described in Section 1003(f)(v) of the NYSE American Company Guide.

Reduction in Force and Operations

The Company’s board of directors approved a staggered reduction in force (“RIF”) under which approximately 65% of the Company’s full-time employees were immediately terminated, effective June 6, 2022, and provided one-time severance payments totaling \$0.6 million. On September 2, 2022, the Company completed the RIF, pursuant to which an additional 20% of the Company’s employees were terminated, with effective dates ranging from August 1, 2022 through September 2, 2022, and were provided one-time severance payments totaling \$0.3 million. The purpose of the RIF was to preserve capital with the goal of maximizing the opportunities available to the Company in furtherance of the board of directors’ review of strategic alternatives. See further discussion in Note 14. *Restructuring and Impairment Charges*.

As a result of the RIF, the discontinuation of enrollment in the atherectomy clinical trial and the board of directors’ review of strategic alternatives, the Company paused all engineering and manufacturing activities during the third quarter of 2022, including the development of a version of the DABRA catheter that is compatible with a standard interventional guidewire. The Company also paused research to prove the feasibility of using a DABRA-

derived catheter technology to fracture calcium in arteries in a procedure known as lithotripsy. On July 5, 2022, the Company announced the receipt of FDA 510(k) clearance for the DABRA 2.0 catheter as part of the DABRA Excimer Laser System. The Company suspended sales of DABRA during the year ended December 31, 2022 and currently has no plans to commercialize DABRA 2.0.

Going Concern

As of December 31, 2022, the Company had cash and cash equivalents of approximately \$15.9 million. For the year ended December 31, 2022, the Company used approximately \$22.6 million in cash for operating activities. The Company has incurred recurring net losses from operations and negative cash flows from operating activities since inception. As of December 31, 2022, the Company had an accumulated deficit of approximately \$205.1 million.

Management expects operating losses and negative cash flows to continue for the foreseeable future as the Company invests in its commercial capabilities. Accrued expenses of approximately \$7.5 million at December 31, 2022 are primarily related to the Merger with Catheter. Additional costs associated with the Merger paid during the year ended December 31, 2022 have substantially depleted the Company's cash. Following the Merger with Catheter, management further reduced staff and other costs while assuming the operating costs of Catheter. Management will continue to monitor its operating costs and seek to reduce its current liabilities. Such actions may impair its ability to proceed with certain strategic activities, and it may be unsuccessful at negotiating existing liabilities to the Company's benefit. If expected revenues are not adequate to fund our planned expenditures, or if the Company is unsuccessful at raising cash through future capital transactions, it may be required to reduce its spending rate to align with expected revenue levels and cash reserves, although there can be no guarantee that it will be successful in doing so. Accordingly, the Company may be required to raise additional cash through debt or equity transactions. It may not be able to secure financing in a timely manner or on favorable terms, if at all.

In January 2023, the Company raised gross proceeds of \$1.3 million from the Warrant Repricing and signed the Securities Purchase Agreement for the Private Placement for \$8.0 million. In March 2023, the Company completed the Private Placement and raised gross proceeds of \$8.0 million.

Management believes its current cash reserves will be sufficient to fund the Company's operations for the next twelve months. These accompanying financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

Note 2. Summary of Significant Accounting Policies

Use of Estimates

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. The Company's financial statements are based upon a number of estimates including, but not limited to, allowance for credit losses, evaluation of impairment of assets, valuation of long-lived assets and their associated estimated useful lives, reserves for warranty costs, evaluation of probable loss contingencies and fair value of equity awards granted.

Segment Reporting

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

Cash and Cash Equivalents

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

Fair Value Measurements

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

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

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

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

Fair Value of Financial Instruments

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

Accounts Receivable

Trade accounts receivable are presented net of allowances for credit losses. Prior to the discontinuation of sales of catheters in June 2022, the Company sold its catheters directly to distributors or physicians and maintained an allowance for credit losses for balances that appeared to have specific collection issues. The collection process was based on the age of the invoice and required attempted contacts with the customer at specified intervals. Delinquent accounts receivable were charged against the allowance for credit losses once the Company determined the amounts were uncollectible. The factors considered in reaching this determination were the apparent financial condition of the customer and the Company's success in contacting and negotiating with the customer. If the financial condition of the Company's customers deteriorated, resulting in an impairment of their ability to make payments, additional allowances might have been required.

The following table shows the activity in the allowance for credit losses for the periods presented (in thousands):

	Year Ended December 31,	
	2022	2021
Balance at beginning of year	\$ 131	\$ 84
Provision for credit losses	21	47
Balance at end of year	<u>\$ 152</u>	<u>\$ 131</u>

Inventories

Inventories are stated at the lower of cost (first-in, first-out method) or net realizable value. Cost includes materials, labor and manufacturing overhead related to the purchase and production of inventories. The Company reduced the carrying value of inventories for those items that were potentially excess, obsolete or slow-moving based on changes in customer demand, technological developments or other economic factors. See Note 14. *Restructuring and Impairment Charges* for a description of the inventory obsolescence charges for the year ended December 31, 2022. There were no inventory obsolescence charges for the year ended December 31, 2021.

Prior to June 6, 2022, the Company's catheters were manufactured in-house and each catheter was tested at various stages of the manufacturing process for adherence to quality standards. Catheters that did not meet

functionality specification at each test point were destroyed and immediately written off, with the expense recorded in cost of revenues in the statements of operations. Once manufactured, completed catheters that passed quality assurance, were sent to a third-party for sterilization and sealed in a sterile container. Upon return from the third-party sterilizer, a sample of catheters from each batch were re-tested. If the sample tests were successful, the batch was accepted into finished goods inventory. If the sample tests were unsuccessful, the entire batch was written off, with the expense recorded in cost of revenues in the statements of operations.

Property and Equipment

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

Lasers	8 years
Machinery and equipment	5-10 years
Computer hardware and software	4-5 years
Furniture and fixtures	5 years

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

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

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

Impairment of Long-Lived Assets

The Company periodically reviewed its long-lived assets for impairment when certain events or changes in circumstances indicate that the carrying value of the long-lived assets may not be recoverable. Should the sum of the undiscounted expected future net cash flows be less than the carrying value, the Company would recognize an impairment loss at that date. See Note 14, *Restructuring and Impairment Charges* for a description of the impairment costs of long-lived assets for the year ended December 31, 2022. There were no impairment charges for the year ended December 31, 2021.

