UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **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 001-39430

ACUTUS MEDICAL, INC.
(Exact name of Registrant as specified in its Charter)

Delaware	**45-1306615**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2210 Faraday Ave., Suite 100, Carlsbad, CA	**92008**
(Address of principal executive offices)	**(Zip code)**

Registrant's telephone number, including area code: (442) 232-6080

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	AFIB	The Nasdaq Stock Market LLC

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 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 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

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

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

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 $1.12 per share of the Registrant's common stock on June 30, 2022, the last business day of the Registrant's most recently completed second fiscal quarter, as reported by the Nasdaq Stock Market LLC on such date, was approximately $31.8 million . For purposes of calculating the aggregate market value of shares held by non-affiliates, we have assumed that all outstanding shares are held by non-affiliates, except for shares owned by each of our executive officers, directors and 5% or greater stockholders. In the case of 5% or greater stockholders, we have not deemed such stockholders to be affiliates unless there are facts and circumstances indicating that such stockholders exercise any control over our company. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose.

On March 20, 2023, there were 28,894,080 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates certain information by reference from the definitive proxy statement for the Registrant's 2023 Annual Meeting of Stockholders to be filed within 120 days of the Registrant's fiscal year ended December 31, 2022 (the "Proxy Statement"). Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

Auditor Name:	KPMG LLP	Auditor Location:	San Diego, California	Auditor Firm ID:	185

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K and certain information incorporated herein by reference contain forward-looking statements within the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. All statements included or incorporated by reference in this Annual Report, other than statements that are purely historical, are forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," "will," "should," "would," "could," "may" and similar expressions also identify forward-looking statements. The forward-looking statements include, without limitation, statements regarding our future operations, financial condition and prospects, operating results, revenues and earnings liquidity, our estimated income tax rate, unrecognized tax positions, amortization expenses, impact of recent accounting pronouncements, our cost management program, our acquisition strategy and our growth plans, expectations regarding our recent acquisitions, and the reasonableness of the carrying value related to specific financial assets and liabilities.

Our expectations, beliefs, objectives, intentions and strategies regarding future results are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from results contemplated by our forward-looking statements.

We urge you to carefully consider risks and uncertainties and review the additional disclosures we make concerning risks and uncertainties that may materially affect the outcome of our forward-looking statements and our future business and operating results, including those made in Item 1A, "Risk Factors" in this Annual Report on Form 10-K, as such risk factors may be amended, supplemented or superseded from time to time by other reports we file with the SEC. We assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of the filing of this Annual Report on Form 10-K.

Risk Factors Summary

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors." These risks include, but are not limited to, the following:

- We have a history of net losses, and we expect to continue to incur losses for at least the next several years. If we ever achieve profitability, we may not be able to sustain it.
- We have a limited history operating as a commercial company; if we fail to effectively train our sales force, increase our sales and marketing capabilities or develop broad brand awareness in a cost-effective manner, our growth will be impeded, and our business will suffer.
- The commercial success of our products will depend upon attaining significant market acceptance of these products among hospitals, physicians, patients and payors.
- We have significant international operations, and intend to further expand our business internationally, which exposes us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.
- We face significant competition, and if we are unable to compete effectively, we may not be able to achieve or maintain significant market penetration or improve our results of operations.
- If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected.
- We may not be able to develop, license or acquire new products, enhance the capabilities of our existing products to keep pace with rapidly changing technology and customer requirements or successfully manage the transition to new product offerings, any of which could have a material adverse effect on our business, financial condition and results of operations.
- Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business.
- We depend upon third-party suppliers, including single-source suppliers, making us vulnerable to supply disruptions and price fluctuations.
- Adoption of our products depends upon appropriate physician training, and inadequate training may lead to negative patient outcomes, affect adoption of our products and adversely affect our business.
- Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as significant costs and negative publicity.

- Coverage and adequate reimbursement may not be available for the procedures that utilize our products, which could diminish our sales or affect our ability to sell our products profitably.
- Regulatory compliance, including compliance with U.S. federal and state fraud and abuse and other healthcare laws and regulations, is expensive, complex and uncertain, and failure to comply could lead to enforcement actions against us and other negative consequences for our business.
- If we are unable to obtain and maintain patent protection or freedom to operate for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any products we may develop, and our technology, may be adversely affected.
- Our operations and financial results may be adversely impacted by the resurgence of COVID-19 or another global pandemic.
- We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine. Our business, financial condition and results of operations may be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine or any other geopolitical tensions.

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PART I

Item 1. Business.

Overview

We are an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated. Despite several decades of effort by the incumbents in this field, the clinical and economic challenges associated with arrhythmia treatment continue to be a huge burden for patients, providers and payors. We are committed to advancing the field of electrophysiology with a unique array of products and technologies which will enable more physicians to treat more patients more effectively and efficiently. Through internal product development, acquisitions and global partnerships, we have established a global sales presence delivering a broad portfolio of highly differentiated electrophysiology products. Our goal is to provide our customers with a complete solution for catheter-based treatment of cardiac arrhythmias in each of our geographic markets.

We design, manufacture and market a range of tools for catheter-based ablation procedures to treat various arrhythmias. Cardiac ablation involves using high-energy radio frequency or extreme cold to target tissue in the heart that is responsible for triggering or sustaining an abnormal heart rhythm. Our product portfolio includes novel access sheaths, diagnostic and mapping catheters, conventional and contact force ablation catheters (currently available only in our European markets), mapping and imaging consoles and accessories, as well as supporting algorithms and software programs. Our foundational and most highly differentiated product is our AcQMap imaging and mapping system, which offers a paradigm-shifting approach to mapping the drivers and maintainers of arrhythmias with unmatched speed and precision. With the ability to rapidly and accurately identify ablation targets and to confirm both ablation success and procedural completion, we believe our AcQMap System addresses the primary unmet need in electrophysiology procedures today.

While multiple trials have established that cardiac ablation is effective when the source of the arrhythmia is accurately identified and successfully ablated, visualization of various complex arrhythmias and creation of durable ablation lesions remains challenging with long, unpredictable procedure times and inconsistent outcomes. For example, data from large, multi-center trials of cardiac ablation have demonstrated that approximately 30 to 50% of ablations for atrial fibrillation result in arrhythmia recurrence within the first 12 months of the initial ablation procedure. Currently marketed mapping systems are not able to quickly and consistently identify the source of the arrhythmia in more complex cases, which can contribute to these unsatisfactory outcomes. Current competitive mapping systems sequentially collect data point-by-point by contacting the heart surface at multiple locations throughout the chamber. This is a time-consuming process that often takes 15 to 20 minutes per map. Additionally, because contact-based mapping relies on a fixed timing reference to sequence the data points, it precludes these systems from being able to quickly and reliably identify the drivers and maintainers of unstable arrhythmias such as atrial fibrillation, many types of supraventricular tachycardias and certain ventricular arrhythmias.

We designed our AcQMap System to improve procedure efficiency and outcomes by rapidly and accurately identifying ablation targets and confirming both ablation success and procedure completion. Our AcQMap System consists of our single-use AcQMap catheter as well as our console, workstation and proprietary software algorithms. With 48 ultrasound transducers interspersed between 48 biopotential electrodes, our innovative mapping catheter collects the data required to create a comprehensive map of the cardiac anatomy and electrical propagation pathways and patterns in under three minutes without contacting the chamber wall. Our proprietary software algorithms analyze the biopotential data and are collectively able to map any type of stable or unstable arrhythmia, including atrial fibrillation as well as all supraventricular tachycardias and ventricular arrhythmias.

We believe that by creating high definition, clinically accurate activation maps of all types of arrhythmias, our AcQMap System offers physicians better decision-making tools to determine where to ablate. Similarly, we believe the speed and ease of creating a map makes it practical for physicians to iteratively map, treat, re-map and adjust additional therapy if and when needed. In the second half of 2022, we received U.S. Food and Drug Administration, or FDA, clearance and Conformité Européenne Mark, or CE Mark, for our AcQMap 8.5 software platform. This release provided significant enhancements to our industry-unique non-contact ultrasound-based anatomical reconstruction. AcQMap anatomies are now higher fidelity and easier to create in less time. AcQMap 8.5 also provided additional workflow enhancements and troubleshooting tools to ensure cases could be run more efficiently.

We have established a broad portfolio of electrophysiology products that complements our AcQMap System. In addition to our AcQMap System, our commercial product portfolio includes a suite of access devices and full product lines of diagnostic and, in our European markets, ablation catheters. In our European markets, our portfolio provides our customers with a complete solution—from vascular access to diagnosis and treatment of arrhythmias. In the United States, we are currently seeking

regulatory approval, for which we filed in 2022, for our ablation catheters to complement our portfolio of access and mapping devices. We also recently expanded our portfolio to include the AcQBlate® FORCE gold-tip, irrigated, radiofrequency force sensing ablation catheters and Qubic Force control unit, or AcQBlate Force Sensing Ablation System, which we commercialized following the December 2020 receipt of CE Mark approval in Europe. Biotronik SE & Co. KG, or Biotronik, had previously performed the BioConcept Study, which was used as the base data for CE Mark submission, and no additional clinical data was required for CE Mark approval. We also completed the AcQForce Flutter investigational device exemption, or IDE, trial for U.S. Food and Drug Administration Premarket Approval, or FDA PMA, in the United States during 2022 to seek a right atrial typical flutter indication. We currently anticipate FDA PMA and the U.S. commercial launch of our AcQBlate Force Sensing Ablation System in the second half of 2023. We will pursue CE Mark for our PFA system following the completion of the trial and satisfactory preparation of regulatory submission documents. We believe that our ability to offer a broad and differentiated product portfolio will support the adoption and utilization of our AcQMap System and drive an efficient business model. Once an AcQMap console and workstation is established in a customer account, our revenue from that account becomes predominantly recurring in nature and derived from the sale of our portfolio of disposable products used with our system.

We market and sell our electrophysiology products worldwide to hospitals and electrophysiologists that treat patients with arrhythmias. We have strategically developed a direct selling presence in the United States and select markets in Western Europe where cardiac ablation is a standard of care and third-party reimbursement is well-established. In other international markets, we leverage our partnership with Biotronik, a large multi-national, privately-held biomedical technology company with a leading portfolio across cardiac rhythm management, electrophysiology and vascular intervention, to sell and distribute our products. In the United States and Western Europe, our target market is highly concentrated. We plan to leverage the concentrated nature of procedure volumes and the recurring nature of our sales to drive an increasingly efficient commercial model.

Our research and development activities are focused on advancing the field of electrophysiology by increasing the AcQMap System's utility and by seeking approval for additional labeled indications as well as by expanding our product portfolio to further improve and simplify the entire procedural experience. Our near-term pipeline includes products that broaden our clinical utility, improve the system's workflow and user experience, and increase functionality and/or reduce costs across catheters, accessory devices, mapping systems and software.

Our Market and Industry

Cardiac arrhythmias, or heart rhythm disorders, are common and can occur when the heart beats too rapidly, too slowly or irregularly. If left untreated, arrhythmias can result in debilitating symptoms, heart failure, stroke and sudden cardiac death.

Atrial fibrillation, or AF, is the most common arrhythmia and is characterized by rapid and irregular activation of the heart. This irregular behavior increases the potential to develop blood clots within the upper chambers of the heart, which can then circulate to other organs, leading to reduced blood flow and strokes. We estimate that there were approximately 624,000 cardiac ablation procedures globally for atrial fibrillation in 2021.

Supraventricular tachycardias, or SVTs, are characterized by a rapid heartbeat in the upper chambers of the heart. These arrhythmias, which include atrial flutter and atrial tachycardia, among others, can arise organically or as a result of an incomplete ablation for atrial fibrillation. These post AF ablation SVT procedures are considered to be "complex" SVT ablation procedures. We estimate there were approximately 494,000 ablation procedures worldwide for SVTs in 2021. Moreover, the number of SVT procedures that fall under the complex category are expected to grow as a result of growth in AF ablation procedures.

Ventricular arrhythmias affect the lower chambers of the heart and consist primarily of ventricular tachycardias, or VTs, and premature ventricular contractions, or PVCs. If left untreated, VTs and PVCs can lead to heart failure, ventricular fibrillation and sudden cardiac death. We estimate that there were approximately 116,000 ablation procedures globally for ventricular arrhythmias in 2021.

Currently marketed mapping systems rely on tissue contact and a fixed timing reference to collect and align data in the proper sequence. As a result, they are designed to map simple, stable and repetitive arrhythmias such as certain SVTs and VTs. Collecting a critical mass of data points to see even a stable rhythm is time consuming with contact mapping technologies, as data collection is sequential and by definition requires contact at all areas to fully map the heart. This time consuming, sequential data collection results in significant variability in the map quality and therefore the diagnostic relevance of the map in guiding therapy. Innovation in contact mapping systems therefore have been limited to enabling faster data collection via adding more sensors to contact mapping catheters. In addition, these technologies are not capable of mapping unstable or

complex arrhythmias such as AF, certain VTs, PVCs or many types of SVTs, thereby generating an unmet need in the market for effective diagnostic and treatment alternatives.

Our Solution

We design, manufacture and market a range of tools for catheter-based ablation procedures to treat various arrhythmias. Our foundational and most highly differentiated product is our AcQMap imaging and mapping system which offers a non-contact map paradigm-shifting approach to mapping the drivers and maintainers of arrhythmias with unmatched speed and precision. With the ability to rapidly and accurately identify ablation targets and to confirm both ablation success and procedural completion, we believe our AcQMap System addresses the primary unmet need in electrophysiology procedures today.

Overview of Our AcQMap System

We developed our AcQMap System to address the key challenges that electrophysiologists face during ablation procedures and remove the barriers to adopting ablation for complex arrhythmia procedures.

Our AcQMap System consists of our AcQMap catheter, console and workstation. Our system uses a paradigm-shifting approach. With 48 ultrasound transducers interspersed between 48 biopotential electrodes, our innovative mapping catheter collects the data required to create a comprehensive map of the cardiac anatomy and electrical propagation patterns and pathways without contacting the chamber wall. This allows us to create comprehensive diagnostic maps of the chamber anatomy and electrical propagation patterns and pathways in under three minutes. Our proprietary software algorithms analyze the biopotential data and are collectively able to map any type of stable or unstable arrhythmia, including atrial fibrillation, as well as all supraventricular tachycardias and ventricular arrhythmias. Our AcQMap 8.5 software platform, which we introduced in the second half of 2022, offers significant enhancements to our industry unique non-contact ultrasound-based anatomical reconstruction enabling higher fidelity anatomies to be created in less time.

Key Benefits of AcQMap

We believe the unique attributes of our AcQMap System offer significant clinical benefits relative to the current standard of care.

Iterative Whole-Chamber Mapping Approach

With increased mapping speed and precision, electrophysiologists are empowered in real time to iteratively map, treat, re-map and adjust additional therapy as needed. This allows physicians to determine when ablation is complete, which we believe will drive more efficient and predictable procedures and better outcomes for a broader range of arrhythmias.

Increased Mapping Accuracy

Ultrasound technology allows us to create an anatomically accurate image of the heart chamber, and non-contact charge density mapping provides a more localized and sharper view of cardiac activation resulting in images with four times higher resolution than voltage-based maps produced by currently marketed contact-based mapping systems. We believe the combination of these two features allows electrophysiologists to reliably identify and ablate the source of the arrhythmia, which will help improve clinical outcomes and reduce the need for repeat procedures.

Ability to Identify Multiple Complex Arrhythmias

The AcQMap System is the only commercially available mapping system that can quickly and reliably map both stable and unstable rhythms, allowing electrophysiologists to see changes in conduction during the procedure and providing them with an optimal solution to better customize therapy.

Demonstrated Clinical Outcomes

Our UNCOVER AF post-market approval trial, which assessed the effectiveness of the AcQMap System in identifying patient-specific targets for ablation, demonstrated favorable freedom from AF outcomes. The results are particularly favorable in the context of other landmark trials in the electrophysiology space, including the STAR AF II trial, which evaluated a similar population of persistent AF patients. We believe the key differentiator in outcomes was the use of our AcQMap System to map and identify key ablation patterns and targets.

Our Broad Portfolio

We have established a broad portfolio of electrophysiology products that complements our AcQMap System. In addition to our AcQMap System, our commercial product portfolio includes a suite of access devices and full product lines of diagnostic and, in our European markets, ablation catheters. In our European markets, our portfolio provides our customers with a complete solution—from vascular access to diagnosis and treatment of arrhythmias. In the United States, we are currently seeking regulatory approval for our ablation catheters to complement our portfolio of access and mapping devices. We also recently expanded our portfolio to include the AcQBlate Force Sensing Ablation System, which we launched following the December 2020 receipt of CE Mark approval in Europe. We completed our IDE trial and filed for FDA PMA in the United States in 2022. We currently anticipate FDA PMA and the U.S. commercial launch of our AcQBlate Force Sensing Ablation Catheter and System in the second half of 2023.

We believe that our ability to offer a broad and differentiated product portfolio will support the adoption and utilization of our AcQMap System and drive an efficient business model. Once an AcQMap console and workstation is established in a customer account, our revenue from that account becomes predominantly recurring in nature and derived from the sale of our portfolio of disposable products used with our system.

Our Growth Strategies

We are committed to advancing the field of electrophysiology with a unique array of products and technologies which will enable more physicians to treat more patients more efficiently and effectively. We seek to establish our AcQMap System as the standard of care for mapping and diagnosis of cardiac arrhythmias and to leverage its paradigm-shifting nature to drive adoption and utilization of our portfolio of differentiated electrophysiology products.

Our growth strategies include:

- utilizing our superior mapping technology and open platform to establish our presence within a geographically targeted base of customer accounts and physicians;
- strategically positioning our commercial organization across targeted geographic regions to increase physician awareness and drive adoption;
- maximizing console utilization and procedure volume growth in targeted geographic regions;
- continuing to strategically expand our portfolio of products and broaden indications for existing products;
- leveraging our strategic partnerships to efficiently scale globally and broaden our product portfolio; and
- continuing to build our clinical evidence base.

Impact of COVID-19

The markets we serve could see continued impacts from COVID-19 for the foreseeable future, and the emergence of new variants of COVID-19 creates significant uncertainty as to how long COVID-19 will continue to impact our business. The magnitude of the impact of the COVID-19 pandemic on our productivity, results of operations and financial position and its disruption to our business and our clinical programs and timelines will depend, in part, on the length and severity of outbreaks, restrictions and other measures designed to prevent the spread of COVID-19 and on our ability to conduct business in the ordinary course.

Corporate Restructuring

In 2022, we completed an organizational workforce reduction and implemented additional cost reduction measures to reduce our operating expenses and optimize our cash resources. The restructuring was the result of a detailed review of our strategic priorities, the external environment and cost structure, and is intended to sharpen our focus and strengthen our financial position. As part of the restructuring, we intend to prioritize maximizing console utilization and procedure volume growth in targeted geographic regions, as well as a more focused scope of product development initiatives.

Competition

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete with manufacturers and distributors of cardiovascular medical devices. Our most significant competitors in the electrophysiology field include Abbott Laboratories,

Biosense Webster Inc. (a Johnson & Johnson Company), Boston Scientific Corporation and Medtronic, Inc. ("Medtronic"). Many of our competitors are large, well-capitalized companies with significantly greater market share and resources than we have. Therefore, they can spend more on product development, marketing, sales and other product initiatives than we can. We also compete with smaller medical device companies that have a single product or a limited range of products. Some of our competitors have:

- significantly greater name recognition;
- broader or deeper relations with healthcare professionals, customers and third-party payors;
- more established distribution networks;
- additional lines of products and the ability to offer rebates or bundle products to offer greater discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- greater financial and human resources for product development, sales and marketing and patent prosecution.