Product Warranty

Products were warrantied against defects in material and workmanship when properly used for their intended purpose and appropriately maintained. Accordingly, the Company generally replaced catheters that kinked or failed to calibrate. The product warranty liability was determined based on historical information such as past experience, product failure rates or number of units repaired, estimated cost of material and labor. The product warranty liability also includes the estimated costs of a product recall.

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

Revenue Recognition

The Company generated revenue from the sales of products and services. Product sales consisted of the sales of catheters for use with the DABRA laser system. The Company paused selling commercial products in late 2020 and was only selling catheters for use in the atherectomy clinical trial prior to the discontinuation of such sales in June 2022. The Company's sales agreements generally did not include right-of-return provisions for any form of consideration, including partial refund or credit against amounts owed to the Company. Services and other revenues primarily consisted of billable services, including fees related to DABRA laser commercial usage agreements.

The Company determined revenue recognition incorporating the following steps:

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

The Company accounted for a contract with a customer when it had a legally enforceable contract with the customer, the arrangement identified the rights of the parties, the contract had commercial substance, and the Company determined it was probable that it would collect the contract consideration. The Company recognized revenue when control of the promised goods or services transferred to customers, in an amount that reflected the consideration the Company expected to be entitled to in exchange for those goods or services. Taxes collected from customers relating to goods or services and remitted to governmental authorities were excluded from revenue.

Catheter Revenue

When engaged in commercial sales, the Company entered into a DABRA laser commercial usage agreement or DABRA laser placement acknowledgement with each customer that was supplied a DABRA laser, collectively the "usage agreement", which provided for specific terms of continued use of the DABRA laser, including a nominal periodic fee. The terms of a usage agreement typically allowed the Company to place a DABRA laser at a customer's specified location without a specified contract term. Under the usage agreement terms, the Company retained all ownership rights to the DABRA laser and was permitted to request the return of the equipment within 10 business days of notification. While the laser periodic fees were nominal, the usage agreement provided the Company the exclusive rights to supply related single-use catheters to the customer which aggregated the majority of the product sales revenue. There were no specified minimum purchase commitments for the catheters.

The Company recognized revenue associated with the usage agreements and catheter supply arrangements in accordance with Financial Accounting Standards Board ("FASB") "Revenue from Contracts with Customers (Topic 606)," ("Topic 606") since (i) the contract primarily included variable payments, (ii) the catheters were priced at their standalone selling price, and (iii) the laser equipment was insignificant in the context of the contract. Revenue was recognized when the performance obligation was satisfied which was generally upon shipment of the catheter.

Shipping and Handling Costs

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

Research and Development

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

Patents

The Company expensed patent costs, including related legal costs, as incurred and recorded such costs as selling, general and administrative expenses in the accompanying statements of operations.

Stock-Based Compensation

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

Income Taxes

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

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

Concentrations of Credit Risk

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

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

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

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity during the period from transactions and other events and non-owner sources. The Company had no such transactions or other events and non-owner sources during the years ended December 31, 2022 and 2021.

Significant Accounting Policies Related to Discontinued Operations

Laser Sales

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

Warranty Service Revenue

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

Contracts With Multiple Performance Obligations

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

Significant Financing Component

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

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

Practical Expedients Elected

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

- not to adjust the promised amount of consideration for the effects of a significant financing component when the Company expects, at contract inception, that the period between the Company's transfer of a promised product or service to a customer and when the customer pays for that product or service will be one year or less;
- to expense costs as incurred for costs to obtain a contract when the amortization period would have been one year or less;

- to exclude government assessed taxes from the transaction price; and
- not to recast revenue for contracts that begin and end in the same fiscal year.

Contract Costs

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

Rental Income

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

These lease arrangements contained one lease component (the laser) and one non-lease component (warranty service) for which the Company elected the practical expedient to not separate the non-lease component from the lease component. The Company accounted for the combined lease component as an operating lease and recognized lease income on a straight-line basis over the lease term.

Recently Adopted Accounting Pronouncement

In August 2020, the FASB issued ASU No. 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06"). The new guidance eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, the new guidance requires that the if-converted method is used in computing diluted earnings per share for all convertible instruments. The update is effective for annual reporting periods, including interim periods, beginning after December 15, 2021. The Company adopted ASU 2020-06 on January 1, 2022 using a modified retrospective approach, and the adoption did not impact its financial statements or per share amounts.

Recently Announced Accounting Pronouncements

On October 28, 2021, the FASB issued Accounting Standards Update ("ASU") No. 2021-08, *Accounting for Contract Assets and Contract Liabilities from Contracts with Customers* ("ASU 2021-08") which amends FASB Accounting Standards Codification 805, *Business Combinations* ("ASC 805") to require acquiring entities to apply Topic 606 to recognize and measure contract assets and contract liabilities in a business combination. The new standard is effective for the Company for its fiscal year beginning January 1, 2023 and interim periods within its fiscal year beginning January 1, 2023. The Company is currently evaluating the impact of adopting this standard.

In June 2022, the FASB issued ASU No. 2022-03, *Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions* ("ASU 2022-03") which clarifies guidance for fair value measurement of an equity security subject to a contractual sale restriction and establishes new disclosure requirements for such equity securities. ASU 2022-03 is effective for fiscal years beginning after December 15, 2023 and for interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of ASU 2022-03 on its financial statements.

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

Note 3. Discontinued Operations

The Company completed the sale of its Dermatology Business to STRATA Skin Sciences, Inc. (“Strata”) on August 16, 2021, for cash proceeds of \$3.7 million. The Company paid broker and legal fees of approximately \$0.2 million related to the sale of the Dermatology Business. In addition, the Company issued a warrant to the broker to purchase 1,484 shares of common stock at an exercise price of \$149.50 per share. The warrant was immediately exercisable and expires five years following the date of issuance. The warrant was valued at approximately \$0.1 million on the grant date using the Black-Scholes model based on the following assumptions: expected volatility of 104.55%, risk-free interest rate of 0.32%, expected dividend yield of 0% and an expected term of 2.5 years.

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

The Company has reported the results of the Dermatology Business as income from discontinued operations and excluded such results from continuing operations in the statement of operations for the year ended December 31, 2021. Certain overhead costs previously allocated to the Dermatology Business for segment reporting purposes did not qualify for classification as discontinued operations and have been reallocated to continuing operations for the year ended December 31, 2021.

The following table summarizes the major classes of items constituting income from discontinued operations in the statement of operations for the year ended December 31, 2021 (in thousands):

Net revenues	
Product sales	\$ 852
Service and other	1,748
Total net revenues	2,600
Cost of revenues	
Product sales	1,201
Service and other	1,089
Total cost of revenues	2,290
Gross income	310
Operating expenses	
Selling, general and administrative	1,110
Research and development	388
Total operating expenses	1,498
Operating loss	(1,188)
Interest income (expense), net	(94)
Loss from discontinued operations	(1,282)
Gain on sale of the Dermatology Business	3,473
Income from discontinued operations	<u>\$ 2,191</u>

Depreciation expense for the Dermatology Business was \$0.3 million for the year ended December 31, 2021. There were no capital expenditures for the Dermatology Business during the year ended December 31, 2021. There was no provision for credit losses for the Dermatology Business for the year ended December 31, 2021. Stock-based compensation expense for the Dermatology Business was approximately \$18,000 for the year ended December 31, 2021. Stock-based compensation expense of approximately \$0.1 million was capitalized to inventory and property and equipment for the Dermatology Business during the year ended December 31, 2021.

Note 4. Fair Value Measurements

As of December 31, 2022 and 2021, the Company had cash equivalents measured at fair value on a recurring basis using Level 1 inputs. As of December 31, 2022, cash equivalents of \$1.7 million were comprised of \$1.4 million of money market funds and \$0.3 million of certificates of deposit. As of December 31, 2021, cash equivalents of \$9.4 million consisted of money market funds.

Note 5. Inventories

Inventories consisted of the following (in thousands):

	December 31,	
	2022	2021
Raw materials	\$ —	\$ 911
Work in process	—	70
Finished goods	—	5
Inventories	\$ —	\$ 986

Due to the RIF and the Company's decision to discontinue enrollment of patients in its atherectomy clinical trial, the Company suspended manufacturing activities in June 2022 and disposed of all inventories, resulting in a write-down of \$1.0 million to net realizable value of its inventories. Such expense is included in restructuring and impairment charges in the statement of operations for the year ended December 31, 2022. See Note 14. *Restructuring and Impairment Charges*.

Note 6. Property and Equipment

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

	December 31,	
	2022	2021
Lasers	\$ —	\$ 3,086
Machinery and equipment	—	858
Computer hardware and software	—	353
Construction in progress	—	168
Leasehold improvements	—	145
Furniture and fixtures	—	48
Property and equipment, gross	—	4,658
Accumulated depreciation	—	(2,849)
Property and equipment, net	\$ —	\$ 1,809

Depreciation expense was \$0.2 million and \$1.0 million for the years ended December 31, 2022 and 2021, respectively. Due to the RIF and the Company's decision to discontinue enrollment of patients in its clinical trial, the Company also suspended manufacturing activities in June 2022. The Company's property and equipment was determined to be impaired, resulting in an impairment charge of \$1.5 million which was based on the actual cash proceeds received in July 2022 upon the sale and disposal of its property and equipment. The impairment charge of \$1.5 million is included in restructuring and impairment charges in the statement of operations for the year ended December 31, 2022. See Note 14. *Restructuring and Impairment Charges*.

Note 7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2022	2021
Legal expenses	\$ 5,195	\$ 1,345
Offering costs	1,356	—
Compensation and related benefits	369	2,004
Warranty expenses (Note 8)	192	195
Other accrued expenses	372	575
Accrued expenses	\$ 7,484	\$ 4,119

Note 8. Accrued Warranty

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

	Year Ended December 31,	
	2022	2021
Balance at beginning of period	\$ 195	\$ 204
Claims satisfied	(3)	(9)
Balance at end of period	\$ 192	\$ 195

The accrued warranty balances at December 31, 2022 and 2021 relate to the voluntary recall of catheters, which was initiated in September 2019.

Note 9. Paycheck Protection Program Promissory Note

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

Note 10. Operating Leases

On October 24, 2022, the Company entered into a lease termination agreement (the “Lease Termination Agreement”) with the landlord, pursuant to which it terminated the lease agreement for its office and manufacturing space in Carlsbad, California, effective October 28, 2022. In accordance with the terms of the Lease Termination Agreement, the Company agreed to (i) release its right to the security deposit of approximately \$36,000 previously paid to the landlord and (ii) pay a \$0.3 million lease termination fee to the landlord. As a result of the Lease Termination Agreement, the Company wrote-off its right-of-use asset, right-of-use liability and security deposit, resulting in a non-cash gain of approximately \$0.1 million. The lease termination fee of \$0.3 million was paid on October 31, 2022.

On October 31, 2022, the Company entered into a month-to-month lease agreement with Avanti Workspace (the “Lease Agreement”) for its corporate headquarters in Carlsbad, California, effective November 1, 2022. The rent expense under the Lease Agreement is approximately \$1,000 per month.

During the year ended December 31, 2021, the Company had two operating leases for office and manufacturing space which required it to pay base rent and certain utilities. Monthly rent expense was recognized on a straight-line basis over the terms of the leases. The office operating lease expired in December 2021 and the office and manufacturing operating lease would have expired in 2027, had it not been terminated.

At December 31, 2021, the remaining lease term for the manufacturing operating lease was six years. The manufacturing operating lease was included in the balance sheet at the present value of the lease payments at a 7% discount rate, the rate of interest that the Company estimated it would have paid to borrow on a collateralized basis over a similar term and amount equal to the lease payments in a similar economic environment, as the lease did not provide an implicit rate.

For the years ended December 31, 2022 and 2021, operating lease expense and cash paid were \$0.4 million and \$0.5 million, respectively. The Company recognized non-cash right-of-use assets and lease liabilities of \$3.2 million upon adoption of ASU 2016-02 on January 1, 2019. Operating lease right-of-use asset amortization was \$0.2 million and \$0.4 million, respectively, for the years ended December 31, 2022 and 2021. Variable costs were *de minimis* for the years ended December 31, 2022 and 2021.

Note 11. Net Loss per Share

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

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

Anti-dilutive common share equivalents excluded from the computation of diluted net loss per share at December 31, 2022 consisted of warrants of 1,150,669, stock options of 990, restricted stock awards of 948, and restricted stock units of 61.