We believe that our proprietary AcQMap System offers a paradigm-shifting approach to mapping the drivers and maintainers of arrhythmias with unmatched speed and precision. With the ability to rapidly and accurately identify ablation targets and to confirm both ablation success and procedural completion, we believe our AcQMap System addresses the primary unmet need in electrophysiology procedures today. We have established a broad portfolio of electrophysiology products that complements our AcQMap System. We compete primarily on the basis that our products are designed to enable more physicians to treat more patients more efficiently and effectively. Our continued success depends on our ability to:

- strategically develop innovative proprietary products that address significant clinical needs in a manner that is safe and effective for patients and easy-to-use for physicians;
- obtain and maintain regulatory clearances or approvals;
- demonstrate safety and effectiveness in our sponsored and third-party clinical trials;
- expand our sales force within key geographic regions to increase physician awareness;
- leverage our strategic partnerships and alliances to achieve distribution at a global scale and broaden our product portfolio;
- obtain and maintain coverage and adequate reimbursement for procedures using our products;
- attract and retain skilled research, development, sales and clinical personnel;
- cost-effectively manufacture, market and sell our products; and
- obtain, maintain, enforce and defend our intellectual property rights and operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

Intellectual Property

Our success depends in part on our ability to obtain, maintain, protect and enforce our intellectual property rights, including our patent rights, to preserve the confidentiality of our trade secrets, to operate without infringing, misappropriating or otherwise violating the intellectual property rights of others and to prevent others from infringing, misappropriating or otherwise violating our intellectual property rights. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to protect the products and technology that we consider important to our business. We also rely on know-how and continuing technological innovation to develop and maintain our competitive position.

As of December 31, 2022, our patent portfolio included 38 solely owned or exclusively licensed U.S. patents and 23 solely owned or exclusively licensed pending U.S. patent applications (including one solely owned Patent Cooperation Treaty, or PCT, applications and four solely owned provisional U.S. patent applications). In addition, we solely owned or exclusively licensed 76 issued patents and 51 pending patent applications in jurisdictions outside the United States. Of our 74 pending patent applications (U.S. and outside the U.S.), 2 have been allowed. Of our 38 owned and exclusively licensed U.S. patents, 36 U.S. patents cover our AcQMap mapping system. Such U.S. patents, and any U.S. patents that may in the future issue from such applications, are scheduled to expire between 2027 and 2041 without taking potential patent term extensions or adjustments into account, and assuming national phase entries are timely made upon our pending PCT application and timely payments of all applicable maintenance or annuity fees are made.

For more information regarding the risks related to our intellectual property, please see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Manufacturing and Supply

We currently manufacture our novel access sheaths, transseptal crossing tools, diagnostic and mapping catheters, ablation catheters, mapping and imaging consoles and accessories at our approximately 50,800 square foot facility in Carlsbad, California. This facility provides approximately 15,750 square feet of space for our production and distribution operations, including manufacturing, quality control and storage. We believe our existing facility is sufficient to meet our current manufacturing needs and we believe that adequate additional space will be available if we require it.

We stock inventory of raw materials, components and finished goods at our facility in Carlsbad and, to a limited extent, with our sales representatives who travel to our hospital customers’ locations as part of their sales efforts. We rely on a single or limited number of suppliers for certain raw materials and components, and we generally have no long-term supply arrangements with our suppliers, as we generally order on a purchase order basis. Furthermore, we rely on third parties to manufacture certain products we offer our customers as part of our product portfolio, including Biotronik for diagnostic and ablation catheters, RF generators and irrigation pumps, and MedFact Engineering GmbH for robotic navigation enabled ablation catheters.

In conjunction with the Asset Purchase Agreement (as defined below), we executed a distribution agreement with Medtronic (the "Distribution Agreement"), pursuant to which we manufacture and supply the Products (as defined below) to Medtronic as exclusive distributor of the product line for up to the next four years.

Our manufacturing and distribution operations are subject to regulatory requirements of the FDA’s Quality System Regulation, or QSR, for medical devices sold in the United States, set forth in 21 CFR part 820, and the European Medical Device Directive 93/42/EEC and amendments, or MDD, and the products comply to ISO 13485 for manufacturing for medical devices marketed in the European Union. In addition, the Carlsbad facility is licensed by the California Food and Drug Branch. We are also subject to applicable local regulations relating to the environment, waste management and health and safety matters including measures relating to the release, use, storage, treatment, transportation, discharge, disposal, sale, labeling, collection, recycling, treatment and remediation of hazardous substances.

Government Regulation

U.S. Food and Drug Administration

Our products and operations are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, as well as other federal and state regulatory bodies in the United States. The laws and regulations govern, among other things, product design and development, preclinical and clinical testing, manufacturing, packaging, labeling, storage, record keeping and reporting, clearance or approval, marketing, distribution, promotion, import and export, and post-marketing surveillance.

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a PMA application. Both the 510(k) clearance and PMA processes can be resource intensive, expensive and lengthy, and require payment of significant user fees, unless an exemption is available.

Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness. Class I devices are deemed to be low risk and are subject to the general controls of the FDCA such as provisions that relate to adulteration, misbranding, registration and listing, notification, including repair, replacement, or refund, records and reports and good manufacturing practices. Most Class I devices are classified as exempt from premarket notification under Section 510(k) of the FDCA, and therefore may be commercially distributed without obtaining 510(k) clearance from the FDA. Class II devices are subject to both general controls and special controls to provide reasonable assurance of safety and effectiveness. Special controls include performance standards, postmarket surveillance, patient registries and guidance documents. A manufacturer may be required to submit to the FDA a premarket notification requesting permission to commercially distribute some Class II devices. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III. A Class III device cannot be marketed in the United States unless the FDA

approves the device after submission of a PMA application. However, there are some Class III devices for which the FDA has not yet called for a PMA. For these devices, the manufacturer must submit a premarket notification and obtain 510(k) clearance in order to commercially distribute these devices. The FDA can also impose sales, marketing or other restrictions on devices in order to assure that they are used in a safe and effective manner.

The Investigational Device Process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of trials deemed to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed, and institutional review board, or IRB, approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the trial protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and effectiveness, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of trial sponsors and trial investigators. Clinical trials must further comply with the FDA's good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product.

The 510(k) Clearance Process

When a 510(k) clearance is required, an applicant must submit a premarket notification to the FDA demonstrating that the proposed device is substantially equivalent to a predicate device, which is a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976. By regulation, a premarket notification must be submitted to the FDA at least 90 days before intent to market the device, and 510(k) clearance must be received from the FDA prior to marketing the device. The Medical Device User Fee Amendments performance goals for a traditional 510(k) clearance is 90 days. As a practical matter, however, clearance often takes longer, because the review clock is paused by the FDA to allow time to resolve any questions the FDA may have on the 510(k). To demonstrate substantial equivalence, 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 different technological characteristics, and the information in the premarket notification demonstrates that the device is equally safe and effective and does not raise different questions of safety and effectiveness. The FDA may require further information including clinical data to make a determination regarding substantial equivalence. If the FDA determines that the device or its intended use is not substantially equivalent to a previously cleared device or use, the FDA will place the device into Class III.

There are three types of 510(k)s: traditional, special and abbreviated. Special 510(k)s are typically for devices that are modified and the results of change evaluation can be sufficiently reviewed in a summary or risk analysis format. Abbreviated 510(k)s are for devices that conform to special controls for the device type or to a recognized standard. The special and abbreviated 510(k)s are intended to streamline review, and the FDA intends to process special 510(k)s within 30 days of receipt.

The PMA Process

A PMA application under section 515 of the FDCA must be submitted to the FDA for Class III devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. The PMA application process is much more demanding than the 510(k) premarket notification process. A PMA is based on a determination by the FDA that the PMA application contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).

After a PMA application is submitted, the FDA has 45 days to determine whether the application is sufficiently complete to permit a substantive review and thus whether the FDA will file the application for review. The FDA has 180 days to review a filed PMA application, although the review of an application generally occurs over a significantly longer period of time and can

take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. Although the FDA is not bound by the advisory panel decision, the panel's recommendations are important to the FDA's overall decision making process. In addition, the FDA may conduct a preapproval inspection of the manufacturing facility to ensure compliance with QSR. The FDA also may inspect one or more clinical sites to assure compliance with the FDA's regulations.

Upon completion of the PMA application review, the FDA may: (i) approve the PMA which authorizes commercial marketing with specific prescribing information for one or more indications which can be more limited than those originally sought; (ii) issue an approvable letter which indicates the FDA's belief that the PMA application is approvable and states what additional information the FDA requires or the post-approval commitments that must be agreed to prior to approval; (iii) issue a not approvable letter which outlines steps required for approval, but which are typically more onerous than those in an approvable letter, and may require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years; or (iv) deny the application. If the FDA issues an approvable or not approvable letter, the applicant has 180 days to respond, after which the FDA's review clock is reset.

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- the FDA's QSR, which requires manufacturers, including their suppliers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- medical device reporting, or MDR, 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 the malfunction were to recur;
- medical device recalls, which require that manufacturers report to the FDA any recall of a medical device, provided the recall was initiated to either reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Public Health, or CDPH. The FDA and CDPH have broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Additionally, our Notified Body, DQS-MED, regularly inspects our manufacturing, design and operational facilities to ensure ongoing ISO 13485 compliance in order to maintain our CE Mark.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

Export of Our Products

Export of products subject to the 510(k) notification requirements, but not yet cleared to market, is permitted with FDA authorization provided certain requirements are met. Unapproved or uncleared products subject to the PMA requirements may

be exported if the exporting company and the device meet certain criteria, including, among other things, that the device complies with the laws of the receiving country and has valid marketing authorization from the appropriate authority and that the company submits a "Simple Notification" to the FDA when it begins to export. Importantly, however, export of such products may be limited to certain countries designated by statutory provisions, and petitions may need to be submitted to the FDA to enable export to countries other than those designated in the statutory provisions. The petitioning process can be difficult, and the FDA may not authorize unapproved or uncleared products to be exported to countries to which a manufacturer wishes to export. Devices that are adulterated, devices whose label and labeling does not comply with requirements of the country receiving the product, and devices that are not promoted in accordance with the law of the receiving country, among others, cannot be exported.

Foreign Government Regulation

The regulatory review process for medical devices varies from country to country, and many countries also impose product standards, packaging requirements, environmental requirements, labeling requirements and import restrictions on devices. Each country has its own tariff regulations, duties, and tax requirements. Failure to comply with applicable foreign regulatory requirements may subject a company to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, criminal prosecution or other consequences.

European Union

Our portfolio of products is regulated in the European Union as a medical device per either the Medical Device Directive (MDD) or the Medical Device Regulations (MDR). The MDD and MDR set out the basic regulatory framework for medical devices in the European Union. The system of regulating medical devices operates by way of a certification for each medical device. Each certified device is marked with the CE Mark which shows that the device has a Certificat de Conformité. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the regulations within their jurisdiction. The means for achieving the requirements for the CE Mark vary according to the nature of the device. Devices are classified in accordance with their perceived risks. The class of a product determines the conformity assessment required before the CE Mark can be placed on a product. Conformity assessments for our products were previously carried out as required by the MDD and are now performed in accordance with the MDR. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states. The CE Mark is contingent upon continued compliance with the applicable regulations and the quality system requirements of the ISO 13485 standard. Our current CE Marks are issued by DQS-MED (Frankfurt, Germany).

After the product has received the CE Mark and been placed on the market in the European Economic Area, or EEA, a manufacturer must comply with a number of regulatory requirements relating to:

- registration of medical devices in individual EEA countries;
- pricing and reimbursement of medical devices;
- establishment of post-marketing surveillance and adverse event reporting procedures;
- field safety corrective actions, including product recalls and withdrawals; and
- interactions with physicians.

Other International Laws

In Europe, various countries have adopted anti-bribery laws providing for severe consequences in the form of criminal penalties and significant fines for individuals or companies committing a bribery offense.

Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

For instance, in the United Kingdom, the U.K. Bribery Act 2010 covers both public and private sector bribery, and prohibits the offer, provision or promise to give a financial or other advantage to induce or reward another individual to improperly perform their relevant functions or activities including any function of a public nature. Bribery of foreign public officials also falls within the scope of the U.K. Bribery Act 2010. An individual found in violation of the U.K. Bribery Act 2010 faces imprisonment of up to ten years. In addition, individuals can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

There are also international privacy laws that impose restrictions on the collection, use, storage, disclosure, transfer and other processing of personal information, including health information. For example, the General Data Protection Regulation, or GDPR, imposes stringent data protection requirements, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations regarding third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other third countries. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

Domestic Government Regulation

In the United States, there are local, state and national laws, directives and regulations that apply to the collection, use, storage, disclosure, transfer and other processing of personal information, including health information. For more information regarding the risks related to privacy laws that apply to us, please see "Risk Factors—Risks Related to Our Business and Products—We are subject to stringent privacy laws, information security policies and contractual obligations governing the use, processing and cross-border transfer of personal information and our data privacy and security policies."

California Consumer Privacy Act

The California Consumer Privacy Act, or CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA went into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA has been amended from time to time, and a new privacy law, the California Privacy Rights Act, or CPRA, which mostly took effect on January 1, 2023, significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. It remains unclear what, if any, further modifications will be made to the CCPA or CPRA, or how such legislation will be interpreted.

Health Insurance Portability and Accountability Act

The federal Health Insurance Portability and Accountability Act, or HIPAA, created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. In addition, HIPAA and its implementing regulations established uniform standards for certain covered entities, which are healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information.

U.S. Federal, State and Foreign Fraud and Abuse Laws

The federal and state governments have enacted, and actively enforce, a number of laws to address fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws. Violations of such laws could result in significant civil, criminal and administrative sanctions, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

Anti-Kickback Statutes

The U.S. federal Anti-Kickback Statute prohibits, subject to certain safe harbors, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual for the furnishing or arranging for a good or service, or for the purchasing, leasing, ordering, or arranging for or recommending any good, facility, service or item for which payment may be made in whole or in part under federal healthcare programs such as the Medicare and Medicaid programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. The term "remuneration" expressly includes kickbacks, bribes or rebates and also has been broadly interpreted to include

anything of value, including, for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Additionally, the intent standard under the Anti-Kickback Statute was amended under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act which is discussed below. Penalties for violations of the Anti-Kickback Statute include, but are not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from Medicare, Medicaid and other federal healthcare programs and the curtailment or restructuring of operations. Various states have adopted laws similar to the Anti-Kickback Statute, and some of these state laws may be broader in scope in that some of these state laws extend to all payors and may not contain safe harbors. In addition, many foreign jurisdictions in which we operate have similar laws and regulations.

Federal False Claims Act

The U.S. federal civil False Claims Act prohibits, among other things, persons or entities from knowingly presenting or causing to be presented a false or fraudulent claim, or the knowing use of false statements, to obtain payment from or approval by the federal government. Suits filed under the federal civil False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government. These individuals, sometimes known as "relators" or "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The number of filings of qui tam actions has increased significantly in recent years, causing more healthcare companies to have to defend a case brought under the federal civil False Claim Act. If an entity is determined to have violated the federal civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government plus civil penalties for each separate false claim. Various states have adopted laws similar to the federal civil False Claims Act, and many of these state laws are broader in scope and apply to all payors and, therefore, are not limited to only those claims submitted to the federal government.

Civil Monetary Penalties

The federal Civil Monetary Penalties Statute, among other things, imposes fines against any person who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, are for an item or service that was not provided as claimed or is false or fraudulent.

Open Payments

The Affordable Care Act also includes a provision, commonly referred to as the Sunshine Act, which requires that any manufacturer of a covered device that provides payment or other transfer of value to a physician or teaching hospital, or to a third party at the request of a physician or teaching hospital, must submit to Centers for Medicare & Medicaid Services, or CMS, information about the payment or other transfer of value annually, with the reported information to be made public on a searchable website.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign government official, political party or candidate for the purpose of improperly influencing any act or decision of a foreign government entity to obtain or retain business. The FCPA also obligates companies whose securities are listed on a national securities exchange in the United States to comply with accounting provisions which require the maintenance of books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls.

U.S. Health Reform

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement for our current and future products. The Affordable Care Act substantially changes the way healthcare is financed by both governmental and private insurers and significantly impacts our industry. The United States and some foreign jurisdictions are considering enacting or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy

makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and has affected medical device manufacturers significantly. The Affordable Care Act provides incentives to programs that increase the federal government's comparative effectiveness research and implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research. We do not yet know the full impact that the Affordable Care Act will have on our business. There have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in the future.

On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and held oral arguments on November 10, 2020. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the Affordable Care Act brought by several states without specifically ruling on the constitutionality of the Affordable Care Act.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

Coverage and Reimbursement

In both U.S. and non-U.S. markets, our ability to successfully commercialize and achieve market acceptance of our products depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including governmental payors (such as the Medicare and Medicaid programs in the United States), managed care organizations and private health insurers. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments. Third-party payors in the United States generally do not provide reimbursement for our products. Rather, we expect certain components of our AcQMap System to continue to be purchased by hospitals and other providers who will then seek reimbursement from third-party payors for the procedures performed using our products. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets there are private insurance systems as well as government-managed systems. While third-party payors currently cover and provide reimbursement for procedures using our currently cleared or approved products, third-party payor reimbursement policies may change in the future.

Third-party payors are increasingly examining the cost effectiveness of products, in addition to their safety and efficacy, when making coverage and payment decisions. Third-party payors have also instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. Additionally, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for procedures that utilize one or more products for which we receive regulatory clearance and approval, less favorable coverage policies and reimbursement rates may be implemented in the future. It is uncertain whether our current products or any planned or future products will be viewed as sufficiently cost effective to warrant coverage and adequate reimbursement levels for procedures using such products.

Human Capital Resources

We are an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated. We are committed to advancing the field of electrophysiology and our team is comprised of passionate, driven and dedicated professionals working to provide better tools for clinicians and making life better for the individuals who suffer from complex cardiac arrhythmias. As of December 31, 2022, we had 225 full-time employees. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel. None of our employees are represented by a labor union or are a party to a collective bargaining agreement.

Culture & Values

We pride ourselves on being an innovative company comprised of dedicated and talented industry leaders working together to make a distinctive mark within the medical device industry. Our team works diligently to fulfill the mission of bringing an advanced tool for identifying and mapping complex arrhythmias to physicians and hospitals in order to optimize and expand the success of cardiac ablation. As employees of Acutus, we are:

- **A**ccountable to patients, physicians and each other;
- **C**ourageously pursuing continuous improvement;
- **U**nited as one team achieving excellence;
- **T**enacious about innovation;
- **U**ncompromising in integrity; and
- **S**cience based-talent driven.

Business Ethics & Compliance

We are committed to conducting our business affairs with employees, customers, suppliers, competitors, the government, the public and our shareholders with honesty and integrity and in accordance with the highest ethical standards. We believe that one of our most valuable assets is our reputation for integrity, professionalism and fairness. We are focused on ensuring that our legal, compliance and risk mitigation policies and programs are designed to hold ourselves to the highest standards of business conduct.

Talent Attraction, Retention & Engagement

We seek to identify, recruit and retain a dynamic and innovative team of professionals that is committed to improving the diagnosis and treatment of cardiac arrhythmias. As of December 31, 2022, 125 employees, or 56% of our workforce, have been at Acutus for at least two years.

Compensation & Benefits

We care about our employees, their career and overall wellbeing. We offer competitive salaries, comprehensive benefits, paid time off, holidays and an onsite health and wellness program.

Company Information

We were incorporated in Delaware on March 25, 2011 as Acutus Medical, Inc. Our principal executive offices and manufacturing facilities are located at 2210 Faraday Ave., Suite 100, Carlsbad, CA 92008, and our telephone number is (442) 232-6080. Our website address is *www.acutusmedical.com*. The information on, or that may be accessed through, our website is not a part of this report and the inclusion of our website address in this report is an inactive textual reference only.

"Acutus," the "Acutus" logo, "Acutus Medical," the "Acutus Medical" logo, "AcQMap," the "AcQMap" logo, "AcQBlate," the "AcQBlate" logo, "AcQGuide," the "AcQGuide" logo, "AcQRef," the "AcQRef" logo, "SuperMap," the "SuperMap" logo, "UNCOVER AF" and the "UNCOVER AF" logo are trademarks or registered trademarks of our company. Our logo and our other trade names, trademarks and service marks appearing in this report are our property. Solely for convenience, our trademarks and trade names referred to in this report appear without the ™ or ® symbol, but those references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks and trade names. Other trade names, trademarks and service marks appearing in this report are the property of their respective owners.

We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports available free of charge at our website as soon as reasonably practicable after they have been filed with the SEC.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation, and an exemption from the requirements to obtain a non-binding advisory vote on executive compensation or golden parachute arrangements.

In addition, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this provision of the JOBS Act. As a result, we will not be subject to new or revised accounting standards at the same time as other public companies that are not emerging growth companies. Therefore, our consolidated financial statements may not be comparable to those of companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of: (i) December 31, 2025; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion; (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes before deciding whether to invest in shares of our common stock. The risks described below are not the only ones facing us. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations and future prospects. Please also see the section titled "Cautionary Note Regarding Forward-Looking Statements."

Risks Related to Our Business and Products

We have a limited history operating as a commercial company; if we fail to effectively train our sales force, increase our sales and marketing capabilities or develop broad brand awareness in a cost-effective manner, our growth will be impeded and our business will suffer.

We were incorporated in 2011, began commercializing our products in 2016 and became a publicly traded company in August 2020. Early versions of our AcQMap System and certain related accessory products have been used in the United States since May 2018 and Western Europe since July 2016 in a limited, pilot launch capacity where our focus was on optimizing workflow and validating our value proposition. We fully commenced the launch of our commercial-grade console and software products in the first quarter of 2020. Accordingly, our limited commercialization experience and limited number of approved or cleared products make it difficult to evaluate our current business and assess our prospects. We also currently have limited sales and marketing experience. If we are unable to establish effective sales and marketing capabilities or if we are unable to commercialize any of our products, we may not be able to effectively generate product revenue, sustain revenue growth and compete effectively. In order to generate future growth, we plan to continue to expand and leverage our sales and marketing infrastructure to increase our customer base and grow our business. Identifying and recruiting qualified sales and marketing personnel and training them on our products, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Any failure to hire, develop and retain talented sales and marketing personnel, to achieve desired productivity levels in a reasonable timeframe or to timely leverage our fixed costs could have a material adverse effect on our business, financial condition and results of operations. Moreover, the members of our direct sales force are at-will employees. The loss of these personnel to competitors or otherwise could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill technical expertise in replacement personnel, our revenue and results of operations could be materially harmed.

Our ability to increase our customer base and achieve broader market acceptance of our products will also depend to a significant extent on our ability to expand our marketing efforts, as we plan to dedicate significant resources to our marketing programs. Our business may be harmed if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of our products and penetrating new customer accounts. Brand promotion activities may not generate patient or physician awareness or increased revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our products.

These factors also make it difficult for us to forecast our financial performance and growth, and such forecasts are subject to a number of uncertainties including our ability to successfully develop additional products that add functionality, to reduce the cost of products sold, to broaden our commercial portfolio offerings and obtain FDA 510(k) clearance or PMA, and to successfully commercialize, market and sell, our planned or future products in the United States or in international markets. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

The commercial success of our products will depend upon attaining significant market acceptance of these products among hospitals, physicians, patients and payors.

Our success will depend, in part, on the acceptance of our products as safe, effective and, with respect to providers, cost-effective. We cannot predict how quickly, if at all, hospitals, physicians, patients or payors will accept our products or, if accepted, how frequently they will be used. Our products and planned or future products we may develop or market may never gain broad market acceptance for some or all of our targeted indications. Hospitals, physicians, patients and payors must believe that our products offer benefits over alternative treatment methods. To date, a substantial majority of our product sales and revenue have been derived from a limited number of customers who have adopted our AcQMap System and accompanying products. Our future growth and profitability largely depend on our ability to increase physician awareness of our system and our products and on the willingness of hospitals, physicians, patients or payors to adopt them. These parties may not adopt our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses that our products are safe, effective and, with respect to providers, cost-effective on a stand-alone basis and relative to competitors' products. Healthcare providers must believe that our products offer benefits over alternative treatment methods. Even if we are able to raise awareness, physicians tend to be slow in changing their medical treatment practices and may be hesitant to select our products for recommendation to their hospitals or patients for a variety of reasons, including:

- long-standing relationships with competing companies and distributors that sell other products;
- competitive responses and negative selling efforts from providers of alternative products;
- lack of experience with our products and concerns that we are relatively new to market;
- lack or perceived lack of sufficient clinical evidence, including long-term data, supporting safety or clinical benefits; and
- time commitment and skill development that may be required to gain familiarity and proficiency with our products.

Physicians play a significant role in determining the course of a patient's treatment, and as a result, the type of treatment that will be utilized and provided to a patient. We focus our sales, marketing and education efforts primarily on cardiac electrophysiologists. However, we cannot assure you that we will achieve broad market acceptance among these practitioners.

For example, if electrophysiologists are not made aware of our products, they may not recommend ablation for their patients or the installation of our AcQMap System in their hospitals. In addition, some physicians may choose to utilize our products on only a subset of their total patient population or may not adopt our products at all. If we are not able to effectively demonstrate that the use of our products is beneficial in a broad range of patients, adoption of our products will be limited and may not occur as rapidly as we anticipate or at all, which would have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that our products will achieve broad market acceptance among hospitals and physicians. Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products, procedures or technologies are considered safer or more cost-effective or otherwise superior. Any failure of our products to generate sufficient demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition and results of operations.

Our reputation among our current or potential customers, as well as among electrophysiologists, could also be negatively affected by safety or customer satisfaction issues involving us or our products, including product recalls. Any product recalls or other safety or customer satisfaction issues relating to our reputation could negatively affect our ability to establish or maintain broad adoption of our products, which would harm our future prospects and have a material adverse effect on our business, financial condition and results of operations.

In most cases, before a hospital can purchase our AcQMap console and workstation for the first time, our system must be approved for use by a hospital's new product or value analysis committee or the staff of a hospital or health system. Such approvals could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals or generate adoption will be successful or increase the use of our products, and if we are not successful, it could have a material adverse effect on our business, financial condition and results of operations.

We have significant international operations and intend to further expand our business internationally, which exposes us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

As of December 31, 2022, we have sold our products directly in the United States, Belgium, the Czech Republic, Denmark, France, Germany, Great Britain, Italy, the Netherlands, Sweden and Switzerland. Our business strategy includes plans for significant expansion in the countries in which we currently operate as well as other international markets and may include

establishing and maintaining physician outreach and education capabilities outside of the United States and expanding our relationships with international payors. During the years ended December 31, 2022 and 2021, 47% and 52%, respectively, of our revenue was generated from customers located outside of the United States, and we anticipate that international sales will continue to represent a substantial portion of our total sales in the future. For example, in May 2020, we entered into expansive bi-lateral distribution agreements with Biotronik (the "Bilateral Distribution Agreements"), pursuant to which Biotronik agreed to distribute our products in Germany, Japan, Mexico, Switzerland and multiple countries in Asia-Pacific, Eastern Europe, the Middle East and South America. In addition, some of our employees including those of our Belgium subsidiary, our suppliers and our other strategic partners are located outside of the United States. Doing business internationally involves a number of risks, including:

- changes in a country's or region's political or economic conditions, including any potential impact resulting from the United Kingdom's, or UK, exit from the European Union, commonly referred to as Brexit;
- difficulties in developing effective marketing campaigns in unfamiliar foreign countries;
- multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- obtaining regulatory approvals where required for the sale of our products in various countries;
- requirements to maintain data and the processing of that data on servers located within such countries;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- trade protection measures, customs clearance and shipping delays;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the effect of local and regional financial pressures on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability including wars, terrorism, political unrest, outbreaks of disease or public health crises (including the impact of the COVID-19 pandemic), boycotts, curtailment of trade and other market restrictions;
- regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the FCPA, U.K. Bribery Act 2010 and comparable laws and regulations in other countries;
- our reliance on international distributors who we do not control to effectively market and sell our products in full compliance with applicable laws;
- differing protection of intellectual property; and
- increased financial accounting and reporting burdens and complexities.

We rely on shipping providers to deliver products to our customers and distributors globally. Labor, tariff or World Trade Organization-related disputes, piracy, physical damage to shipping facilities or equipment caused by severe weather or terrorist incidents, congestion at shipping facilities, inadequate equipment to load, dock and offload our products, energy-related tie-ups, outbreaks of disease or public health crises (including the impact of the COVID-19 pandemic) or other factors could disrupt or delay shipping or off-loading of our products domestically and internationally. Such disruptions or delays could materially and adversely affect our business, financial condition and results of operations.

If one or more of these risks are realized, our business, financial condition and results of operations could be materially and adversely affected.

We rely on our strategic relationship with Biotronik to enhance our product portfolio and to distribute our products in key international markets.

We entered into expansive Bi-Lateral Distribution Agreements with Biotronik in May 2020 to round out our product portfolio with a full suite of diagnostic and ablation catheters, and to rapidly and efficiently establish a sales presence globally. Pursuant to our Bi-Lateral Distribution Agreements with Biotronik, we obtained a non-exclusive license to distribute a range of Biotronik's therapeutic and diagnostic electrophysiology products and accessories in the United States, Canada, China, Hong Kong and multiple countries in Western Europe under our own private label. Biotronik has also agreed to distribute our products and accessories in Germany, Japan, Mexico, Switzerland and multiple countries in Asia-Pacific, Eastern Europe, the Middle East and South America. Accordingly, the Bi-Lateral Distribution Agreements significantly expand both our product

portfolio and our international sales presence. If Biotronik is unable to successfully market and sell our products in these markets, or if we are unable to successfully market Biotronik's products in the United States and geographies where we have or establish a direct selling presence, it could materially adversely impact our growth prospects in these markets and our relationship with Biotronik, which would harm our business, financial condition and results of operations. Our strategic alliance with Biotronik also includes cooperative arrangements with respect to regulatory approval and the commercialization, manufacture and marketing of our respective products in various geographic markets. While we will depend on Biotronik to sell our products in its designated territories and otherwise cooperate with us in our strategic alliance, we do not control the time and resources Biotronik devotes to such activities, and we may not have the resources available to satisfy expectations, which may adversely affect our relationship.

Either party may terminate the Bi-Lateral Distribution Agreements with respect to a country if the other party does not meet specified purchase targets for that country following a specified ramp-up period. Any termination of the Bi-Lateral Distribution Agreements for this or other reasons could have a material adverse effect on our business, financial condition and results of operations. For example, recruiting and retaining qualified third-party distributors and training them in our technology and products requires significant time and resources. Further, if our relationship with Biotronik terminates, we may be unable to replace this relationship or develop a direct sales channel without disruption to our business.

We may also seek to enter into additional strategic partnerships with other third parties in the future, including distribution arrangements. If we fail to develop new relationships with any other strategic partners we seek to engage, including in new markets, if we fail to manage, train or incentivize distributors effectively, or if we fail to provide distributors with competitive products on attractive terms, or if these distributors are not successful in their sales and marketing efforts, our ability to generate revenue growth could suffer, which could have a material adverse effect on our business, financial condition and results of operations. Moreover, these strategic partnerships may be non-exclusive, and some of our strategic partners may also have cooperative relationships with certain of our competitors. These relationships may not continue, may not be commercially successful or may require our expenditure of significant financial, personnel and administrative resources from time to time. If we are unable to leverage our existing and future strategic partnerships to achieve and maintain distribution at a global scale or establish and maintain a broad product portfolio, it could have a material adverse effect on our business, financial condition and results of operations.

We face significant competition, and if we are unable to compete effectively, we may not be able to achieve or maintain significant market penetration or improve our results of operations.

The medical device industry is intensely competitive, is subject to rapid change and is significantly affected by new product introductions and other market activities of industry participants. We compete with manufacturers and distributors of cardiovascular medical devices. Our most significant competitors in the electrophysiology field include Abbott Laboratories, Biosense Webster Inc. (a Johnson & Johnson Company), Boston Scientific Corporation and Medtronic, Inc.. Many of our competitors are large, well-capitalized companies with significantly greater market share and resources than we have. Therefore, they can spend more on product development, marketing, sales and other product initiatives than we can. We also compete with smaller medical device companies that have a single product or a limited range of products. Some of our competitors have:

- significantly greater name recognition;
- broader or deeper relations with healthcare professionals, customers and third-party payors;
- more established distribution networks;
- additional lines of products and the ability to offer rebates or bundle products to offer greater discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- greater financial and human resources for product development, sales and marketing and patent prosecution.

We compete primarily on the basis that our products are designed to enable more physicians to treat more patients more efficiently and effectively.

Our continued success depends on our ability to:

- continue to develop innovative, proprietary products that address significant clinical needs in a manner that is safe and effective for patients and easy-to-use for physicians;

- obtain and maintain regulatory clearances or approvals;
- demonstrate safety and effectiveness in our sponsored and third-party clinical trials;
- increase the productivity of our sales force across key geographic markets;
- leverage our strategic partnerships and alliances to achieve distribution at a global scale, to broaden our product portfolio and to enable and accelerate global connectivity;
- obtain and maintain coverage and adequate reimbursement for procedures using our products;
- attract and retain skilled research, development, sales and clinical personnel;
- cost-effectively manufacture, market and sell our products; and
- obtain, maintain, enforce and defend our intellectual property rights and operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

We can provide no assurance that we will be successful in developing new products or commercializing them in ways that achieve market acceptance. If we develop new products, sales of those products may reduce revenue generated from our existing products. Moreover, any significant delays in our product launches may significantly impede our ability to enter into or compete within a given market and may reduce the sales that we are able to generate from these products. We may experience delays in any phase of a product development, including during research and development, clinical trials, regulatory review, manufacturing and marketing. Delays in product introductions could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected.

Any growth that we experience in the future could require us to expand our sales and marketing personnel and manufacturing operations and general and administrative infrastructure. In addition to the need to scale our organization, future growth will impose significant added responsibilities on management including the need to identify, recruit, train and integrate additional employees. We cannot assure you that any increases in scale-related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. Rapid expansion in personnel could mean that less experienced people manufacture, market and sell our products, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure and could require significant capital expenditures that may divert financial resources from other projects such as research and development of potential future products. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls and our reporting systems and procedures. If we are unable to manage our growth effectively, including by failing to implement necessary procedures, to transition to new processes or to hire necessary personnel, it may be difficult for us to execute our business strategy and our business could be adversely affected.

We may not be able to develop, license or acquire new products, enhance the capabilities of our existing products to keep pace with rapidly changing technology and customer requirements or successfully manage the transition to new product offerings, any of which could have a material adverse effect on our business, financial condition and results of operations.

Our success depends on our ability to develop, license or acquire and commercialize additional products and to develop new applications for our technologies in existing and new markets while improving the performance and cost-effectiveness of our existing products, in each case in ways that address current and anticipated customer requirements. We intend to develop and commercialize additional products through our research and development program and by licensing or acquiring additional products and technologies from third parties. Such success is dependent upon several factors including functionality, competitive pricing, ease of use, the safety and efficacy of our products and our ability to identify, select and acquire the rights to products and technologies on terms that are acceptable to us.

The medical device industry is characterized by rapid technological change and innovation. New technologies, techniques or products could emerge that might offer better combinations of price and performance or better address customer requirements as compared to our current or future products. Competitors who may have greater financial, marketing and sales resources may be able to respond more quickly and effectively to new or changing opportunities, technologies, standards or customer requirements. Any new product we identify for internal development, licensing or acquisition may require additional development efforts prior to commercial sale, including extensive clinical testing and approval or clearance by the FDA and applicable foreign regulatory authorities. Due to the significant lead time and complexity involved in bringing a new product to

market, we are required to make a number of assumptions and estimates regarding the commercial feasibility of a new product. These assumptions and estimates may prove incorrect, resulting in our introduction of a product that is not competitive at the time of launch. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies. Our ability to mitigate downward pressure on our selling prices will be dependent upon our ability to maintain or increase the value we offer to hospitals, physicians, patients and payors. All new products are prone to the risks of failure inherent in medical device product development, including the possibility that the product will not be shown to be sufficiently safe and effective for approval or clearance by regulatory authorities. In addition, we cannot assure you that any such products that are approved or cleared will be manufactured or produced economically, be successfully commercialized or be widely accepted in the marketplace. The expenses or losses associated with unsuccessful product development or launch activities, or a lack of market acceptance of our new products, could adversely affect our business, financial condition and results of operations.

Our ability to attract new customer accounts and increase revenue from existing customers depends in large part on our ability to enhance and improve our existing products and to introduce compelling new products. The success of any enhancement to our products depends on several factors, including our ability to drive increased installations of our AcQMap console and workstation in customer accounts, to accomplish timely completion and delivery, to formulate competitive pricing and to instill overall market acceptance. Any new product that we develop may not be introduced in a timely or cost-effective manner, may contain defects or may not achieve the market acceptance necessary to generate significant revenue. If we are unable to successfully develop, license or acquire new products, enhance our existing products to meet customer requirements or otherwise gain market acceptance, our business, financial condition and results of operations would be harmed.

The typical development cycle of new medical device products can be lengthy and complicated and may require complex technology and engineering. Such developments may involve external suppliers and service providers, making the management of development projects complex and subject to risks and uncertainties regarding timing, timely delivery of required components or services and satisfactory technical performance of such components or assembled products. If we do not achieve the required technical specifications or successfully manage new product development processes, or if development work is not performed according to schedule, then such new technologies or products may be adversely impacted and our business and operating results may be harmed.

Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business.

Our quarterly and annual results of operations, including our revenue, profitability and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or other period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Factors that may cause fluctuations in our quarterly and annual results include, without limitation:

- the level of demand for our products, which may vary significantly from period to period;
- the expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- the timing and cost of clinical trials, including obtaining regulatory approvals or clearances for planned or future products;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein;
- the degree of competition in our industry and any change in the competitive landscape of our industry including consolidation among our competitors or future partners;
- the coverage and reimbursement policies with respect to the procedures using our products and potential future products that compete with our products;
- the timing and success or failure of clinical trials for our current or planned products or any future products we develop or competing products;
- the timing of customer orders or medical procedures, the timing and number of installations of our AcQMap console and workstation, the number of available selling days in a particular period, which can be impacted by a number of factors, such as holidays or days of severe inclement weather in a particular geography, the mix of products sold and the geographic mix of where products are sold;

- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our products, which may change from time to time;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
- the occurrence of natural disasters, outbreaks of disease or public health crises such as the COVID-19 pandemic;
- the timing and nature of any future acquisitions or strategic partnerships; and
- future accounting pronouncements or changes in our accounting policies.