Anti-dilutive common share equivalents excluded from the computation of diluted net loss per share at December 31, 2021 consisted of warrants of 48,365, stock options of 2,094, restricted stock units of 1,402, restricted stock awards of 3,586 and ESPP shares of 452.

Note 12. Equity Offerings

At-The-Market Sales Agreement

On September 2, 2022, the Company entered into the At-The-Market Sales Agreement (the "ATM Agreement") under which the Company could sell its common stock from time to time having an aggregate offering price of up to \$7.6 million. The Company completed the sale of 1,071,240 shares of common stock under the ATM Agreement on October 7, 2022, at a weighted average price of \$7.09 per share, resulting in net proceeds of approximately \$7.4 million, after offering fees withheld of approximately \$0.2 million.

Warrant Repricing

On July 22, 2022, the Company reduced the exercise price of all outstanding warrants, consisting of Series A warrants and Series B warrants, that were issued in the public offering on February 8, 2022 (the "Offering") from \$25.00 per share to \$14.00 per share (the "Warrant Repricing"). Following the Warrant Repricing, the Company entered into warrant inducement offer letters (the "Inducement Letters") with certain investors. In response to the Inducement Letters, investors exercised approximately 0.4 million Series A warrants and no Series B warrants. Investors who exercised their Series A warrants received Series C warrants to purchase 100% of the shares exercised pursuant to the Series A warrants. The Series C warrants have an exercise price of \$14.00, are immediately exercisable and expire in five years. The Company received net proceeds of approximately \$4.9 million from the exercises of the Series A warrants, after deducting underwriter commissions and fees withheld of \$0.6 million and other offering expenses paid or payable of \$0.7 million.

The Warrant Repricing resulted in an immediate and incremental increase of approximately \$2.3 million in the estimated fair value of the Series A warrants and Series B warrants issued in the Offering.

The Series A warrants and Series B warrants were valued on the date of the Warrant Repricing using the Black-Scholes model based on the following assumptions:

	Series A	Series B
Risk-free interest rate	2.97%	2.85%
Volatility	137.87%	90.44%
Expected dividend yield	0.00%	0.00%
Expected life (in years)	0.6	6.6

The Series C warrants were valued on the date of the Warrant Repricing at approximately \$2.3 million using the Black-Scholes model based on the following assumptions:

Risk-free interest rate	2.87%
Volatility	96.70%
Expected dividend yield	0.00%
Expected life (in years)	5.0

The Company entered into an agreement with a former placement agent that, subject to satisfaction of the requirements contained therein, called for a cash tail fee payable based on capital raised from certain investors for a definitive time following the expiration of the agreement. The accrued cash tail fee of approximately \$0.5 million related to the Warrant Repricing is included in accrued expenses in the balance sheet as of December 31, 2022. Additionally, the agreement called for the issuance of a warrant to purchase approximately 31,000 shares of common stock with an exercise price of \$17.50 per share, expiring five years from the date issued. This warrant was valued at approximately \$0.2 million on the Warrant Repricing date using the Black-Scholes model based on the following assumptions: expected volatility of 96.7%, risk-free interest rate of 2.87%, expected dividend yield of 0% and an expected term of 5.0 years. This warrant has not been issued by the Company as of the date of this Annual Report.

Public Offering

On February 8, 2022, the Company completed the Offering in which it issued and sold (i) 190,700 shares of common stock, (ii) 480,052 warrants to purchase one share of common stock at an exercise price of \$25.00 that were immediately exercisable and expire one year from the date of issuance, or Series A warrants, and (iii) 480,052 warrants to purchase one share of common stock at an exercise price of \$25.00 that were immediately exercisable and expire seven years from the date of issuance, or Series B warrants, and (iv) 289,352 pre-funded warrants to purchase one share of common stock at an exercise price of \$0.005 per share that were immediately exercisable and expire twenty years from the date of issuance. In addition, the Company granted the underwriters of the Offering a 45-day option (the "Overallotment Option") to purchase up to (i) 72,000 additional shares of common stock, (ii) 72,000 additional Series A warrants and/or (iii) 72,000 additional Series B warrants, solely to cover overallotments.

The Series A warrants and Series B warrants were valued at approximately \$11.6 million using the Black-Scholes model based on the following assumptions:

	Series A	Series B
Risk-free interest rate	0.91%	1.93%
Volatility	131.07%	85.38%
Expected dividend yield	0.00%	0.00%
Expected life (in years)	1.0	7.0

Pursuant to the exercise of the Overallotment Option in February 2022, the Company issued 24,902 shares of common stock, 72,000 Series A warrants and 72,000 Series B warrants, net of underwriting discounts. On various dates in February 2022 and March 2022, the Company issued 289,352 shares of common stock upon the exercise of all of the pre-funded warrants issued in the Offering. In addition, in March 2022, the Company issued 1,000 shares of common stock in connection with the exercise of 500 each of Series A warrants and Series B warrants issued in

the Offering. In July 2022, the Company issued 800 shares of common stock in connection with the exercise of 800 Series A warrants issued in the Offering.

Net proceeds received from the Offering were approximately \$11.5 million, after deducting underwriter commissions and fees withheld of approximately \$1.1 million. In addition, the Company incurred offering expenses paid or payable of \$1.8 million.

The Company entered into an agreement with a former placement agent that, subject to satisfaction of the requirements contained therein, called for a cash tail fee payable based on capital raised from certain investors for a definitive time following the expiration of the agreement. The accrued cash tail fee of approximately \$0.9 million related to the Offering is included in accrued expenses in the balance sheet as of December 31, 2022. Additionally, the agreement called for the issuance of a warrant to purchase approximately 33,000 shares of common stock at an exercise price of \$31.25 per share. Such warrant would be immediately exercisable and expire five years from the date issued. This warrant was originally valued at approximately \$0.4 million on the date of the Offering using the Black-Scholes model based on the following assumptions: expected volatility of 93.25%, risk-free interest rate of 1.81%, expected dividend yield of 0% and an expected term of 5 years. On the date of the Warrant Repricing, this warrant was revalued at approximately \$0.4 million using the Black-Scholes model based on the following assumptions: expected volatility of 98.9%, risk-free interest rate of 2.87%, expected dividend yield of 0% and an expected term of 4.6 years. This warrant has not been issued by the Company as of the date of this Annual Report.