Because our quarterly and annual results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

In addition, this variability and unpredictability could result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it may result in a decrease in the price of our common stock.

We depend upon third-party suppliers including single-source suppliers, making us vulnerable to supply disruptions and price fluctuations.

We rely on third-party suppliers to provide us with certain components of our products, some of which are single-source suppliers. In some cases, we do not have long-term supply agreements with, or guaranteed commitments from, our suppliers, including single-source suppliers. We depend on our suppliers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. For example, the single-source supplier of raw materials for one of our products was unable to meet our shipment demands during late 2022, which impacted our ability to produce finished goods. Our suppliers may also cease producing the components we purchase from them or otherwise decide to cease doing business with us. Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components used in our products would limit our ability to manufacture our products and could have a material adverse effect on our business, financial condition and results of operations.

Adoption of our products depends upon appropriate physician training, and inadequate training may lead to negative patient outcomes, affect adoption of our products and adversely affect our business.

The success of our products depends in part on our customers' adherence to appropriate patient selection and proper techniques provided in training sessions conducted by our training faculty. For example, we train our customers to ensure correct use of our AcQMap System. However, physicians rely on their previous medical training and experience, and we cannot guarantee that all such physicians will have the necessary skills or training to effectively utilize our products. We do not control which physicians use our products or how much training they receive, and physicians who have not completed our training sessions may nonetheless attempt to use our products. If physicians use our products in a manner that is inconsistent with their labeled indications, with components that are not compatible with our products or without adhering to or completing our training sessions, their patient outcomes may not be consistent with the outcomes achieved by other physicians or in our clinical trials. This result may negatively impact the perception of patient benefit and safety and limit adoption of our products, which would have a material adverse effect on our business, financial condition and results of operations.

Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as to significant costs and negative publicity.

Our business is subject to significant risks associated with manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses or inadequate disclosure of product-related information could also result in an unsafe condition or in the injury or death of a patient. These problems could lead to a recall or market withdrawal of, or issuance of a safety alert relating to, our products and could result in significant costs, negative publicity and adverse competitive pressure. Furthermore, the reporting of product defects or voluntary recalls to the FDA or analogous regulatory bodies outside the United States could result in manufacturing audits, inspections and broader recalls or other disruptions to our manufacturing processes. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products could have a material adverse effect on our business, financial condition and results of operations.

We provide a limited warranty that our products are free of material defects and conform to specifications, and we offer to repair, replace or refund the purchase price of defective products. As a result, we bear the risk of potential warranty claims on our products. In the event that we attempt to recover some or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery and any recovery from such vendor or supplier may not be adequate.

The medical device industry has historically been subject to extensive litigation over product liability claims. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death, even if due to physician error. In addition, an injury or death that is caused by the activities of our suppliers such as those that provide us with components and raw materials, or by an aspect of a treatment used in combination with our products such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, physicians or others purchasing or using our products, even if our products were not the actual cause of such injury or death. We may choose to settle any such claims even if we believe that such injuries were not due to failure of our products. An adverse outcome of any such claim involving one of our products could result in reduced market acceptance and demand for any or all of our products and could harm our reputation or brand and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Although we carry product liability insurance, including for clinical trials and product marketing, we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not continue to be available on acceptable terms, if at all. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation, significantly increase our expenses and reduce product sales. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. Product liability claims could cause us to incur significant legal fees and deductibles, and claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results. Defending a suit regardless of its merit or eventual outcome could be costly, could divert management's attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, in product recalls or in market withdrawals.

We are required to file adverse event reports under MDR regulations with the FDA which are publicly available on the FDA's website. 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. See "—Risks Related to Government Regulation—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."

Coverage and adequate reimbursement may not be available for the procedures that utilize our products, which could diminish our sales or affect our ability to sell our products profitably.

In both U.S. and non-U.S. markets, our ability to successfully commercialize and achieve market acceptance of our products depends, in significant part, on the availability of adequate financial coverage and reimbursement from third-party payors including governmental payors (such as the Medicare and Medicaid programs in the United States), managed care organizations and private health insurers. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments. Our products are purchased by hospitals and other providers who then seek reimbursement from third-party payors for the procedures performed using our products. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In certain international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Furthermore, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets there are private insurance systems as well as government-managed systems.

While third-party payors currently cover and provide reimbursement for procedures using our currently cleared or approved products, we can give no assurance that these third-party payors will continue to provide coverage and adequate reimbursement for the procedures using our products, or permit hospitals and doctors to offer procedures using our products to patients requiring treatment, or that current reimbursement levels for procedures using our products will continue. If sufficient coverage and reimbursement is not available for the procedures using our products in either the United States or internationally, the demand for our products and our revenue will be adversely affected. Furthermore, although we believe there is potential to

improve on the current reimbursement profile for our products in the future, the overall amount of reimbursement available for procedures intended to diagnose and treat complex heart arrhythmias could remain at current levels or could decrease in the future. Failure by hospitals and other users of our products to obtain and maintain coverage and adequate reimbursement for the procedures using our products would materially adversely affect our business, financial condition and results of operations.

Third-party payors are also increasingly examining the cost effectiveness of products in addition to their safety and efficacy when making coverage and payment decisions. Third-party payors have also instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority on the basis of randomized clinical trials, or require pre-approval of coverage for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. Additionally, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. It is uncertain whether our current products or any planned or future products will be viewed as sufficiently cost effective to warrant coverage and adequate reimbursement levels for procedures using such products in any given jurisdiction.

Our operations and financial results may be adversely impacted by the resurgence of COVID-19 or another global pandemic.

The markets we serve could see continued impacts from COVID-19 for the foreseeable future, and the emergence of new variants of COVID-19 creates significant uncertainty as to how long COVID-19 will continue to impact our business. The magnitude of the impact of the COVID-19 pandemic on our productivity, results of operations and financial position, and its disruption to our business and our clinical programs and timelines will depend, in part, on the length and severity of outbreaks, on restrictions and other measures designed to prevent the spread of COVID-19 and on our ability to conduct business in the ordinary course.

The uncertainty of future pandemics or resurgences of COVID-19 could severely impact our business including:

- significant interruptions to, or temporary closures of, our operations, including our manufacturing facility or our commercial organization;
- adverse effects on macroeconomic conditions as well as within the economies and financial markets of specific regions in which our products are marketed;
- continued depressed demand for installations of our AcQMap console and workstation and for our disposable products during a prolonged delay in physicians performing elective procedures using our products, or due to focusing their resources elsewhere;
- continued or increased delays or difficulties in enrolling patients in our clinical trials or the interruption or delay of key clinical trial activities such as clinical trial site monitoring arising from limitations on access to trial sites or limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in resources that would otherwise be focused on the conduct of our business, including because of sickness or the desire to avoid contact with large groups of people or as a result of government-imposed shelter-in-place or similar working restrictions;
- difficulties in recruitment of qualified sales and marketing personnel and mappers during a period in which we are seeking to significantly expand our commercial organization; and
- interruption in global shipping that may affect the shipment of our products or the transport of clinical trial materials.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine. Our business, financial condition and results of operations may be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine or any other geopolitical tensions.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the military conflict between Russia and Ukraine. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions including significant volatility in credit and capital markets.

Additionally, Russia's prior annexation of Crimea, recent recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military interventions in Ukraine have led to sanctions and other penalties being levied by the United States, European Union and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so-called Donetsk People's Republic and the so-called Luhansk People's Republic, including an agreement to remove certain Russian financial institutions from the Society for Worldwide Interbank Financial Telecommunication payment system. Additional potential sanctions and penalties have also been proposed and/or threatened. Russian military actions and the resulting sanctions could adversely affect the global economy and financial markets.

Any of the above mentioned factors could affect our business, prospects, financial condition and operating results. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this Annual Report on Form 10-K.

The continuing development of our products depends upon our maintaining strong working relationships with hospitals, physicians and other medical personnel.

The research, development, marketing and sale of our current products and potential new and improved products for which we receive regulatory clearance or approval depend upon our maintaining working relationships with hospitals, physicians and other medical personnel. We rely on these relationships to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. For example, physicians assist us in clinical trials and in marketing and as researchers, product consultants and public speakers. If we cannot maintain our strong working relationships and continue to receive such advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

At the same time, the medical device industry's relationship with physicians is under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General, or OIG, the U.S. Department of Justice, or DOJ, the state attorney generals and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry's relationships with physicians or an investigation into our compliance by the OIG, the DOJ, state attorney generals and other government agencies could have a material adverse effect on our business, financial condition and results of operations. Additional information regarding the laws impacting our relationships with physicians and other healthcare professionals can be found below under "—Risks Related to Government Regulation."

We depend on our senior management team, and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business.

Our success depends largely on the continued services of key members of our executive management team and others in key management positions. We do not currently maintain key-person life insurance policies on any of our employees. If we lose one or more key employees, we may experience difficulties in competing effectively, in developing our technologies and in implementing our business strategy.

In addition, our research and development programs, clinical operations and sales and marketing efforts depend on our ability to attract and retain highly skilled scientists, engineers and sales professionals. Competition for skilled personnel in our market is intense, and we have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. Furthermore, our common stock is currently trading at a price below the exercise price of most of our outstanding stock options. As a result, these "underwater" options are less useful as a motivation and retention tool for our existing employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but keep limited components, sub-assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our third-party manufacturers and suppliers, we forecast anticipated materials requirements and demand for our

products in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our limited historical commercial experience, rapid growth, failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand, including as a result of our introduction of product enhancements, may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs, which could have a material adverse effect on our business, financial condition and results of operations. Conversely, if we underestimate customer demand for our products or our own requirements for components, subassemblies and materials, our third-party manufacturers and suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements, which could result in inadequate inventory levels or interruptions, delays or cancellations of deliveries to our customers, any of which would damage our reputation, customer relationships and business. In addition, several components, sub-assemblies and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available when required on terms that are acceptable to us, or at all, and our third-party manufacturers and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our business, our financial condition and our results of operations.

The failure of third parties to meet their contractual, regulatory and other obligations could adversely affect our business.

We rely on suppliers, vendors, outsourcing partners, consultants, alliance partners and other third parties to research, develop, manufacture and commercialize our products. Using third parties poses a number of risks, such as: (i) they may not perform to our standards or legal requirements; (ii) they may not produce reliable results; (iii) they may not perform in a timely manner; (iv) they may not maintain confidentiality of our proprietary information; (v) disputes may arise with respect to ownership of rights to technology developed with our partners; (vi) changes in the cost of these purchases due to inflation, exchange rates, tariffs or other factors; and (vii) disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration. Moreover, some third parties are located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory and other obligations may have a material adverse effect on our business, financial condition and results of operations.

Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability.

In an effort to reduce costs, many hospitals in the United States have become members of Group Purchasing Organizations, or GPOs, and Integrated Delivery Networks, or IDNs. GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new or maintain existing contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our revenue and margins.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative products due to the price or quality offered by other companies, which could result in a decline in our revenue.

We may not be able to achieve or maintain satisfactory pricing and margins for our products.

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. Any decline in the amount that payors reimburse our customers for procedures involving the use of our products could make it difficult for customers to continue using or adopting our products and could create additional pricing pressure for us. If we are forced to

lower the price we charge for our products, our revenue and gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase, for example, due to increased inflation and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business, financial condition and results of operations.

We have significant customer concentration with a limited number of customers accounting for a significant portion of our 2022 revenue. If we fail to retain these customers, our revenue could decline significantly.

We currently derive a significant portion of our revenue from a relatively small number of customers. Our top three and top five customers accounted for 42% and 50% of our revenue in 2022, respectively. There are inherent risks whenever a large percentage of revenue is concentrated with a limited number of customers. Our revenue could fluctuate materially and could be materially and disproportionately impacted by purchasing decisions of these customers or any other significant customer. In the future, any of our significant customers may decide to purchase less than they have in the past, may alter their purchasing patterns at any time with limited notice or may decide not to continue to purchase our products at all, any of which could cause our revenue to decline and could have a material adverse effect on our business, financial condition and results of operations. If we do not diversify our customer base, we will continue to be susceptible to risks associated with customer concentration.

If our facility becomes damaged or inoperable or if we are required to vacate a facility, we may be unable to manufacture our products or we may experience delays in production or an increase in costs, which could adversely affect our results of operations.

We currently maintain our research and development, manufacturing and administrative operations in a building located in Carlsbad, California, and we do not have redundant facilities. Should our building be significantly damaged or destroyed by natural or man-made disasters such as earthquakes, fires (both of which are prevalent in California) or other events, it could take months to relocate or rebuild, during which time our employees may seek other positions, our research, development and manufacturing would cease or be delayed and our products may be unavailable. Because of the time required to authorize manufacturing in a new facility under federal, state and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity. While we maintain property and business interruption insurance, such insurance has limits and would not cover all damages, including losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. The inability to perform our research, development and manufacturing activities if our facilities become inoperable, combined with our limited inventory of materials and components and manufactured products, may cause physicians to discontinue using our products or harm our reputation, and we may be unable to re-establish relationships with such physicians in the future. Consequently, a catastrophic event at our current facility or any future facilities could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, the current lease for our manufacturing facility expires at the end of 2027, and we may be unable to renew our lease or find a new facility on commercially reasonable terms. If we were unable or unwilling to renew at the proposed rates, relocating our manufacturing facility would involve significant expense in connection with the movement and installation of key manufacturing equipment and any necessary recertification with regulatory bodies, and we cannot assure you that such a move would not delay or otherwise adversely affect our manufacturing activities or operating results. If our manufacturing capabilities were impaired by our move, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business.

We have limited experience manufacturing our products in commercial quantities, which could harm our business.

Because we have only limited experience in manufacturing our products in commercial quantities, we may encounter production delays or shortfalls. Such production delays or shortfalls may be caused by many factors, including the following:

- our intent to expand our manufacturing capacity, as a result of which our production processes may have to change;
- key components of our products are provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components; if we experience a shortage or quality issues in any of these components, we would need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays;
- a delay in completing validation and verification testing for new controlled environment rooms at our manufacturing facility;

- state and federal regulations including the FDA's QSR for the manufacture of our products, noncompliance with which could cause an interruption in our manufacturing; and
- attraction and retention of qualified employees for our operations in order to significantly increase our manufacturing output.

If we are unable to keep up with demand for our products, our growth could be impaired, and market acceptance for our products could be harmed and physicians may instead elect to use our competitors' products. Our inability to successfully manufacture our products in sufficient quantities would materially harm our business.

In addition, our manufacturing facility and processes and those of our third-party suppliers are subject to unannounced FDA and state regulatory inspections for compliance with the QSR. Developing and maintaining a compliant quality system is time consuming and expensive. Failure to maintain compliance with, or not fully complying with the requirements of the FDA and state regulators, could result in enforcement actions against us or our third-party suppliers, which could include the issuance of warning letters, seizures, prohibitions on product sales, recalls and civil and criminal penalties, any one of which could significantly impact our manufacturing supply and impair our financial results.

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

The medical device market is characterized by extensive research and development and rapid technological change. There can be no assurance that other companies, including current competitors or new entrants, will not succeed in developing or marketing products that are more effective than our products or that would render our products obsolete or noncompetitive. Additionally, new surgical procedures, medications and other therapies could be developed that replace or reduce the importance of our products. If we are unable to innovate successfully, our products could become obsolete and our revenue would decline as our customers purchase our competitors' products. Our failure to develop new products, applications or features could result from insufficient cash resources, high employee turnover, an inability to hire personnel with sufficient technical skills, a lack of other research and development resources or from other constraints. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our current or future competitors could have a material adverse effect on our business, financial condition and results of operations.

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

Many medical device companies are consolidating to create new companies with greater market power. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for our products. If we reduce our prices because of consolidation in the healthcare industry, our revenue would decrease, which could have a material adverse effect on our business, financial condition and results of operations.

We have limited data and experience regarding the safety and efficacy of our products. Results of earlier trials may not be predictive of future clinical trial results, and planned trials may not establish an adequate safety or efficacy profile for such products and other planned or future products, which would affect market acceptance of these products.

We have performed clinical trials with only limited patient populations. The long-term effects of using our products in a large number of patients have not been studied and the results of short-term clinical use of such products do not necessarily predict long-term clinical benefits or reveal long-term adverse effects. The results of clinical trials of our products conducted to date and ongoing or future trials and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials in other patient populations. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials and subsequently failed to obtain marketing approval. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials.

If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be harmed.

Clinical development is a long, expensive and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may

take several years or more. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching an agreement on acceptable clinical trial terms with prospective sites, in obtaining IRB approval at each site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials.

We cannot provide any assurance that we will successfully, or in a timely manner, enroll our clinical trials, that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities.

We may experience numerous unforeseen events during, or because of, the clinical trial process that could delay or prevent us from receiving regulatory clearance or approval for new products or modifications of existing products, including new indications for existing products, including:

- enrollment in our clinical trials may be slower than we anticipate, or we may experience high screen failure rates in our clinical trials, resulting in significant delays;
- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing which may be expensive and time-consuming;
- trial results may not meet the level of statistical significance required by the FDA or other regulatory authorities;
- the FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans;
- the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;
- there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities;
- there may be delays in obtaining IRB approvals or governmental approvals to conduct clinical trials at prospective sites;
- the FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory;
- the FDA or similar foreign regulatory authorities may change their review policies or adopt new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications;
- we may have trouble in managing multiple clinical sites;
- we may have trouble finding patients to enroll in our trials;
- we may experience delays in agreeing on acceptable terms with third-party research organizations and trial sites that may help us conduct the clinical trials; and
- we or regulators may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks.

Failures or perceived failures in our clinical trials will delay and may prevent our product development and regulatory approval process, damage our business prospects and negatively affect our reputation and competitive position.

Clinical trials may be delayed, suspended or terminated for many reasons, which will increase our expenses and delay the time it takes to develop new products or seek new indications.

We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, will need to be redesigned, will enroll an adequate number of patients on time or will be completed on schedule, if at all. The commencement and completion of clinical trials for future products or indications may be delayed, suspended or terminated as a result of many factors, including:

- the FDA or other regulators disagreeing as to the design, protocol or implementation of our clinical trials;
- the delay or refusal of regulators or IRBs to authorize us to commence a clinical trial at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;

- delays in reaching, or failure to reach, agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials to observe statistically significant treatment effects in the trial;
- having clinical sites deviate from the trial protocol or dropping out of a trial;
- negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we expect to be promising;
- safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- reports from preclinical or clinical testing of other similar therapies that raise safety or efficacy concerns;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, from deviating from the protocol or by dropping out of a trial;
- delays relating to adding new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- the quality of the products falling below acceptable standards;
- the inability to manufacture sufficient quantities of our products to commence or complete clinical trials; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or the Ethics Committees of institutions at which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors including a failure to conduct the clinical trial in accordance with regulatory requirements including the FDA's current Good Clinical Practice, or GCP, regulations or our clinical protocols, an inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, an unforeseen safety issue or adverse side effect, a failure to demonstrate safety and effectiveness, a change in governmental regulation or administrative action or a lack of adequate funding to continue the clinical trial.