During the year ended December 31, 2021, the Company completed ATM offerings of 76,223 shares of common stock at a weighted average price of \$210.41 per share. The Company received approximately \$15.5 million in net proceeds, after deducting placement agent fees. The Company also incurred approximately \$0.4 million in offering fees and other expenses.

Warrants Outstanding

As of December 31, 2022, the Company had 1,150,669 shares of common stock reserved for issuance pursuant to the warrants issued by the Company at a weighted average exercise price of \$33.67.

Note 13. Stock-Based Compensation

2018 Equity Incentive Plan

In September 2018, the Company's board of directors adopted, and the Company's stockholders approved, the 2018 Equity Incentive Plan (the "2018 Plan") which provided for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, performance-based stock awards and other forms of equity compensation to the Company's employees, directors and consultants. Stock options granted under the 2018 Plan generally vest one-fourth on the first anniversary of the vesting commencement date with the balance vesting monthly over the remaining three years. Restricted stock units granted under the 2018 Plan generally vest one third on the first anniversary of the vesting commencement date and one sixth every six months thereafter such that the award will be fully vested on the third anniversary of the vesting commencement date. As of December 31, 2022, 8,552 shares of common stock were reserved for future issuance pursuant to the 2018 Plan. The number of shares available for issuance under the 2018 Plan also includes an annual increase on the first day of each fiscal year equal to the lesser of (1) 1,305 shares; (2) 5% of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or 3) such other amount as the Company's board of directors may determine.

2020 Inducement Equity Incentive Plan

In March 2020, the Company adopted the 2020 Inducement Equity Incentive Plan (the "2020 Plan") for the purpose of attracting, retaining and incentivizing employees in furtherance of the Company's success. The 2020 Plan was adopted without stockholder approval pursuant to Rule 303A.08 of the New York Stock Exchange. The 2020 Plan is used to offer equity awards as material inducements for new employees to join the Company. Upon adoption of the 2020 Plan, 640 shares of common stock were reserved for the granting of inducement stock options, restricted stock awards, restricted stock units and other forms of equity awards. As of December 31, 2022, 181 shares of common stock were reserved for future issuance under the 2020 Plan.

Stock Options

The following is a summary of stock option activity for the year ended December 31, 2022:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	2,094	\$ 17,138		
Canceled/forfeited	(1,104)	\$ 22,279		
Outstanding at December 31, 2022	990	\$ 11,405	4.14	\$ —
Vested and expected to vest at December 31, 2022	990	\$ 11,405	4.14	\$ —
Exercisable at December 31, 2022	849	\$ 13,077	3.92	\$ —

The Company did not grant any stock options during the years ended December 31, 2022 and 2021.

Restricted Stock Units

The following is a summary of the restricted stock unit activity for the 2018 Plan for employees of continuing operations and discontinued operations for the year ended December 31, 2022:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2021	1,402	\$ 258.48
Vested	(117)	\$ 892.00
Canceled/forfeited	(1,224)	\$ 188.35
Outstanding at December 31, 2022	61	\$ 450.46

Restricted Stock Awards

A summary of the restricted stock award activity for the year ended December 31, 2022 is presented below:

	Restricted Stock Awards	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2021	3,586	\$ 235.03
Vested	(1,660)	\$ 241.38
Canceled/forfeited	(978)	\$ 211.24
Outstanding at December 31, 2022	948	\$ 248.48

Employee Stock Purchase Plan

In September 2018, the Company's board of directors adopted the 2018 Employee Stock Purchase Plan (the "ESPP") which permitted eligible employees to purchase the Company's common stock at a discount through payroll deductions during defined offering periods. Eligible employees could elect to withhold up to 15% of their base earnings to purchase shares of the Company's common stock at a price equal to 85% of the fair market value on the first day of the offering period or the purchase date, whichever was lower. The number of shares of common stock reserved for issuance under the ESPP automatically increased on January 1 of each fiscal year by the lesser of (1) 237 shares, (2) 1.25% of the total number of shares outstanding on December 31 of the preceding fiscal year, or (3) such other amount as the Company's board of directors may determine.

For the years ended December 31, 2022 and 2021, cash received from the exercise of purchase rights under the ESPP was approximately \$5,000 and \$0.1 million, respectively. The Company paused the ESPP in May 2022.

As of December 31, 2022, the Company had issued 950 shares of common stock since inception of the ESPP, and no shares were reserved for future issuance.

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

	Year Ended December 31,	
	2022	2021
Selling, general and administrative	\$ 387	\$ 1,750
Research and development	60	304
Stock-based compensation in operating expenses	\$ 447	\$ 2,054

Stock-based compensation of approximately \$5,000 and \$0.1 million was capitalized to property and equipment and inventory during the years ended December 31, 2022 and 2021, respectively.

Total unrecognized estimated stock-based compensation expense by award type and the remaining weighted average recognition period over which such expense is expected to be recognized at December 31, 2022 was as follows:

	December 31, 2022	
	Unrecognized Expense (in thousands)	Remaining Weighted Average Recognition Period (in years)
Stock options	\$ 93	1.2
Restricted stock awards	\$ 186	1.0
Restricted stock units	\$ 14	1.0

Note 14. Restructuring and Impairment Charges

Restructuring and impairment charges consisted of the following for the year ended December 31, 2022 (in thousands):

Impairment of property and equipment	\$ 1,548
Inventory obsolescence	1,000
Severance expense	910
Prepaid expenses	395
Contract termination fees	319
Total restructuring and impairment charges	\$ 4,172

The Company's RIF was completed in September 2022 and impacted approximately 85% of its full-time employees, resulting in one-time severance payments totaling approximately \$0.9 million. In addition, the Company discontinued enrollment of patients in its clinical trial, ceased engineering and manufacturing activities, sold or disposed of substantially all of its property and equipment, inventories and research and development supplies, resulting in impairment and inventory obsolescence charges and the write-off of prepaid research and development supplies totaling approximately \$2.9 million during the year ended December 31, 2022.