In addition, we may encounter delays if the FDA concludes that our financial relationships with investigators result in a perceived or actual conflict of interest that may have affected the interpretation of a trial, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or stock-based compensation in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the trial result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the trial, then the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in a delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing any of our products currently in development.

If we experience delays in the commencement or completion of any clinical trial of our products, or if any of our clinical trials are terminated, the commercial prospects of our products may be harmed, and our ability to generate revenue from sales may be delayed or materially diminished.

We do not know whether any of our future preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Any delays in completing our clinical trials will increase our costs, will slow down our product development and approval process and will jeopardize our ability to commence sales and generate associated revenue. Any of these occurrences may significantly harm our business, financial condition and results of operations. In addition, many of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial, suspension or revocation of expanded regulatory clearance or approval of our products. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to

commercialize our products, or it could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our products.

The sizes of the markets for our current and future products have not been established with precision and may be smaller than we estimate.

Our estimates of the total addressable markets for our current products and products under development are based on a number of internal and third-party estimates, including, without limitation, the number of patients with cardiac arrhythmias and the assumed prices at which we can sell our products in markets that have not been established or that we have not yet entered. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these estimates. As a result, our estimates of the total addressable market for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell products or the total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

The use, misuse or off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.

Our products have been cleared by the FDA for the treatment of complex heart arrhythmias. If physicians expand the patient population in which they elect to use our products that is outside of the intended use approved or cleared by the FDA, then the use, misuse or off-label use of our products may result in outcomes and adverse events including stroke and death, potentially leading to product liability claims. Our products are not indicated for use in all patients with complex heart arrhythmias, and therefore cannot be marketed or advertised in the United States for certain uses without additional clearances from the FDA. However, we cannot prevent a physician from using our products for off-label applications or using components or products that are not our products. In addition, we cannot guarantee that physicians are trained by us or their peers prior to utilizing our products. Complications resulting from the use of our products off-label or use by physicians who have not been trained appropriately, or at all, may expose us to product liability claims and harm our reputation. Moreover, if the FDA determines that our promotional materials or physician training, including our paid consultants' educational materials, constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to enforcement action, including warning letters, untitled letters, fines, penalties or seizures. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines and/or other penalties against companies for alleged improper promotion and has investigated, prosecuted and/or enjoined several companies from engaging in off-label promotion.

We may acquire other companies or technologies, which could fail to result in a commercial product or net sales, divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results.

We have acquired and may in the future seek to acquire or invest in additional businesses, products or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. For example, in June 2019, we added an integrated product family of transseptal crossing and steerable introducer systems to our product portfolio through our acquisition of Rhythm Xience, and in July 2019, we acquired our AcQBlate Force Sensing Ablation System from Biotronik pursuant to a license agreement, or Biotronik License Agreement. However, we have limited experience in acquiring other businesses, products or technologies. The process of integrating an acquired company, business or technology may create unforeseen operating challenges, risks and expenditures, including that the acquisitions do not advance our corporate strategy, that we get an unsatisfactory return on our investment, that the acquisitions distract management, or that we may have difficulty: (i) integrating an acquired company's accounting, financial reporting, management information and information security, human resource and other administrative systems to permit effective management; (ii) integrating the controls, procedures and policies at companies we acquire into our internal control over financial reporting; and (iii) transitioning the acquired company's operations, suppliers and customers to us. It may take longer than expected to realize the full benefits from these acquisitions such as increased revenue, enhanced efficiencies or increased market share, or the benefit may ultimately be smaller than we expected. Moreover, if any of our acquisitions or investments increase our international operations, it would expose us to additional risks relating to operating outside the United States including increased operational and regulatory risks. Our failure to address these risks or other problems encountered in connection with our past or future acquisitions and investments could cause us to fail to realize the anticipated benefits of such acquisitions or investments, to incur unanticipated liabilities and may harm our business generally. If an acquired business, product or technology fails to meet our expectations or results in unanticipated costs and expenses, our business, financial condition and results of operations may suffer.

We also cannot assure you that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product or technology in a cost-effective and non-disruptive manner. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or to obtain the expected benefits of any acquisition or investment. In addition, under our amended and restated credit agreement dated as of June 30, 2022, with the lenders from time to time party thereto and Wilmington Trust National Association ("Wilmington Trust") as administrative agent (the "2022 Credit Agreement"), we may require the prior written consent of such agents and the required lenders prior to consummating any acquisition or investment.

Acquisitions could also result in dilutive issuances of equity or equity-linked securities, in the use of our available cash or in the incurrence of debt, whether to fund the upfront purchase price of the transaction or to fund deferred or contingent payments to which we agreed as part of the transaction. For further information regarding our recent strategic transactions, see the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.”

The terms of our 2022 Credit Agreement, require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

On June 30, 2022, we amended and restated our prior debt facility under the 2019 credit agreement with the 2022 Credit Agreement, which provided us with a senior term loan facility in aggregate principal amount of $35.0 million

Our payment obligations under the 2022 Credit Agreement reduced cash available to fund working capital, capital expenditures, research and development and general corporate needs. In addition, indebtedness under the 2022 Credit Agreement bore interest at a variable rate, making us vulnerable to increases in market interest rates. If market rates increase, we will have to pay additional interest on this indebtedness, which would further reduce cash available for our other business needs.

Our obligations under the 2022 Credit Agreement are secured by substantially all of our assets and the assets of our wholly-owned subsidiary. The security interest granted over our assets could limit our ability to obtain additional debt financing. In addition, the 2022 Credit Agreement contains customary affirmative and negative covenants restricting our activities, including limitations on:

- dispositions, mergers or acquisitions; encumbering our intellectual property;
- incurring indebtedness or liens;
- paying dividends or redeeming stock or making other distributions;
- making certain investments;
- liquidating our company;
- modifying our organizational documents;
- entering into sale-leaseback arrangements; and,
- engaging in certain other business transactions.

In addition, we are required to maintain a minimum liquidity amount of $20.0 million. Failure to comply with the covenants in the 2022 Credit Agreement, including the minimum liquidity covenant, could result in the acceleration of our obligations under the 2022 Credit Agreement, and, if such acceleration were to occur, would materially and adversely affect our business, financial condition and results of operations.

We may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under our debt arrangement. The obligations under the 2022 Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to regulatory approvals and a material adverse change in our business, operations or other financial condition. If an event of default (other than certain events of bankruptcy or insolvency) occurs and is continuing, Wilmington Trust may declare all or any portion of the outstanding principal amount of the borrowings plus accrued and unpaid interest to be due and payable. Upon the occurrence of certain events of bankruptcy or insolvency, all of the outstanding principal amount of the borrowings plus accrued and unpaid interest will automatically become due and payable. The 2022

Credit Agreement also provides for final payment fees of an additional $1.9 million that are due upon prepayment, on the maturity date or upon acceleration, as well as prepayment penalties.

Our outstanding indebtedness and any future indebtedness combined with our other financial obligations could increase our vulnerability to adverse changes in general economic, industry and market conditions, limit our flexibility in planning for, or reacting to, changes in our business and the industry and impose a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

Our results may be impacted by changes in foreign currency exchange rates.

Our reporting currency is the U.S. dollar and our sales outside the United States are primarily denominated in Euros and British Pound Sterling. For the years ended December 31, 2022 and 2021, approximately 21% and 27%, respectively, of our sales were denominated in currencies other than U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States and Europe. If our operations in countries outside of the United States grows, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. For example, if the value of the U.S. dollar increases relative to foreign currencies in the absence of a corresponding change in local currency prices, our revenue could be adversely affected as we convert revenue from local currencies to U.S. dollars. In addition, because we conduct business in currencies other than the U.S. dollar but report our results of operations in U.S. dollars, we also face remeasurement exposure to fluctuations in currency exchange rates, which could hinder our ability to predict our future results and earnings and could impact our results of operations. We do not currently maintain a program to hedge exposures to non-U.S. dollar currencies. If we are unable to address these risks effectively, it could have a material adverse effect on our business, financial condition and results of operations.

Taxing authorities may successfully assert that we should have collected or in the future should collect sales and use, gross receipts, value added or similar taxes and may successfully impose additional obligations on us, and any such assessments or obligations could adversely affect our business, financial condition and results of operations.

We have not historically collected sales and use, gross receipts, value added or similar taxes, although we may be subject to such taxes in various jurisdictions. One or more jurisdictions may seek to impose additional tax collection obligations on us, including for past sales. A successful assertion by a state, country or other jurisdiction that we should have been or should be collecting additional sales, use or other taxes on our services could, among other things, result in substantial tax liabilities for past sales, create significant administrative burdens for us, discourage users from purchasing our products or otherwise harm our business, results of operations and financial condition.

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

As of December 31, 2022, we had U.S. federal and state net operating loss, or NOL, carryforwards of approximately $390.5 million and $102.6 million, respectively. We may use these NOLs to offset against taxable income for U.S. federal and state income tax purposes. If not utilized, our U.S. federal NOLs (and our state NOLs in conforming states) arising in taxable years beginning before 2018 will begin to expire in 2031. Deductibility of U.S. federal NOLs arising in taxable years beginning after 2017 may be carried forward 20 years and are limited to 80% of our taxable income before the deduction for such NOLs. Additionally, Section 382 of the Internal Revenue Code of 1986, as amended, may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We have not conducted a Section 382 study to determine whether the use of our NOLs is impaired. We may have previously undergone an "ownership change." In addition, future issuances or sales of our stock, including certain transactions involving our stock that are outside of our control, could result in future "ownership changes." "Ownership changes" that have occurred in the past or that may occur in the future could result in the imposition of an annual limit on the amount of pre-ownership change NOLs and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could, depending on the extent of such limitation and the NOLs previously used, result in our retaining less cash after payment of U.S. federal and state income taxes during any year in which we have taxable net income than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal and state income tax reporting purposes, which could adversely impact operating results.

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

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing and inventory management. We do not have redundant information technology systems at this time. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. We could be subject to any number of unintentional events that could involve a third party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data or result in release of our confidential information. Technological interruptions could 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. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or result in inappropriate disclosure of confidential or proprietary information, we could incur liability, and the further development and commercialization of our products could be delayed or disrupted.

Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount and may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related data and system disruptions. We cannot be certain that such potential losses will not exceed our policy limits, whether insurance will continue to be available to us on economically reasonable terms, or at all, or whether any insurer will not deny coverage as to any future claim. In addition, we may be subject to changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements. 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.

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

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

Additionally, we cannot be certain that any insurance coverage that we may maintain will be adequate or otherwise protect us with respect to claims, expenses, fines, penalties, business loss, data loss, litigation, regulatory actions or other impacts arising out of security breaches or other disruptions, or that such coverage will continue to be available on acceptable terms or at all. Any of these results could adversely affect our business, financial condition and results of operations.

We are subject to stringent privacy laws, information security policies and contractual obligations governing the use, processing and cross-border transfer of personal information and our data privacy and security policies.

We receive, generate and store significant and increasing volumes of sensitive information such as health information, insurance information and other potentially personally identifiable information. We face a number of risks relative to protecting this critical information including loss of access risk, inappropriate use or disclosure, inappropriate modification and the risk of our being unable to adequately monitor, audit and modify our controls over our critical information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data.

We are subject to a variety of local, state, national and international laws, directives and regulations that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the different jurisdictions in which we operate, including comprehensive regulatory systems in the U.S. and Europe. Further, various states such as California, Massachusetts and Virginia have implemented privacy laws and regulations that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. California enacted the CCPA, which creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA went into effect on January 1, 2020, and the California Attorney General may now bring enforcement actions for violations. The CCPA has been amended from time to time, and further, a new privacy law, the CPRA, was approved by California voters in the November 3, 2020 election. The CPRA mostly took effect on January 1, 2023 and significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also created a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. It remains unclear what, if any, further modifications will be made to the CCPA or CPRA, or how such legislation will be interpreted. This may potentially result in further uncertainty and require us to incur additional costs and expenses in efforts to comply. Certain other state laws impose similar privacy obligations and all 50 states have laws including obligations to provide notification of security breaches of computer databases that contain personal information to affected individuals, to state officers and to others. For example, the CCPA has prompted a number of proposals for new federal and state-level privacy legislation such as in Nevada, New Hampshire, Illinois and Nebraska. This legislation may add additional complexity, variation in requirements, restrictions and potential legal risk, may require additional investment of resources in compliance programs, may impact strategies, and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. In addition, we may obtain health information from third parties (including hospitals) that are subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act and regulations promulgated thereunder. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use, or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA.

The collection and use of personal data in the European Union are governed by the GDPR. The GDPR imposes stringent requirements for controllers and processors of personal data, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data such as health data, and additional obligations when we contract with third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union, or EU, to the United States and other third countries. In July 2020, the Court of Justice of the European Union issued a decision that struck down the EU-U.S. Privacy Shield framework, which provided companies with a mechanism to comply with data protection requirements when transferring personal data from the EU to the United States, and additionally called into question the validity of the European Commission's Standard Contractual Clauses, on which U.S. companies rely to transfer personal data from Europe to the United States and elsewhere. In September 2020, the Swiss Federal Data Protection and Information Commissioner issued an opinion that stated it no longer considers the Swiss-U.S. Privacy Shield adequate for the purposes of personal data transfers from Switzerland to the United States. These developments may result in European data protection regulators applying differing standards for, and requiring ad hoc verification of, transfers of personal data from Europe to the United States. To the extent that we engage in such transfers, if we are unable to implement safeguards to ensure that our transfers are lawful or if any safeguards upon which we rely are invalidated, we will face increased exposure to litigation, regulatory actions, fines and injunctions against data processing. If we are unable to engage in such transfers because there is no lawful mechanism to do so, the functionality or effectiveness of our products and services may decrease and our marketing efforts, plans and activities may be adversely impacted. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including biometric or health data.

The GDPR applies extraterritorially, and we may be subject to the GDPR because of our data processing activities that involve the personal data of individuals located in the European Union, such as in connection with any European Union clinical trials or related to any employees in Europe. GDPR regulations may impose additional responsibility and liability in relation to the personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities, and materially and adversely affect our business, financial condition and results of operations.

Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations which could increase our compliance costs and the risks associated with non-compliance. We cannot guarantee that we or our vendors may be in compliance with all applicable international regulations as they are enforced now or as they evolve. For example, our privacy and cybersecurity policies may be insufficient to protect any personal information we collect, or may not comply with applicable laws, in which case we may be subject to regulatory enforcement actions, lawsuits or reputational damage, all of which may adversely affect our business. If we or our vendors fail to comply with the GDPR and the applicable national data protection laws of the European Union member states, or if regulators assert we have failed to comply with these laws, it may lead to regulatory enforcement actions which can result in monetary penalties of up to €20.0 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and may result in restrictions on data processing and other administrative penalties.

Further, in January 2021, following its exit from the EU, the United Kingdom transposed the GDPR into its domestic law with its own version of the GDPR (combining the GDPR and the UK Data Protection Act of 2018), or UK GDPR, which currently imposes the same obligations as the GDPR in most material respects and provides for fines of up to £17.5 million or 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, for noncompliance. In addition, an actual or asserted violation of the GDPR or UK GDPR could result in regulatory investigation, reputational damage, orders to cease or change our processing of our data, enforcement notices and/or assessment notices for a compulsory audit. We also may face civil claims, including representative actions and other class action-type litigation where individuals have suffered harm, potentially resulting in our paying significant compensation or damages, or incurring other significant liabilities as well as associated costs, a diversion of internal resources and an infliction of reputational harm. Going forward, there is increasing risk for divergence in application, interpretation, and enforcement of the data protection laws as between the United Kingdom and the EEA. Furthermore, the relationship between the United Kingdom and the EEA in relation to certain aspects of data protection law remains uncertain. For example, on June 28, 2021, the European Commission announced a decision of "adequacy," concluding that the United Kingdom ensures an equivalent level of data protection to the GDPR, which provides some relief regarding the legality of continued personal data flows from the EEA to the United Kingdom. This adequacy determination will automatically expire in June 2025 unless the European Commission renews or extends, and it may be modified or revoked in the interim. We may incur liabilities, expenses, costs and other operational losses under the GDPR, UK GDPR and privacy laws of the applicable EU Member States and the United Kingdom in connection with any measures we take to comply with them.

Compliance with U.S. and international data protection 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. Penalties for violations of these laws vary. Moreover, complying with these various laws 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. In addition, we rely on third-party vendors to collect, process and store data on our behalf and we cannot guarantee that such vendors are in compliance with all applicable data protection laws and regulations. Our or our vendors' failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions which could include civil or criminal penalties, private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, that we failed to comply with data protection laws or that we breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition and results of operations.

Certain of our operating results and financial metrics may be difficult to predict as a result of seasonality.

While we have not yet experienced significant seasonality in our results, it is not uncommon in our industry to experience seasonally weaker revenue during the summer months and end-of-year holiday season. We may be affected by seasonal trends in the future, particularly as our business matures. Additionally, this seasonality may be reflected to a much lesser extent, and sometimes may not be immediately apparent, in our revenue. To the extent we experience this seasonality, it may cause fluctuations in our operating results and financial metrics and make forecasting our future operating results and financial metrics more difficult.

Risks Related to Our Financial Position and Need for Additional Capital

We have a history of net losses, and we expect to continue to incur losses for at least the next several years. If we ever achieve profitability, we may not be able to sustain it.

We have incurred net losses since our inception in March 2011. For the years ended December 31, 2022 and 2021, we had a net loss of $39.6 million and $117.7 million, respectively, and we expect to continue to incur additional net losses for at least the next several years. As a result of these losses, as of December 31, 2022 and 2021, we had an accumulated deficit of $518.3 million and $478.7 million, respectively. Our operations have been financed primarily by aggregate net proceeds from the sale of equity and debt securities, as well as other indebtedness. Our losses and accumulated deficit have primarily been due to the significant investments we have made in our sales and marketing organization, clinical trials designed to provide clinical evidence of the safety and efficacy of our products and research and development and regulatory affairs to develop our products and support appropriate regulatory submissions. We have also invested in acquisitions of businesses, products and technologies that we believe complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. In addition, we have experienced negative gross margins in recent periods as a result of significant investments in our infrastructure to support our commercial launch and to enable our production volumes to scale as our business grows.

We expect to continue to incur significant sales and marketing, research and development, regulatory and other expenses as we expand our marketing efforts to increase adoption of our products, expand existing relationships with our customers, obtain regulatory clearances or approvals for our planned or future products, conduct clinical trials on our existing and planned or future products and develop new products or add new features to our existing products. In addition, as a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. Accordingly, we expect to continue to incur operating losses and net losses for at least the next couple years, and we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future would make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations.

In order to support our continued operations and the growth of our business, we may seek to raise additional capital, which may not be available to us on acceptable terms, or at all.

We expect capital expenditures and operating expenses to increase over the next several years as we continue to operate our business and expand our infrastructure, commercial operations and research and development activities. Our primary uses of capital are, and we expect will continue to be, investment in our commercial organization and related expenses, clinical research and development services, laboratory and related supplies, legal and other regulatory expenses, general administrative costs and working capital. In addition, we have acquired, and may in the future seek to acquire or invest in, additional businesses, products or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. For further information regarding our recent strategic transactions, see the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources."

Because of these and other factors, we expect to continue to incur substantial net losses and negative cash flows from operations for at least the next several years. Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our revenue growth;
- our research and development efforts;
- our sales and marketing activities;
- our success in leveraging our strategic partnerships, including with Biotronik, as well as entrance into any other strategic partnerships or strategic transactions in the future;
- our ability to raise additional funds to finance our operations;
- the outcome, costs and timing of any clinical trial results for our current or future products;
- the emergence and effect of competing or complementary products;
- the availability and amount of reimbursement for procedures using our products;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make or may receive in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

- our ability to retain our current employees and the need and ability to hire additional management and sales, scientific and medical personnel;
- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- debt service requirements;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the impact of the COVID-19 pandemic.

If we determine to raise additional funds, we may do so through equity or debt financings, which may not be available to us on the timing needed or on terms that we deem to be favorable. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected, including potentially requiring us to delay, limit, reduce or terminate certain of our product discovery and development activities or future commercialization efforts.

Moreover, in the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to products or technologies we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms.

As of December 31, 2022 and 2021, we had $70.4 million and $107.9 million, respectively, in cash, cash equivalents and marketable securities. While we believe our existing cash, cash equivalents and marketable securities and anticipated cash generated from sales of our products will be sufficient to meet our anticipated cash needs for at least 12 months following the date of this Annual Report on Form 10-K, we cannot assure you that we will be able to generate sufficient liquidity as and when needed, or that revenue from commercial sales will be adequate to fund our operating needs or achieve or sustain profitability. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Risks Related to Government Regulation

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

Our current products are subject to extensive regulation by the FDA in the United States, our Notified Body in the European Union and certain other non-U.S. regulatory agencies. Complying with these regulations is costly, time-consuming, complex and uncertain. Government regulations specific to medical devices are wide-ranging and include, among other things, oversight of:

- product design, development, manufacture (including our suppliers) and testing;
- laboratory, preclinical and clinical trials;
- product safety and effectiveness;
- product labeling;
- product storage and shipping;
- record keeping;
- premarket clearance or approval;
- marketing, advertising and promotion;
- product sales and distribution;
- product changes;
- product recalls; and

- post-market surveillance and reporting of deaths or serious injuries and certain malfunctions.

Before a new medical device or service or a new intended use for an existing product or service can be marketed in the United States, a company must first submit and receive either 510(k) clearance or PMA from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is substantially equivalent to a legally-marketed predicate device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be substantially equivalent, the proposed device must have the same intended use as the predicate device and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence.

In the process of obtaining PMA, the FDA must determine that a proposed device is safe and effective for its intended use based, in part on extensive data including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Either the 510(k) or PMA process can be expensive, lengthy and unpredictable. We may not be able to obtain any necessary clearances or approval or may be unduly delayed in doing so, which will negatively affect our business, financial condition and results of operations. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained 510(k) clearance to market our products, our clearance can be revoked if safety or efficacy problems develop.

In order to sell our products in member countries of the EEA, our products must comply with the essential requirements of the MDD. Compliance with these requirements is a prerequisite to be able to affix the CE Mark to our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements, we must undergo a conformity assessment procedure which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices) where the manufacturer can issue an European Commission Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the MDD, a conformity assessment procedure requires the intervention by a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE Mark to our products, which would prevent us from selling them within the EEA.

Further, all of our potential products and improvements of our current products will be subject to extensive regulation and will likely require permission from regulatory agencies and ethics boards to conduct clinical trials and clearance or gain approval from the FDA and non-U.S. regulatory agencies prior to commercial sale and distribution. Failure to comply with applicable U.S. requirements regarding, for example, promoting, manufacturing or labeling our products, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. The FDA can also refuse to clear or approve pending applications.

Any enforcement action by the FDA and other comparable non-U.S. regulatory agencies could have a material adverse effect on our business, financial condition and results of operations. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state or international agencies, which may include any of the following actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement or refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA of new products or modified products;

- operating restrictions;
- withdrawing 510(k) clearances or PMA that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

If any of these events were to occur, it would have a material and adverse effect on our business, financial condition and results of operations.

The FDA and the Federal Trade Commission, or FTC, also regulates the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

Our 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 current Good Manufacturing Processes under QSR; filing reports with the FDA, and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting certain device field removals and corrections to the FDA; and obtaining premarket notification 510(k) clearance for devices prior to marketing. Some devices known as "510(k)-exempt" devices can be marketed without prior marketing-clearance or approval from the FDA. In addition to the "general controls," some Class II medical devices are also subject to "special controls," including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510(k) clearance, most Class III devices are subject to PMA. As a company, we do not have prior experience in obtaining PMA.

The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices and product quality management. Such reviews and investigations may result in civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of our products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies; and could result in our incurring substantial unanticipated costs and the diversion of key personnel and management's attention from their regular duties, any of which may have a material and adverse effect on our business, financial condition and results of operations, and may result in greater and continuing governmental scrutiny of our business in the future.

Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, Open Payments requires us to annually report to 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. Failure to comply with these legal and regulatory requirements could impact our business, and we have spent 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.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our planned or future products and to manufacture, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations will change, and what the impact of such changes, if any, may be.

In addition, on April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the MDD. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i.e., without the need for adoption of EEA member state laws implementing them, in all EEA member states, and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and to ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation took effect on May 26, 2021. The new regulations, among other things:

- strengthens the rules on placing devices on the market and reinforces surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- sets up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union; and
- strengthens rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an effect on the way we conduct our business in the EEA.

Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

If we fail to comply with U.S. federal and state fraud and abuse and other healthcare laws and regulations, including those relating to kickbacks and false claims for reimbursement, we could face substantial penalties and our business operations and financial condition could be adversely affected.

Healthcare providers and third-party payors play a primary role in the distribution, recommendation, ordering and purchasing of any medical device for which we have obtained or will obtain marketing clearance or approval. Through our arrangements with principal investigators, healthcare professionals and customers, we are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our marketed medical devices. We have a compliance program, code of business conduct and ethics and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations.

In the United States, we are subject to various state and federal anti-fraud and abuse laws, including, without limitation, the federal healthcare Anti-Kickback Statute and federal civil False Claims Act, federal data privacy and security laws and federal transparency laws related to payments and/or other transfers of value made to physicians and other healthcare professionals and teaching hospitals. There are similar laws in other countries. Our relationships and our distributors' relationships with physicians, other health care professionals and hospitals are subject to scrutiny under these laws.

Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order or recommendation of items or services for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. In addition, the government may assert that a claim, including items or services resulting from a violation of the Anti-Kickback Statute, constitutes a false or fraudulent claim for purposes of the federal civil False

Claims Act. The Anti-Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the Anti-Kickback Statute; however, those exceptions and safe harbors are drawn narrowly, and there may be limited or no exception or safe harbor for many common business activities such as reimbursement support programs, educational and research grants or charitable donations. Practices that involve remuneration to those who prescribe, purchase or recommend medical devices, including discounts, providing items or services for free or engaging such individuals as consultants, advisors or speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor and would be subject to a facts and circumstances analysis to determine compliance with the Anti-Kickback Statute. Our practices, such as trial periods or purchase of certain components of our mapping systems from customers, may not in all cases meet all of the criteria for statutory exception or regulatory safe harbor protection from anti-kickback liability. CMS issued a final rule effective January 19, 2021 that created new safe harbors for, among other things, certain value-based arrangements and patient engagement tools that modified and clarified the scope of existing safe harbors for warranties and personal service agreements.The impact of the new safe harbor regulations on our operations is not yet clear;

- federal civil and criminal false claims laws, including the federal civil False Claims Act, and the Civil Monetary Penalties Laws, which prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Actions under the federal civil False Claims Act may be brought by the government or as a qui tam action by a private individual in the name of the government. These individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial financial settlements with the federal government under the federal civil False Claims Act for a variety of alleged improper activities, including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non-reimbursable uses and interactions with prescribers and other customers, including those that may have affected their billing or coding practices and submission of claims to the federal government. Federal civil False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory monetary penalties for each false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and medical device companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings;
- HIPAA, which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the HITECH Act, and their implementing regulations, also impose obligations including mandatory contractual terms on covered entities subject to the rule such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates and covered subcontractors that perform certain services for them or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We believe we are not a covered entity or typically a business associate for purposes of HIPAA;
- the federal Physician Payments Sunshine Act, also known as Open Payments, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions, to the CMS information related to payments or other "transfers of value" made to physicians, as defined to include doctors, dentists, optometrists, podiatrists and chiropractors and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers are required to report information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse-midwives; and

- analogous state and foreign law equivalents of each of the above federal laws such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor including commercial insurers; state laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or to otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state beneficiary inducement laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. The Bipartisan Budget Act of 2018, or BBA, increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have continued regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient support programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, federal civil False Claims Act and HIPAA's healthcare fraud and privacy provisions.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including certain sales and marketing practices, and financial arrangements with physicians, other healthcare providers and other customers, could be subject to challenge under one or more such laws. If an arrangement were deemed to violate the Anti-Kickback Statute, it may also subject us to violations under other fraud and abuse laws such as the federal civil False Claims Act and the Civil Monetary Penalties Laws. Moreover, such arrangements could be found to violate comparable state fraud and abuse laws.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If we or our employees are found to have violated any of the above laws, we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Companies settling federal civil False Claims Act, Anti-Kickback Statute or the Civil Monetary Penalties Laws cases also may be required to enter into a Corporate Integrity Agreement with the OIG in order to avoid exclusion from participation (i.e., loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs on companies to ensure compliance. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses and could divert our management's attention from the operation of our business, and may have a material adverse effect on our business, financial condition and results of operations.

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

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of 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. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition and results of operations.

For example, in the United States in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges and the expansion of the Medicaid program. Implementation of the Affordable Care Act will impact existing government healthcare programs and will result in the development of new programs.

There have been executive challenges to certain aspects of the Affordable Care Act. For example, President Trump signed executive orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress

has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. Legislation enacted in 2017, informally known as the Tax Cuts and Jobs Act, or TCJA, included a provision that repealed the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Further, the BBA, among other things, amended the Affordable Care Act to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the TCJA. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the Affordable Care Act. On June 17, 2021, the U.S. Supreme Court dismissed the judicial challenge to the Affordable Care Act on procedural grounds without specifically ruling on the constitutionality of the Affordable Care Act. Thus, the Affordable Care Act will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, reexamining policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. Further, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 ("IRA 2022") which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA 2022 also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law which, among other things, includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2031 unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 up to 4% in the final fiscal year of this sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, reduced Medicare payments to several providers including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We cannot assure you that the Affordable Care Act as currently enacted or as amended in the future will not harm our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

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. While some of these measures may require additional authorization to become effective, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control product costs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs.

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

Various new healthcare reform proposals are emerging at the federal and state level. It is also possible that additional governmental action will be taken to address the COVID-19 pandemic. 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.

If we fail to comply with the FDA's QSR, or FDA or EU requirements that pertain to clinical trials or investigations, the FDA or the competent EU authority could take various enforcement actions including halting our manufacturing operations, and our business would suffer.

In the United States, as a manufacturer of a medical device, we are required to demonstrate and maintain compliance with the FDA's QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of medical devices. The FDA enforces the QSR through periodic inspections and unannounced "for cause" inspections.

We are subject to periodic FDA inspections to determine compliance with QSR and pursuant to the Bioresearch Monitoring Program, which may in the future result in the FDA issuing Form 483s, including during the conduct of clinical trials. Outside the United States, our products and operations are also often required to comply with standards set by industrial standards bodies such as the International Organization for Standardization. Foreign regulatory bodies may evaluate our products or the testing that our products undergo against these standards. The specific standards, types of evaluation and scope of review differ among foreign regulatory bodies. Our failure to comply with FDA or local requirements that pertain to clinical trials/investigations, including GCP requirements and the QSR (in the United States), or failure to take satisfactory and prompt corrective action in response to an adverse inspection, could result in enforcement actions including a warning letter, adverse publicity, a shutdown of or restrictions on our manufacturing operations, delays in approving or clearing our products, refusal to permit the import or export of our product, prohibition on sales of our product, a recall or seizure of our products, fines, injunctions, civil or criminal penalties or other sanctions, any of which could cause our business and operating results to suffer.

Our global operations expose us to numerous and sometimes conflicting legal and regulatory requirements, and violation of these requirements could harm our business.

We are subject to numerous and sometimes conflicting legal regimes in the countries in which we operate, including on matters as diverse as health and safety standards, marketing and promotional activities, anti-corruption, import/export controls, content requirements, trade restrictions, tariffs, taxation, sanctions, immigration, internal and disclosure control obligations, securities regulation, anti-competition, data privacy and labor relations. This includes in emerging markets where legal systems may be less developed or familiar to us. We strive to abide by and maintain compliance with these laws and regulations. Compliance with diverse legal requirements is costly, time-consuming and requires significant resources. Violations of one or more of these regulations in the conduct of our business could result in significant fines, criminal sanctions against us or our officers, prohibitions on doing business and damage to our reputation. Violations of these regulations in connection with the performance of our obligations to our customers also could result in liability for significant monetary damages, fines and/or criminal prosecution, unfavorable publicity and other reputational damage, restrictions on our ability to process information and the allegation by our customers or distributors that we have not performed our contractual obligations. Due to the varying degrees of development of the legal systems of the countries in which we operate, local laws might be insufficient to protect our rights.

Our international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, products and solutions, pricing, reimbursement and marketing of our products and solutions, as well as by inter-governmental disputes. Any of these changes could adversely affect our business. The imposition of new laws or regulations including potential trade barriers may increase our operating costs, impose restrictions on our operations or require us to spend additional funds to gain compliance with the new rules, if possible, which could have an adverse impact on our financial condition and results of operations.

Material modifications to our products may require new 510(k) clearances, new CE Marks or other premarket approvals or may require us to recall or cease marketing our products and services until clearances are obtained.

Material modifications to the intended use or technological characteristics of any of our products will require new 510(k) clearances, new premarket approvals or new CE Mark grants, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to

initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA cleared device or service that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a new premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our products in a timely fashion or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

We have made modifications to our products in the past that we believe do not require additional clearances or approvals, and we may make additional modifications in the future. If the FDA or an EU Notified Body disagrees and requires new clearances or approvals for any of these modifications, we may be required to recall and to stop selling or marketing our products as modified, which could harm our operating results and require us to redesign our products or services. In these circumstances, we may be subject to significant enforcement actions.

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

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

If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

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 MDR regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under FDA 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 and impose sanctions 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, would 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.

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

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

incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs including legal fees and the diversion of the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition and results of operations.

Failure to comply with anti-bribery, anti-corruption and anti-money laundering laws including the FCPA, as well as export control laws, customs laws, sanctions laws and other laws governing our operations, could result in civil or criminal penalties, other remedial measures and legal expenses.

As we grow our international presence, we are increasingly exposed to anti-corruption, trade and economic sanctions and other restrictions imposed by the United States, the European Union and other governments and organizations. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. In addition, the U.K. Bribery Act 2010 prohibits both domestic and international bribery as well as bribery across both private and public sectors. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. Violations of the FCPA, U.K. Bribery Act 2010 and anti-corruption laws could result in fines, criminal sanctions against us, our officers or our employees, and prohibitions on the conduct of our business. Violations would also negatively affect our business and reputation, financial condition and results of operations.

In addition, our solutions may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our solutions, or our failure to obtain any required import or export authorization for our solutions when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our solutions may create delays in the introduction of our solutions in international markets or, in some cases, prevent the export of our solutions 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, penalties could be imposed including fines and/or 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 products targeted by such regulations, could result in decreased use of our solutions by, or in our decreased ability to export our solutions to, existing or potential customers with international operations. Any decreased use of our solutions or limitation on our ability to export or sell access to our solutions would likely adversely affect our business.

We have implemented policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, the U.K. Bribery Act 2010, export control and economic sanctions laws and other anti-corruption, anti-money-laundering and anti-terrorism laws and regulations. We cannot assure you, however, that our policies and procedures are or will be sufficient or that directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in prohibited conduct for which we may be held responsible. Violations of the FCPA, the U.K. Bribery Act 2010, export control and economic sanctions laws or other anti-corruption, anti-money laundering and anti-terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations.

Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject us to significant liability.

Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal,

remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive, and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future, or have not occurred in the past, as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and results of operations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection or freedom to operate for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any products we may develop, and our technology, may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our products and technology we develop.

We seek to protect our position by in-licensing intellectual property relating to our products and filing patent applications in the United States and abroad related to our technologies and products that are important to our business. We also rely on a combination of contractual provisions, confidentiality procedures and copyright, trademark, trade secret and other intellectual property rights to protect the proprietary aspects of our brands, technologies and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success will depend, in part, on obtaining and maintaining patents, preserving our trade secrets, maintaining the security of our data and know-how and obtaining other intellectual property rights.

We may not be able to obtain and maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage. For example, our trade secrets, data and know-how could be subject to unauthorized use, misappropriation or disclosure to unauthorized parties despite our efforts to enter into confidentiality agreements with our employees, consultants, contractors, clients and other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. In addition, 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, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our intellectual property at all. Despite our efforts to protect our intellectual property, unauthorized parties may be able to obtain and use information that we regard as proprietary. 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, consultants, contractors, collaborators, vendors and other third parties, any of whom may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States 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 our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. Changes in either the patent laws or their interpretation in the United States 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 owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors 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. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from

competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged, narrowed or invalidated by third parties. Additionally, our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Third parties may also have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable or not infringed, in which case our competitors and other third parties may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Given that patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

In addition, given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Our other intellectual property including our trademarks could also be challenged, invalidated, infringed and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks, in which case we could be forced to re-brand our products, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands and suffer other competitive harm. Third parties may also adopt trademarks similar to ours which could harm our brand identity and lead to market confusion.

We may in the future also be subject to claims by our former employees, consultants or contractors asserting an ownership right in our patents or patent applications as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants, contractors and any other partners or collaborators who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

Failure to obtain and maintain patents, trademarks and other intellectual property rights necessary to our business, and failure to protect, monitor and control the use of our intellectual property rights, could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our patents, trademarks, data, technology and other intellectual property, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, this could arise if the research resulting in certain of our owned or in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture

products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

Moreover, a portion of our intellectual property has been acquired from one or more third parties. While we have conducted diligence with respect to such acquisitions, and because we did not participate in the development or prosecution of much of the acquired intellectual property, we cannot guarantee that our diligence efforts identified and/or remedied all issues related to such intellectual property, including potential ownership errors, potential errors during prosecution of such intellectual property and potential encumbrances that could limit our ability to enforce such intellectual property rights

We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use product names. Because patent applications can take years to issue and are often afforded confidentiality for some period of time, there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third party's patent or trademark or of misappropriating a third party's trade secret, or any indemnification granted by such vendors may not be sufficient to address any liability and costs we incur as a result of such claims. Additionally, we may be obligated to indemnify our customers or business partners in connection with litigation and to obtain licenses or refund subscription fees, which could further exhaust our resources.

Even if we believe a third party's intellectual property claims are without merit, there is no assurance that a court would find in our favor, including on questions of infringement, validity, enforceability or priority of patents. The strength of our defenses will depend on the patents asserted, the interpretation of these patents and our ability to invalidate the asserted patents. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any products or technology we may develop and any other products or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Conversely, the patent owner need only prove infringement by a preponderance of the evidence, which is a lower burden of proof.

Further, if patents, trademarks or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from developing, manufacturing or selling our products, or result in obligations to pay license fees, damages, attorney fees and court costs, which could be significant. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties.