Note 15. Income Taxes

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

	Year Ended December 31,	
	2022	2021
Tax computed at the federal statutory rate	21%	21%
Section 382 NOL limitation	(42.6)	—
Nondeductible expenses	(1.3)	—
State income taxes, net of federal benefits	0.2	1.3
Stock-based compensation	—	(2.6)
Tax exempt income	—	1.7
Other	0.4	—
Change in valuation allowance	22.3	(21.4)
	<u>—</u>	<u>—</u>

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

	Year Ended December 31,	
	2022	2021
Current		
Federal	\$ —	\$ —
State	3	4
	<u>3</u>	<u>4</u>
Deferred		
Federal	—	—
State	—	—
	<u>—</u>	<u>—</u>
Income tax expense	<u>\$ 3</u>	<u>\$ 4</u>

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for tax purposes, and (b) operating losses and tax credit carryforwards.

The tax effects of significant components of the Company's deferred tax assets (liabilities) are as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 518	\$ 9,706
Stock-based compensation	5,162	4,605
Capitalized research and development	1,528	—
Reserves	95	169
Intangible assets	35	56
Accrued legal settlement	1,355	—
Operating lease liabilities	—	556
Accrued compensation	—	399
Other accruals	1	71
Total gross deferred tax assets	8,694	15,562
Deferred tax liabilities:		
Property and equipment	—	(348)
Operating lease right-of-use assets	—	(518)
Other	—	—
Total gross deferred tax liabilities	—	(866)
Valuation allowance	(8,694)	(14,696)
Total deferred taxes	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2022, the Company had federal and state net operating loss ("NOL") carryforwards of approximately \$54.5 million and \$47.8 million, respectively. The state NOL carryforwards begin expiring in 2030. Use of these NOL carryforwards may be significantly limited under the tax rules regarding the use of losses following an ownership change under Internal Revenue Code ("IRC") Section 382. Management performed a Section 382 analysis regarding the limitation of net operating losses through December 31, 2020 and determined that ownership changes occurred in May 2020. The Company believes further ownership changes occurred during each of the years ended December 31, 2022 and 2021. Accordingly, utilization of the Company's NOLs is subject to an annual limitation for federal tax purposes under IRC Section 382. Due to the changes in control, the Company estimated that all of its \$54.5 million federal NOL carryforwards are effectively eliminated, in accordance with IRC Section 382. In addition, \$40.8 million of its \$47.8 million in state NOL carryforwards is also eliminated. As a result of these eliminations, the Company's federal and state NOLs were reduced to zero and \$6.9 million, respectively, before taking into consideration the valuation allowance. Also, as described in Note 18 *Subsequent Events*, the Company completed the Merger on January 9, 2023.

The valuation allowance relates to deferred tax assets for certain items that will be deductible for income tax purposes under very limited circumstances and for which the Company believes it is not more likely than not that it will realize the associated tax benefit. However, in the event that the Company determines that it would be able to realize more or less than the recorded amount of net deferred tax assets, an adjustment to the deferred tax asset valuation allowance would be recorded in the period such a determination is made. In assessing the realizability of deferred tax assets, management considers whether it is more-likely-than-not that some portion of all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward periods), projected future taxable income and tax planning strategies in making this assessment. Based upon the levels of historical taxable income, projection of future taxable income and the reversal of deferred tax liabilities over the periods in which the deferred tax assets are deductible, management believes it is more-likely-than-not that the Company will not realize the benefits of these deductible differences, net of the existing valuation allowance. The amount of deferred tax asset considered realizable, however, could change in the near term if estimates which require significant judgment of future taxable income during the carryforward period are increased or decreased.

As of December 31, 2022, the Company does not have any unrecognized tax benefits. The Company does not anticipate that the amount of unrecognized tax benefits will significantly increase in the next 12 months. There were no interest and penalties accrued as of December 31, 2022. The Company files U.S. federal and various states income tax returns, which are subject to examination by the taxing authorities for years 2018 and later. However, the federal net operating loss carryover may be adjusted three years from the date the loss is utilized on an income tax return.

Note 16. Commitments and Contingencies

Securities Class Action

On June 7, 2019, a putative securities class action complaint captioned *Derr v. Ra Medical Systems, Inc., et al*, (Civil Action no. 19CV1079 LAB NLS) was filed in the U.S. District Court for the Southern District of California against the Company, certain current and former officers and directors, and certain underwriters of the Company's initial public offering. Following the appointment of a lead plaintiff and the filing of a subsequent amended complaint, the lawsuit alleges that the defendants made material misstatements or omissions in the Company's registration statement in violation of Sections 11 and 15 of the Securities Act of 1933 (the "Securities Act") and between September 27, 2018 and November 27, 2019, inclusive, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). On March 11, 2020, lead plaintiffs voluntarily dismissed the underwriter defendants without prejudice. On March 13, 2020, defendants filed a motion to dismiss the amended complaint. On March 24, 2021, the court issued an order granting defendants' motion to dismiss claims under the Securities Act in full and certain claims under the Exchange Act and denying defendants' motion to dismiss certain Exchange Act claims. Plaintiffs filed their second amended complaint on April 19, 2021, realleging the Securities Act claims and certain of the previously dismissed Exchange Act claims. On June 10, 2021, defendants moved to dismiss the second amended complaint. On November 12, 2021, following a private settlement mediation with the lead plaintiffs, the parties executed a stipulation of settlement that resolved the claims asserted in the securities class action. The settlement provides for a payment to the plaintiff class of \$10.0 million. On March 18, 2022, the Company paid approximately \$0.6 million towards the settlement to satisfy its self-insured retention/deductible. The Company's insurers paid the remainder of the settlement. The proposed settlement required both preliminary and final approval by the court. On February 11, 2022, the court granted preliminary approval of the settlement, scheduled a hearing on final approval of the settlement and denied the pending motion to dismiss without prejudice. On May 2, 2022, plaintiffs filed a motion for final approval of the settlement and plan of allocation, and lead counsel filed a motion for an award of attorneys' fees and reimbursement of litigation expenses. On September 23, 2022, the court granted final approval of the settlement, certified the settlement class, granted in part lead counsel's motion for an award of attorneys' fees and reimbursement of litigation expenses, dismissed plaintiffs' claims with prejudice, and entered final judgment.

Shareholder Derivative Litigation

On October 1, 2019, a shareholder derivative complaint captioned *Noel Borg v. Dean Irwin, et al* (Civil Action no. 1:99-cv-09999) was filed in the U.S. District Court for the District of Delaware against certain current and former officers and directors, purportedly on behalf of the Company, which is named as a nominal defendant in the action. The complaint alleges breaches of fiduciary duty, unjust enrichment, waste, and violations of Section 14(a) of the Exchange Act. On October 21, 2019, pursuant to the parties' stipulation, the court stayed the derivative lawsuit until the related class action is resolved. On November 10, 2022, the plaintiff filed a notice voluntarily dismissing the case without prejudice.

Settlement Agreements with the Department of Justice and Participating States

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

Pursuant to the terms of the Settlement Agreements, (a) if the Company's revenue exceeds \$10 million in any of fiscal years 2021-2024, the Company also is required to pay for the corresponding year: \$500,000 for 2021,

\$750,000 for 2022, \$1 million for 2023, and \$1.25 million for 2024; (b) if the Company is acquired or is otherwise involved in a change in control transaction before the end of 2024, the Company was required to pay an additional settlement amount of \$5 million, plus 4% of the value attributed to the Company in the transaction, so long as the attributed value is in excess of \$100 million, with the total change in control payment never to exceed \$28 million; and (c) if the Company's obligations under the Settlement Agreements are avoided by bankruptcy, the U.S. may rescind the releases and bring an action against the Company in which the Company agrees is not subject to an automatic stay, is not subject to any statute of limitations, estoppel or laches defense, and is a valid claim in the amount of \$56 million, minus any prior change in control payments. As a result of the Merger, the Company recorded \$5.0 million related to the Settlement Agreements as of December 31, 2022, which is included in accrued expenses in the accompanying balance sheet. See Note 18. *Subsequent Events*.

Filing of Complaint

On September 29, 2022, a purported stockholder of the Company filed a complaint captioned *David Nguyen v. Ra Medical Systems, Inc. et al.* (Civil Action no. 3:22-cv-01470-BEN-MSB) in the U.S. District Court for the Southern District of California against us and our current directors. The complaint alleges violations of Sections 14(a) and 20(a) of the Exchange Act based on alleged deficiencies in our preliminary proxy, filed with the SEC on September 23, 2022. On February 7, 2023, plaintiff filed a notice voluntarily dismissing the case without prejudice.

Other Litigation

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

Services Agreement

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

Note 17. Employee Benefit Plan

In January 2019, the Company established a defined contribution plan under Section 401(k) of the Internal Revenue Code ("401(k) Plan"). Under the terms of the 401(k) Plan, all full-time employees were eligible to make voluntary contributions as a percentage or defined amount of compensation. The Company made matching contributions based on 100% of each employee's contribution up to 3% and 50% of contributions between 3% and 5%, with the match-eligible contribution limited to 4% of the employee's eligible compensation. The Company's expense related to the matching contributions was approximately \$0.2 million and \$0.3 million for the years ended December 31, 2022 and 2021, respectively.

Note 18. Subsequent Events

Settlement Agreements with the Department of Justice and Participating States

In February 2023, the Company made payments of \$4.7 million and \$0.3 million to the DOJ and the participating states, respectively, pursuant to the terms of the Settlement Agreements.

Merger with Catheter

On January 9, 2023, the Company completed the Merger for the purpose of acquiring Catheter's existing and developing product lines based on electrophysiology technology. Pursuant to the Merger Agreement, the Company issued 14,649,591 shares of Series X Preferred Stock to Catheter debtholders and stockholders in exchange for 100% of the issued and outstanding common shares of Catheter and the cancellation of the principal amount.

The estimated total purchase consideration for the Merger was approximately \$82.9 million which represents the sum of the (i) estimated fair value of the 14,649,591 Series X Preferred Stock issued and (ii) the portion of the estimated fair value of the options issued as replacement of share-based payment awards, as required under ASC 805.

The fair value of the Series X Preferred Stock includes certain discounts applied to the closing stock price of the Company on January 9, 2023 of \$6.41, with a 15% discount applied to reflect the Series X Preferred Stock's lack of marketability.

The following table summarizes the preliminary estimated fair value of the consideration associated with the Merger (in thousands):

Fair value of 14,649,591 Series X Preferred Stock issued	\$	79,840
Fair value of Catheter's fully vested stock options		3,027
Total purchase price	\$	<u>82,867</u>

The Merger is being accounted for as a business combination in accordance with ASC 805. The Company has determined the preliminary fair values of the assets acquired and liabilities assumed in the Merger. These values have been prepared based on preliminary estimates of fair value of consideration, assets acquired and liabilities assumed. Differences between these preliminary estimates and the final acquisition accounting are likely to occur and these differences could be material.

The following table summarizes the preliminary purchase price allocations related to the Merger (in thousands):

Estimated consideration	\$	<u>82,867</u>
Assets (liabilities) assumed:		
Cash and cash equivalents		33
Other assets		152
Long-term assets		145
Accounts payable, accrued expenses and other liabilities		(2,806)
Royalties payable, long-term		(7,591)
Intangible assets		37,000
Net assets assumed		<u>26,933</u>
Deferred tax liability		(10,108)
Excess of consideration over net assets assumed	\$	<u>66,042</u>

Excess of the purchase price over the estimated fair value of the net assets assumed has been reflected as goodwill.

All intangible assets acquired are subject to amortization and their associated estimated acquisition date fair values and estimated useful lives are as follows (in thousands except for estimated useful life which is in years):

	Estimated Fair Value	Estimated Useful Life
Developed technology – VIVO	\$ 8,020	8
Developed technology – LockeT	27,060	6
Customer Relationships	220	5
Trademark – VIVO	1,480	9
Trademark – LockeT	220	8
	<u>\$ 37,000</u>	

ASC 805 requires that an acquirer in a business combination report provisional amounts when measurements are incomplete as of the end of the reporting period covering the business combination. In accordance with ASC 805, the acquirer has a period of time, referred to as the measurement period, to finalize the accounting for a

business combination. The measurement period provides companies with a reasonable period of time to determine the value of the identifiable assets acquired, liabilities assumed, and the consideration transferred for the acquiree. In accordance with ASC 805, the measurement period ends as soon as the acquirer receives all necessary information about the facts and circumstances that existed as of the acquisition date for the provisional amounts or has otherwise learned that more information is not obtainable. However, the measurement period cannot exceed one year from the acquisition date. ASC 805 requires that measurement period adjustments be recognized in the reporting period in which the adjustment amount is determined.