Although patent, trademark, trade secret and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. In addition, if any license we obtain is non-exclusive, we may not be able to prevent our competitors and other third parties from using the intellectual property or technology covered by such license to compete with us. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement. Any of these events could materially and adversely affect our business, financial condition and results of operations.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or USPTO, may be necessary to determine priority with respect to our patents, patent applications, trademarks or trademark applications. We may also become involved in other proceedings such as reexamination, *inter partes* review, derivation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a significant adverse impact on our business, financial condition and results of operations.

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual property, which we may not always be able to detect. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property or alleging that our intellectual property is invalid or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may raise challenges to the validity of certain of our owned or in-licensed patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). In any such lawsuit or other proceedings, a court or other administrative body may decide that a patent of ours is invalid or unenforceable, in whole or in part, may construe the patent's claims narrowly or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or products that we may develop. If our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Any of these events could materially and adversely affect our business, financial condition and results of operations.

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

Our rights to develop and commercialize our products are subject, in part, to the terms and conditions of licenses granted to us by others.

We rely, in part, upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our products and technology. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner

consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. This could materially and adversely affect our business, financial condition and results of operations.

The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. In spite of our best efforts, our licensors might also conclude that we have materially breached our license agreements and terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could materially and adversely affect our business, financial condition and results of operations.

We may not be successful in obtaining necessary rights to any products we may develop through acquisitions and in-licenses.

We may need to obtain additional licenses from our existing licensors or otherwise acquire or in-license any intellectual property rights from third parties that we identify as necessary for our products. It is possible that we may be unable to obtain any additional licenses or acquire such intellectual property rights at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. In that event, we may be required to expend significant time and resources to redesign our technology, products, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially and adversely affect our business, financial condition and results of operations.

If we are unable to protect the confidentiality of our other proprietary information, our business and competitive position may be harmed.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect and some courts are less willing or are unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, contractors, collaborators and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use, misappropriation or disclosure of such trade secrets, know-how or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. The laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may

be unable to prevent our proprietary technology from being exploited in the United States and abroad, which could affect our ability to expand in domestic and international markets or require costly efforts to protect our technology.

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information.

Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets, and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on issued patents and patent applications will be due to the USPTO and foreign patent agencies over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which could have a material adverse effect on our business, financial condition and results of operations.

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

A company may attempt to commercialize competing products utilizing our proprietary design, trademarks or trade names in foreign countries where we do not have any patents or patent applications and where legal recourse may be limited or unavailable. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting and defending patents or trademarks on our current and future products in all countries throughout the world would be prohibitively expensive. The requirements for patentability and trademarking may differ in certain countries, particularly developing countries. The laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from utilizing our inventions and trademarks in all countries outside the United States. Competitors may use our technologies or trademarks in jurisdictions where we have not obtained patent or trademark protection to develop or market their own products and, further, may export

otherwise infringing products to territories where we have patent and trademark protection but enforcement on infringing activities is inadequate. These products may compete with our products, and our patents, trademarks 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, trademarks and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our intellectual property 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 and trademarks at risk of being invalidated or interpreted narrowly 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. In addition, many countries, including India, China and certain countries in Europe, 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 those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

We may be subject to claims that we or our employees, consultants or contractors have wrongfully used, disclosed or otherwise misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors or claims asserting an ownership interest in intellectual property we regard as our own.

Many of our employees, consultants and contractors were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, used, disclosed or otherwise misappropriated intellectual property, including trade secrets or other proprietary information of their former employers or our competitors or potential competitors. Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own based on claims that our employees, consultants or contractors have breached an obligation to assign inventions to another employer, to a former employer or to another person or entity.

Litigation may be necessary to defend against such claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. For example, a court could prohibit us from using technologies or features that are essential to our products if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employer. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our products. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, financial condition and results of operations.

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

We or our licensors may be subject to claims that former consultants, contractors or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced

to bring claims against third parties or defend claims that they may bring against us to determine the ownership of what we regard as our intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights such as exclusive ownership of, or right to use, intellectual property that is important to our products. Any such events could have a material adverse effect on our business, financial condition and results of operations.

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

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a "first-to-invent" system to a "first-inventor-to-file" system, that allow third-party submission of prior art to the USPTO during patent prosecution and that set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings including post-grant review, *inter partes* review and derivation proceedings. Under a first-inventor-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular the first to file provisions, became effective in 2013. Accordingly, it is not clear what impact, if any, the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

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

We rely on trademarks, service marks, trade names and brand names to distinguish our products from the products of our competitors, and we have registered or applied to register these trademarks. Our registered or unregistered trademarks, service marks, trade names and brand names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. Additionally, we cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected.

Risks Related to Our Common Stock

The market price for our common stock has been volatile, it may decline regardless of our operating performance, and an active trading market may not be sustained in our common stock.

The market price of our common stock has been volatile, and it may fluctuate or decline substantially due to a number of factors such as those listed in the section "Risks Related to Our Business and Strategy" and the following:

- actual or anticipated changes or fluctuations in our operating results;
- the failure by our customers to obtain coverage at reimbursement levels that would be sufficient to support product sales to our customers;
- unanticipated serious safety concerns related to the use of our products;
- the financial projections we may provide to the public, and any changes in these projections or our failure to meet these projections;
- announcements by us or our competitors of new products, significant acquisitions, strategic partnerships, joint venture, capital commitments or other transactions;
- industry or financial analyst or investor reaction to our press releases, and other public announcements and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- future sales or expected future sales of our common stock;
- price and volume fluctuations in the overall stock market from time to time;
- changes in operating performance and stock market valuations of other medical device companies generally, or those in our industry in particular;
- our cash position;
- sales of shares of our common stock by us or our shareholders;
- failure of industry or financial analysts to maintain coverage of us, changes in financial estimates by any analysts who follow our company or our failure to meet these estimates or the expectations of investors;
- actual or anticipated developments in our business or our competitors' businesses or the competitive landscape generally;
- our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- accusations that we have violated a law or regulation;
- recalls of our products;
- developments or disputes concerning our intellectual property rights, our solutions or third-party proprietary rights;
- any delay in any regulatory filings for our planned or 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 or clearance of our planned and future products or to maintain regulatory approval or clearance for our existing products;
- changes in laws or regulations applicable to our products;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- breaches of, or failures relating to, security, privacy or data protection;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- any major changes in our management or our board of directors;
- changes in accounting principles;
- ineffectiveness of our internal controls;

- actual or anticipated changes in healthcare policy and reimbursement levels;
- general economic conditions including increased inflation and slow or negative growth of our markets; and
- other events or factors including those resulting from war, incidents of terrorism or responses to these events.

We also cannot assure you that a trading market for our common stock will be maintained. The stock markets, and securities of medical device companies in particular, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many medical device companies. Stock prices of many medical device companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock has been volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We and certain of our current officers have been named as defendants in two putative securities class action lawsuits filed by putative stockholders in the United States District Court for the Southern District of California on February 15, 2022 and March 23, 2022 (case numbers 22CV206 and 22CV0388). The plaintiffs allege that the defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 and Section 20(a) of the Exchange Act. The complaints allege that the defendants made false and misleading statements about our business, prospects and operations. The putative claims are based upon statements made in filings made by us with the SEC, press releases and on earnings calls between May 13, 2021 and November 11, 2021. The lawsuits seek, among other relief, a determination that the alleged claims may be asserted on a class-wide basis, unspecified compensatory damages, attorney's fees, other expenses and costs. On July 19, 2022, the court consolidated the two actions, appointed a lead plaintiff and appointed lead counsel for the proposed class. On September 16, 2022, the lead plaintiff filed a consolidated amended complaint. We thereafter filed a motion to dismiss. While we are defending the actions, due to the complex nature of the legal and factual issues involved in these matters, the outcome is not presently determinable. If these matters were to proceed beyond the pleading stage, we could be required to incur substantial costs and expenses to defend these matters and/or be required to pay substantial damages or settlement costs, which could materially adversely affect our business, financial condition and results of operations.

We may also be the target of this type of litigation in the future. Securities litigation against us, including the putative class actions described above, could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

The issuance of additional shares of our common stock in connection with our financings, acquisitions, investments, share incentive plans or otherwise will dilute all other stockholders.

Our amended and restated certificate of incorporation authorizes us to issue up to 260,000,000 shares of our common stock and up to 5,000,000 shares of preferred stock with such rights and preferences as included in our amended and restated certificate of incorporation. Subject to compliance with applicable rules and regulations, we may issue common stock or securities convertible into common stock from time to time in connection with our financing, acquisition, investment, equity incentive plans or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the market price of our common stock to decline.

We currently do not intend to declare dividends on our common stock in the foreseeable future and, as a result, your only opportunity to achieve a return on your investment is if the price of our common stock appreciates.

We currently do not expect to declare any dividends on our common stock in the foreseeable future. Instead, we anticipate that all of our earnings, if any, in the foreseeable future will be used to provide working capital to support our operations and to finance the growth and development of our business. Any determination to declare or pay dividends in the future will be at the discretion of our board of directors, subject to applicable laws and dependent upon a number of factors including our earnings, capital requirements and overall financial conditions. In addition, our ability to pay dividends on our common stock is currently limited by the covenants of our 2022 Credit Agreement and may be further restricted by the terms of any future debt or preferred securities. Accordingly, your only opportunity to achieve a return on your investment in our company may be if the market price of our common stock appreciates and you sell your shares at a profit. The market price for our common stock may never exceed, and may fall below, the price that you pay for such common stock.

We are an emerging growth company and a smaller reporting company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors.

We are an emerging growth company as defined in the JOBS Act and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including:

- no requirement for our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and Annual Report on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could be an emerging growth company until December 31, 2025. Our status as an emerging growth company will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have more than $1.235 billion in annual revenue;
- the last day of the fiscal year in which we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or
- December 31, 2025, the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering or IPO.

We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded emerging growth companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock 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 provision of the JOBS Act. As a result, we will not be subject to new or revised accounting standards at the same time as other public companies that are not emerging growth companies. Therefore, our consolidated financial statements may not be comparable to those of companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Our directors, executive officers and principal stockholders and their respective affiliates have substantial influence over us and could delay or prevent a change in corporate control; our principal stockholders may have interests that conflict with your interests as an investor in our common stock.

As of December 31, 2022, our directors, executive officers and holders of more than 5% of our common stock beneficially owned, as a group, approximately 22.0% of our common stock. As of December 31, 2022, funds affiliated with certain of our directors also held all of the 6,666 outstanding shares of our Series A Common Equivalent Preferred Stock, convertible into up to 6,665,841 shares of our common stock (which conversion is subject to certain beneficial ownership limitations set forth in our Certificate of Designation of Preferences, Rights and Limitations of the Series A Common Equivalent Preferred Stock). In addition, as of December 31, 2022, we had $36.8 million remaining in aggregate principal amount of outstanding long-term debt under our 2022 Credit Agreement with certain entities affiliated with Deerfield Management Company, of which one entity is a 5% holder of our common stock. Our principal stockholders, in the aggregate, will continue to have substantial influence over the outcome of matters submitted to our stockholders for approval including the election of directors and any matter

related to the merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, in the aggregate, will continue to have significant influence over the management and affairs of our company. Accordingly, this concentration of ownership may have the effect of:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

The interests of our principal stockholders may conflict with your interests as a stockholder. You should carefully consider these potential conflicts of interest before deciding whether to invest in shares of our common stock.

Provisions in our organizational documents and agreements with third parties could delay or prevent a change of control.

Certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws may have the effect of delaying or preventing a merger, acquisition, tender offer, takeover attempt or other change of control transaction that a stockholder might consider to be in its best interest, including attempts that might result in a premium over the market price of our common stock.

These provisions include the following:

- establish a classified board of directors so that not all members of our board of directors are elected at one time;
- authorize the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- permit the board of directors to establish the number of directors and fill any vacancies and newly-created directorships;
- provide that directors may only be removed for cause;
- require super-majority voting to amend some provisions in our certificate of incorporation and bylaws;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- provide that the board of directors is expressly authorized to make, alter or repeal our bylaws;
- restrict the forum for certain litigation against us to Delaware; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

These provisions could make it more difficult for a third party to acquire us, even if the third party's offer may be considered beneficial by many of our stockholders. As a result, our stockholders may be limited in their ability to obtain a premium for their shares.

In addition, our agreements with Biotronik contain provisions that may have the effect of delaying, deterring or preventing a change in control transaction involving us. Under the Biotronik License Agreement, if we undergo a change in control with certain competitors of the Biotronik Parties (as defined therein), our exclusive license to our AcQBlate Force Sensing Ablation System in the United States would convert to co-exclusive licenses with the Biotronik Parties, certain milestone payments would become immediately due and payable (regardless of achievement) and we would be required to pay up to $25.0 million to the Biotronik Parties (to the extent such amount has not already been paid as unit-based royalties). In addition, the non-distributing party of each Bi-Lateral Distribution Agreement has the right to terminate the agreement in the case of a change in control of either party, whereas the distributing party of each Bi-Lateral Distribution Agreement has the right in certain circumstances to terminate the agreement in the case of a change in control of the non-distributing party.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; 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 amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Our board of directors is authorized to issue and designate shares of our preferred stock in additional series without stockholder approval.

Our amended and restated certificate of incorporation authorizes our board of directors, without the approval of our stockholders, to issue shares of our preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, as shares of preferred stock in series, to establish from time to time the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of preferred stock may be senior to or on parity with our common stock, which may reduce its value.

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.

Our common stock is currently listed on the Nasdaq Global Select Market. In order to maintain this listing, we must satisfy minimum financial and other requirements. On both June 22, 2022 and November 2, 2022, we received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") notifying us that, for the last 30 consecutive business days, the closing bid price of our common stock has not been maintained at the minimum required closing bid price of at least $1.00 per share as required for continued listing on the Nasdaq Global Select Market pursuant to Listing Rule 5450(a)(1) (the "Minimum Bid Price Rule"). In both instances, on July 26, 2022 and January 10, 2023, respectively, we received a letter from Nasdaq notifying us that we had regained full compliance with the Minimum Bid Price Rule, and that the matter was closed. Our continued compliance with the Minimum Bid Price Rule is dependent on our share price and there can be no assurance that we will continue to satisfy Nasdaq's minimum financial and other requirements in future periods.

The perception among investors that we are at heightened risk of a deficiency under the Minimum Bid Price Rule and of subsequent delisting could negatively affect the market price of our securities and trading volume of our common stock. Additionally, any delisting determination, if made following the notification of a deficiency and expiration of any applicable

cure period, could seriously decrease or eliminate the value of an investment in our common stock. While an alternative listing on an over-the-counter exchange could maintain some degree of a market in our common stock, we could face substantial material adverse consequences including, but not limited to: limited availability for market quotations for our common stock; reduced liquidity with respect to our common stock; a determination that our common stock is a "penny stock" under SEC rules, subjecting brokers trading our common stock to more stringent rules on disclosure and the class of investors to which the broker may sell the common stock; and limited news and analyst coverage.

General Risk Factors

Our quarterly operating results fluctuate and may fall short of prior periods, our projections or the expectations of securities analysts or investors, which could materially adversely affect our stock price.

Our operating results have fluctuated from quarter to quarter at points in the past, and they may do so in the future. Therefore, results of any one quarter are not a reliable indication of results to be expected for any other quarter or for any year. If we fail to increase our results over prior periods, to achieve our projected results or to meet the expectations of securities analysts or investors, our stock price may decline, and the decrease in the stock price may be disproportionate to the shortfall in our financial performance. Results may be affected by various factors including those described in these risk factors. We maintain a forecasting process that seeks to plan sales and align expenses. If we do not control costs or appropriately adjust costs to actual results, or if actual results differ significantly from our forecast, our financial performance could be materially adversely affected.

Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and investments and to timely pay key vendors and others.

Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and investments and to timely pay key vendors and others. For example, on March 10, 2023, Silicon Valley Bank (SVB), where we maintain certain accounts, was placed into receivership with the Federal Deposit Insurance Corporation (FDIC), which resulted in all funds held at SVB being temporarily inaccessible by SVB's customers. If other banks and financial institutions with whom we have banking relationships enter receivership or become insolvent in the future, we may be unable to access, and we may lose, some or all of our existing cash, cash equivalents and investments to the extent those funds are not insured or otherwise protected by the FDIC. In addition, in such circumstances we might not be able to timely pay key vendors and others. We regularly maintain cash balances that are not insured or are in excess of the FDIC's insurance limit. Any delay in our ability to access our cash, cash equivalents and investments (or the loss of some or all of such funds) or to timely pay key vendors and others could have a material adverse effect on our operations and cause us to need to seek additional capital sooner than planned.

Economic conditions may adversely affect our business.

Adverse worldwide economic market and geopolitical conditions including, but not limited to, recession, inflation, deflation, consumer credit activity, consumer debt levels, fuel and energy costs, interest rates, tax rates and policy, unemployment trends, the impact of natural disasters such as pandemics, civil disturbances, terrorist activities and acts of war, including the recent Russian invasion of Ukraine and those related to the COVID-19 pandemic, may negatively impact our business. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in their purchases and also in our receivable collections, and additional allowances may be required, which could adversely affect our business, financial condition and results of operations. Adverse worldwide economic conditions may also adversely impact our suppliers' ability to provide us with materials and components, which 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 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 and certain of our current officers have been named as defendants in two putative securities class action lawsuits filed by putative stockholders in the United States District Court for the Southern District of California on February 15, 2022 and March 23, 2022 (case numbers 22CV206 and 22CV0388). Plaintiffs allege that the defendants violated Section 10(b) of the Exchange Act and Rule 10b-5, and Section 20(a) of the Exchange Act. The complaints allege that the defendants made false and misleading statements about our business, prospects and operations. The putative claims are based upon statements made in filings made by us with the SEC, press releases and on earnings calls between May 13, 2021 and November 11, 2021. The lawsuits seek, among other relief, a

determination that the alleged claims may be asserted on a class-wide basis, unspecified compensatory damages, attorney's fees, other expenses and costs. On July 19, 2022, the court consolidated the two actions, appointed a lead plaintiff and appointed lead counsel for the proposed class. On September 16, 2022, the lead plaintiff filed a consolidated amended complaint. We thereafter filed a motion to dismiss. While we are defending the actions, due to the complex nature of the legal and factual issues involved in these class action matters, the outcome is not presently determinable. If these matters were to proceed beyond the pleading stage, we could be required to incur substantial costs and expenses to defend these matters and/or be required to pay substantial damages or settlement costs, which could materially adversely affect our business, financial condition and results of operations.

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.

If securities analysts do not publish research or reports about our business or if they downgrade our stock or our sector, our stock price and trading volume could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business or industry. We do not control these analysts. Furthermore, if one or more of the analysts who do cover us downgrade our stock or our industry or the stock of any of our competitors, or publish inaccurate or unfavorable research about our business or industry, the price of our stock could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline. In addition, if we fail to meet the expectations of any analysts that covers us, our stock price could decline.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

We are subject to the reporting and corporate governance requirements of the Exchange Act, the listing requirements of Nasdaq and other applicable securities rules and regulations, including the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an emerging growth company as defined in the JOBS Act. Among other things, the Exchange Act requires that we file annual, quarterly and current reports with respect to our business and results of operations and maintain effective disclosure controls and procedures and internal control over financial reporting. In order to improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business, financial condition, results of operations and prospects. Although we have already hired additional personnel to help comply with these requirements, we may need to further expand our legal and finance departments in the future, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expense and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies, regulatory authorities may initiate legal proceedings against us and our business and prospects may be harmed. As a result of disclosure of information in the filings required of a public company, our business and financial condition have become more visible, which may result in threatened or actual litigation including by competitors and other third parties. If such claims are successful, our business, financial condition, results of operations and prospects could be materially harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims and the time and resources necessary to resolve them could divert the resources of our management and materially harm our business, financial condition, results of operations and prospects.