Unaudited Pro Forma Financial Information

The following table represents the revenue, net loss and net loss per share effect of the acquired company, as reported on a pro forma basis as if the acquisition occurred on January 1, 2022. These pro forma results are not necessarily indicative of the results that would have occurred if the acquisition had occurred on the first day of the periods presented, nor does the pro forma financial information purport to represent the results of operations for future periods. The following information for the year ended December 31, 2022 is presented in thousands except for the per share data:

Revenues	\$	355
Net loss		(41,559)
Basic and diluted net loss per share – on a pro forma basis (unaudited)		(22.30)

Conversion of Series X Preferred Stock

On March 21, 2023, the Company held a special meeting of stockholders (the “Stockholders’ Meeting”), at which the stockholders approved, among other things, the issuance of 1,993,627 shares of common stock upon the conversion of 1,993,627 of Series X Preferred Stock which were issued upon the closing of the Merger. The remaining 12,655,965 shares of Series X Preferred Stock are expected to remain outstanding until at least July 9, 2024, and will convert thereafter into up to 12,655,965 shares of common stock, only if the Company meets the initial listing standards of the NYSE American or another national securities exchange or are delisted from the NYSE American.

Warrant Inducement Offer

On January 9, 2023, the Company reduced the exercise price of certain existing warrants, or the Existing Warrants, exercisable for 331,608 shares of the Company’s common stock held by a certain investor (the “Investor”), with exercise prices ranging from \$14.00 to \$526.50 per share to \$4.00 per share, or the Warrant Repricing. In connection with the Warrant Repricing, the Company entered into a warrant inducement offer letter, or the Inducement Letter, with the Investor pursuant to which it would exercise up to all of the 331,608 Existing Warrants, or the Inducement Offer. In consideration for exercising the Existing Warrants pursuant to the terms of the Inducement Letter, the Company received approximately \$1.3 million in gross proceeds. The Company paid the placement agent aggregate cash fees of approximately \$0.2 million related to the Inducement Offer which represented 8.0% of the gross proceeds received from the Inducement Offer plus other offering costs. In consideration for exercising the Existing Warrants pursuant to the terms of the Inducement Letter, the Company issued the Investor a new Series E common stock purchase warrant, or Series E Warrant, to purchase 331,608 shares of common stock at an exercise price of \$4.00 per share. The Series E Warrant is exercisable for five years from the date of stockholder approval. Exercise of the Series E Warrant in full was subject to approval of the pre-closing holders of Ra Medical’s stockholders which was obtained at the Stockholders’ Meeting.

Based on the Black Scholes model, the Warrant Repricing resulted in an immediate and incremental increase of approximately \$0.3 million in the estimated fair value of the Existing Warrants which will be reported in the statement of stockholders’ equity for the three months ending March 31, 2023. In addition, based on the Black-Scholes model, the Company estimated the fair value of the Series E Warrant issued to be approximately \$1.9 million.

On January 9, 2023, the Company entered into a Securities Purchase Agreement (“Securities Purchase Agreement”) for a private placement (“Private Placement”), with the Investor. Pursuant to the Securities Purchase Agreement, the Investor agreed to purchase, for an aggregate purchase price of approximately \$8.0 million, (a) Class A units at a price that is the lower of \$3.00 per unit and 90% of the 5 day volume weighted average price of the Company’s common stock immediately prior to obtainment of the approval of the Company’s stockholders of conversion of the PIPE Preferred Stock and PIPE Warrants (as each are defined below), each consisting of one share of common stock, one Series F common stock purchase warrant, or Series F Warrant, and one Series G common stock purchase warrant, or Series G Warrant, and together with the Series F Warrants (the “PIPE Warrants”) and (b) Class B units at a price of \$1,000 per unit, each consisting of one share of a new series of the Company’s preferred stock, designated as Series A Convertible Preferred Stock (the “PIPE Preferred Stock”), par value \$0.0001, and one Series F Warrant and one Series G Warrant for each share of the Company’s common stock underlying the PIPE Preferred Stock (each share of which is convertible into a number of shares of the Company’s common stock equal to \$1,000 divided by the lower of \$3.00 and 90% of the 5 day volume weighted average closing price of the Company’s common stock immediately prior to the obtainment of the approval of the Company’s stockholders of conversion of the PIPE Preferred Stock and PIPE Warrants, or the Preferred Conversion Rate. The closing under the Securities Purchase Agreement and the sale and issuance of the Class A units and Class B units (and the issuance of any underlying common stock) were approved at the Stockholders’ Meeting. At the closing of the Private Placement, the Company issued 497,908 Class A units for proceeds of approximately \$0.8 million and 7,203 Class B units for proceeds of approximately \$7.2 million which are convertible into up to 4,501,060 shares of common stock, as well as the issuance of warrants described below.

The PIPE Warrants are exercisable at an exercise price of \$3.00 per share, subject to adjustments as provided under the terms of the PIPE Warrants. The PIPE Warrants are exercisable at any time on or after the closing date of the Private Placement until the expiration thereof, except that the PIPE Warrants cannot be exercised if, after giving effect thereto, the purchaser would beneficially own more than 4.99%, or the Maximum Percentage, of the outstanding shares of common stock of the Company, which Maximum Percentage may be increased or decreased by the purchaser with written notice to the Company to any other percentage specified not in excess of 9.99%. The Series F Warrants have a term of two years from the date of stockholder approval, and the Series G Warrants have a term of six years from the date of stockholder approval. The Series F Warrants and Series G Warrants were approved at the Stockholders’ Meeting.

Shares of PIPE Preferred Stock, the conversion of which was approved at the Stockholders’ Meeting, convert into common stock at the option of the holder at the Preferred Conversion Rate, subject to certain ownership limitations as described below. The conversion price is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

Subject to limited exceptions, holders of shares of PIPE Preferred Stock will not have the right to convert any portion of their Preferred Stock if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or up to 9.99% at the election of the holder) of the number of shares of the Company’s common stock outstanding immediately after giving effect to its conversion.

Holders of PIPE Preferred Stock will be entitled to receive dividends on shares of PIPE Preferred Stock equal, on an as-if-converted-to-common stock basis, and in the same form as dividends actually paid on shares of the common stock. Except as otherwise required by law, the PIPE Preferred Stock does not have voting rights.

The Company also entered into a registration rights agreement with the purchasers requiring the Company to register the resale of the shares of common stock, the shares issuable upon exercise of the Warrants and the shares issuable upon the conversion of the PIPE Preferred Stock.