Our status as a public company and these new rules and regulations make it more expensive for us to obtain director and officer liability insurance, which may require us to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our board of directors, particularly to serve on our audit committee and compensation committee.

In addition, as a result of our disclosure obligations as a public company, we have reduced strategic flexibility and are under pressure to focus on short-term results, which may materially and adversely affect our ability to achieve long-term profitability.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties.

As of December 31, 2022, we lease approximately 50,800 square feet of office space for our corporate headquarters and manufacturing facility located in Carlsbad, California under a noncancelable operating lease that expires on December 31, 2027, with the option to renew for a period of an additional five years upon the expiration date of this lease. We also lease approximately 3,900 square feet of office space in Brussels, Belgium under a noncancelable operating lease that expires on December 31, 2024, with the option to renew for a period of an additional three years upon the expiration date of this lease. We believe that these facilities are sufficient to meet our current and anticipated needs in the near term and that additional space can be obtained on commercially reasonable terms as needed.

Item 3. Legal Proceedings.

From time to time, we are involved in legal proceedings, including litigation arising from the normal course of our business activities. We have also received, and may from time to time receive, letters from third parties alleging patent infringement, violation of employment practices or trademark infringement, and we may in the future participate in litigation to defend ourselves. The results of any current or future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. Other than the matters listed below, we are not currently party to any pending legal proceedings that we believe would, individually or in the aggregate, have a material adverse effect on our financial condition, cash flows or results of operations.

We and certain of our current officers have been named as defendants in two putative securities class action lawsuits filed by putative stockholders in the United States District Court for the Southern District of California on February 15, 2022 and March 23, 2022 (case numbers 22CV206 and 22CV0388). Plaintiffs allege violations of Section 10(b) of the Exchange Act and Rule 10b-5, and Section 20(a) of the Exchange Act. The complaints allege that the defendants made false and misleading statements about our business, prospects and operations. The putative claims are based upon statements made in filings made by us with the SEC, press releases and on earnings calls between May 13, 2021 and November 11, 2021. The lawsuits seek, among other relief, a determination that the alleged claims may be asserted on a class-wide basis, unspecified compensatory damages, attorney's fees, other expenses and costs. On July 19, 2022, the court consolidated the two actions, appointed a lead plaintiff and appointed lead counsel for the proposed class. On September 16, 2022, the lead plaintiff filed a consolidated amended complaint. We thereafter filed a motion to dismiss. We are defending the actions.

Due to the complex nature of the legal and factual issues involved in these class action matters, the outcome is not presently determinable. If these matters were to proceed beyond the pleading stage, we could be required to incur substantial costs and expenses to defend these matters and/or be required to pay substantial damages or settlement costs, which could materially adversely affect our business, financial condition and results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Common Stock Market Prices and Dividends

Our common stock is listed on the Nasdaq Stock Market LLC (the "Nasdaq") and trades under the symbol "AFIB". Public trading of our stock began on August 6, 2020. Prior to that, there was no public market for our stock. The closing price of our common stock on the Nasdaq as of December 31, 2022 and 2021 was $1.15 and $3.41, respectively.

The approximate number of record holders of our common stock on March 20, 2023 was 72. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

Unregistered Sales of Equity Securities:

We had no sales of unregistered equity securities during the period covered by this report that were not previously reported in a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Stock Performance Graph

As a smaller reporting company as defined by Item 10 of Regulation S-K, we are not required to provide this information.

Dividend Policy

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our capital stock. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws and will depend on then existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Item 6. Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Overview

We are an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated. Despite several decades of effort by the incumbents in this field, the clinical and economic challenges associated with arrhythmia treatment continue to be a huge burden for patients, providers and payors. We are committed to advancing the field of electrophysiology with a unique array of products and technologies which will enable more physicians to treat more patients more effectively and efficiently. Through internal product development, acquisitions and global partnerships, we have established a global sales presence delivering a broad portfolio of highly differentiated electrophysiology products. Our goal is to provide our customers with a complete solution for catheter-based treatment of cardiac arrhythmias in each of our geographic markets.

Our product portfolio includes novel diagnostic and mapping catheters, ablation catheters, mapping and imaging consoles and accessories, as well as supporting algorithms and software programs. Our foundational and most highly differentiated product is our AcQMap imaging and mapping system. Our paradigm-shifting AcQMap System offers a novel approach to mapping the drivers and maintainers of arrhythmias with unmatched speed and precision. With the ability to rapidly and accurately identify ablation targets and to confirm both ablation success and procedural completion, we believe our AcQMap System addresses the primary unmet need in electrophysiology procedures today.

We were incorporated in the state of Delaware on March 25, 2011 and are headquartered in Carlsbad, California. Early versions of our AcQMap System and certain related accessory products have been used in the United States since May 2018 and Western Europe since July 2016 in a limited, pilot launch capacity, where our focus was on optimizing workflow and validating our value proposition. We fully commenced the launch of our commercial-grade console and software products in the first quarter of 2020. Critical to our launch and future market adoption are a series of strategic transactions, regulatory approvals, and clinical trial milestones including: ongoing development and expansion of our Bi-Lateral Distribution Agreements with Biotronik , FDA 510(k) clearance and CE Mark of our second-generation AcQMap console and SuperMap software suite; and the completion of enrollment in our US clinical study for the AcQBlate Force Sensing Ablation catheter and system.

On June 30, 2022, we completed the First Closing of the sale of our left-heart access portfolio to Medtronic as described further below. On November 3, 2022, we announced our achievement of the OEM Earnout Conditions (as defined in the Asset Purchase Agreement) set forth in the agreement. Further, on December 1, 2022, Medtronic qualified us as an original equipment manufacturer ("OEM") and accordingly, we will manufacture this product line exclusively for Medtronic for a period of up to four years until such time that Medtronic transfers the product to a dedicated manufacturing facility and becomes the manufacturer of record. Additionally, on December 21, 2022, we achieved a $17.0 million Transfer Earnout as set forth in the agreement.

We market our electrophysiology products worldwide to hospitals and electrophysiologists that treat patients with arrhythmias. We have strategically developed a direct selling presence in the United States and select markets in Western Europe where cardiac ablation is a standard of care and third-party reimbursement is well-established. In these markets, we install our AcQMap console and workstation with customer accounts and then sell our disposable products to those accounts for use with our system. In other international markets, we leverage our partnership with Biotronik to install our AcQMap console and workstation with customer accounts and then to sell our disposable products to those accounts. Once an AcQMap console and workstation is established in a customer account, our revenue from that account becomes predominantly recurring in nature and derived from the sale of our portfolio of disposable products used with our system. Our currently marketed disposable products include access sheaths, diagnostic and mapping catheters, ablation catheters and accessories. We plan to leverage the geographically concentrated nature of procedure volumes and the recurring nature of our sales to drive an increasingly efficient commercial model.

For the years ended December 31, 2022 and 2021, we generated revenue of $16.4 million and $17.3 million, respectively, of which 47% and 52%, respectively, was from customers located outside of the United States. Since our inception, we have generated significant losses. Our net loss was $39.6 million and $117.7 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022 and 2021, we had an accumulated deficit of $518.3 million and $478.7 million, respectively, and working capital of $98.0 million and $107.8 million, respectively.

Our sales organization will continue to focus on driving utilization and procedure growth in targeted geographic regions. Investments in research and development and clinical and regulatory affairs will have a focused scope on key product development initiatives. Additionally, we will continue to incur costs as a public company that we did not incur prior to our IPO or incurred prior to our IPO at lower rates, including increased costs for employee-related expenses, director and officer insurance premiums, audit and legal fees, investor relations fees, fees to members of our Board of Directors and expenses for compliance with public company reporting requirements under the Exchange Act and rules implemented by the SEC, as well as Nasdaq rules. Because of these and other factors, we expect to continue to incur net losses and negative cash flows from operations for at least the next couple years.

Restructuring

In 2022, we completed an organizational workforce reduction and implemented additional cost reduction measures to reduce our operating expenses and optimize our cash resources. The restructuring was the result of a detailed review of our strategic priorities, the external environment, and cost structure and is intended to sharpen our focus and strengthen our financial position. As part of the restructuring, we intend to prioritize maximizing console utilization and procedure volume growth in targeted geographic regions, as well as a more focused scope of product development initiatives.

Repricing

Effective July 25, 2022, and in accordance with the terms of the Acutus Medical, Inc. 2011 Equity Incentive Plan and the Acutus Medical, Inc. 2020 Equity Incentive Plan, we reduced the exercise price of outstanding options to purchase our common stock held by employees who were employed on July 25, 2022 (and who had not provided a notice of resignation prior to such date) to $1.34 per share, which was the closing price for our common stock on July 25, 2022.

Contingent Consideration Relating to Sale of Left-heart Access Portfolio

On June 30, 2022, we completed the first closing (the “First Closing”) in accordance with the Asset Purchase Agreement entered into on April 26, 2022 (the "Asset Purchase Agreement") with Medtronic, pursuant to which we agreed to sell to Medtronic certain transseptal access and sheath assets which make up our left-heart access portfolio (and which comprised the Rhythm Xience product line acquired as part of the Rhythm Xience Acquisition) (the "Products"). Pursuant to the Asset Purchase Agreement, Medtronic paid $50.0 million at the First Closing, of which $4.0 million was paid into an indemnity escrow account for a period of 18 months following the First Closing to secure our indemnification obligations under the Asset Purchase Agreement, which we recorded as restricted cash on our consolidated balance sheets as of December 31, 2022.

The Company is also eligible to receive the following contingent cash consideration pursuant to the Asset Purchase Agreement:

(i) $20.0 million upon its completion, to the reasonable satisfaction of Medtronic, of certain conditions set forth in the Asset Purchase Agreement relating to the Company becoming a qualified supplier of Medtronic for the Products, including demonstration of ISO 14971:2019 compliance, completion of certain test method validations and compliance with certain other reporting requirements (the "OEM Earnout");

(ii) $17.0 million upon the earlier of (A) the Second Closing (as defined below) or (B) the Company’s initial submission for CE Mark certification of the Products under the European Union Medical Devices Regulation to the reasonable satisfaction of a third-party regulatory consultant, subject to certain other conditions as set forth in the Asset Purchase Agreement (the "Transfer Earnout"); and

(iii) amounts equal to 100%, 75%, 50% and 50%, respectively, of quarterly Net Sales (as defined in the Asset Purchase Agreement) from sales of the Products achieved by Medtronic over each year over four years beginning on the first full quarter after Medtronic’s first commercial sale of a Product and achievement of the OEM Earnout.

The $20.0 million OEM Earnout was achieved on October 31, 2022 and payment was received in November 2022, of which $1.6 million is held in escrow and recorded as restricted cash on the consolidated balance sheets. The $17.0 million Transfer Earnout was achieved as of December 31, 2022 and recorded as a receivable on the consolidated balance sheets. Payment was received from Medtronic on January 14, 2023. No amounts under item (iii) were earned or received as of December 31, 2022.

With the achievement of the OEM Earnout Conditions (as defined in the Asset Purchase Agreement) and upon notice from Medtronic, Medtronic became the Company's exclusive distributor of the Products under the Distribution Agreement in connection with the Asset Purchase Agreement.

A second closing would occur on a date determined by Medtronic, but no later than the fourth anniversary of the First Closing, subject to the satisfaction of customary closing conditions (the "Second Closing"). Upon the Second Closing, Medtronic will acquire certain additional assets relating to the Products, primarily supplier agreements and permits and design and specification files required for Medtronic to become the manufacturer of record of the Products.

Key Business Metrics

We regularly review a number of operating and financial metrics, including the following key business metrics, to evaluate our business, measure our performance, identify trends affecting our business, formulate financial projections and make strategic decisions. We believe that the following metrics are representative of our current business. However, we anticipate these metrics may change or may be substituted for additional or different metrics as our business grows and as we introduce new products.

Installed Base

Our mapping and therapy platform is enabled by our AcQMap console that we install at customer sites globally. We believe our installed base is a key driver of our business model, enabling utilization and disposable pull-through. We define our installed base as the cumulative number of AcQMap consoles and workstations placed into service at customer sites. Beginning in late 2019, we began to install our second-generation AcQMap console and workstation with customers under evaluation contracts. Under these evaluation contracts, we place our AcQMap console and workstation with customers for no upfront fee to the customer during the applicable evaluation period and seek to reach agreement with the customer for the purchase of the console and workstation in the form of a contractual commitment to purchase a minimum amount of our disposable products or a cash purchase. Our total installed base as of December 31, 2022 and 2021 is set forth in the table below:

	Year Ended December 31,	
	2022	2021
U.S.	32	42
Outside the U.S.	44	35
Total Acutus net system placements	76	77

Procedure Volumes

Once an AcQMap console and workstation is established in a customer account, our revenue from that account becomes predominantly recurring in nature and derived from the sale of our portfolio of disposable products used with our system. Procedure volumes and the utilization of our AcQMap console will be the primary driver of our business over the long-term.

Our total procedure volumes as of December 31, 2022 and 2021 is set forth in the table below:

	Year Ended December 31,	
	2022	2021
Procedure volumes	1,861	1,570

Factors Affecting Our Performance

There are a number of factors that have impacted, and we believe will continue to impact, or that we expect to impact, our results of operations and growth.

Market Acceptance.

The growth of our business will depend substantially on our ability to increase our installed base. Once an AcQMap console and workstation is established in a customer account, our revenue from that account becomes predominantly recurring in nature and derived from the sale of our portfolio of disposable products used with our system.

Our ability to increase our installed base will depend on our ability to gain broader acceptance of our AcQMap System by continuing to make physicians and other hospital staff aware of the benefits of the AcQMap System, thereby generating increased demand for system installations and the frequency of use of our disposable products. Although we are attempting to increase our installed base through our established relationships and focused sales efforts, we cannot provide assurance that our efforts will be successful.

Commercial Organization Size and Effectiveness

As of December 31, 2022, our commercial organization consisted of 53 individuals with substantial applicable medical device, sales and clinical experience, which is comprised of sales representatives, sales managers, mappers and marketing personnel. We intend to continue to make significant investments in our commercial organization in training, developing, continuing education, and targeted increases in sales representatives, sales managers and mappers to help facilitate further adoption of our products among existing and new customer accounts. The effectiveness with which we manage our commercial organization and the speed at which newly hired personnel contribute to business performance can impact our revenue growth or our costs incurred in anticipation of such growth.

Strategic Partnerships and Acquisitions

We have in the past, and may in the future, enter into strategic partnerships and acquire complementary businesses, products or technologies. For example, we acquired our AcQBlate Force Sensing Ablation System from Biotronik in July 2019 and entered into our Global Alliance for Electrophysiology with Biotronik in May 2020. In addition, as part of the Asset Purchase Agreement with Medtronic, we will be their OEM supplier of the Products for up to the next four years.

Our strategic partnerships and acquisitions have helped us establish a global sales presence delivering a broad portfolio of highly differentiated electrophysiology products. Our ability to grow our revenue will depend substantially on our ability to leverage our strategic partnerships and acquisitions to achieve distribution at a global scale, broaden our product portfolio and enable and accelerate global connectivity.

Continued Investment in Innovation

Our business strategy relies significantly on innovation to develop and introduce new products and to differentiate our products from our competitors. In 2022, research and development continued to provide both new products as well as generational improvements to the current product lines through the release of multiple versions of software and disposable products including significant improvements to our mapping system hardware. Additionally, research efforts evolved into development projects for advanced therapies, improved navigational accuracy and enhanced mapping capabilities.

We expect our investments in research and development to decrease as we have a focused scope on key product development initiatives. We plan our research and development expenditures with internal initiatives, as well as potentially licensing or acquiring technology from third parties. We also expect expenditures associated with our manufacturing organization to grow over time as production volume increases and we bring new products to market. Our internal and external investments will be focused on initiatives that we believe will offer the greatest opportunity for growth and profitability. With a significant investment in research and development, a strong focus on innovation and a well-managed innovation process, we believe we can continue to innovate and grow.

Introducing additional, innovative products is also expected to help support our existing installed base and help drive demand for additional installations of our system. If, however, our future innovations are not successful in meeting customers' needs or prove to be too costly relative to their perceived benefit, we may not be successful. Moreover, as cost of products sold, operating expenses and capital expenditures fluctuate over time, we may experience short-term, negative impacts to our results of operations and cash flows, but we are undertaking such investments in the belief that they will contribute to long-term growth.

Product and Geographic Mix and Timing

Our financial results, including our gross margins, may fluctuate from period to period due to a variety of factors, including: average selling prices; production volumes; the cost of direct materials; the timing of customer orders or medical procedures and the timing and number of system installations; the number of available selling days in a particular period, which can be impacted by a number of factors such as holidays or days of severe inclement weather in a particular geography; the mix of products sold and the geographic mix of where products are sold; the level of reimbursement available for our products; discounting practices; manufacturing costs; product yields; headcount and cost-reduction strategies. For example, gross margins on the sale of our products by our direct selling organization in the United States and Western Europe are higher than gross margins on the sale of our products by Biotronik in other parts of the world. Moreover, gross margins on the sale of our proprietary products are generally higher than gross margins on the sale of products we source through our strategic partnerships with third parties.

Future selling prices and gross margins for our products may fluctuate due to a variety of other factors, including the introduction by others of competing products or the attempted integration by third parties of capabilities similar to ours into their existing products. We aim to mitigate downward pressure on our selling prices by increasing the value proposition offered by our products through innovation. While we have not yet experienced significant seasonality in our results, it is not uncommon in our industry to experience seasonally weaker revenue during the summer months and end-of-year holiday season.

Regulatory Approvals / Clearances and Timing and Efficiency of New Product Introductions

In May 2022, we completed enrollment in our U.S. IDE study for the AcQBlate Force Sensing Ablation System for use in right atrial flutters. We filed for PMA in the second half of 2022. In December 2022, we announced receipt of MDR CE mark of the AcQMap 3D imaging and mapping catheter. In July 2022, we announced approval of the AcQMap High Resolution Imaging and Mapping System and the AcQMap 3D Imaging and Mapping Catheter in Japan.

In May 2021, we received FDA approval to initialize an atrial fibrillation IDE trial in the United States with the AcQBlate Force Sensing Ablation System. Additionally, we received CE Mark approval for a broad suite of electrophysiology products that includes the next-generation AcQGuide MAX and AcQGuide VUE large bore delivery sheaths and the next-generation AcQMap mapping catheter in May 2021. Further, we received CE Mark in December 2020 in Europe for the use of our AcQBlate Force Sensing Ablation System and are seeking FDA PMA for this system in the United States, as well as regulatory clearance or approval of our other pipeline products in the United States and in international markets.

Our ability to grow our revenue will depend on our obtaining necessary regulatory approvals or clearances for our products. In addition, as we introduce new products, we expect to build our inventory of components and finished goods in advance of sales, which may cause quarterly and annual fluctuations in our results of operations.

Competition

Our industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. Our most significant competitors are large, well-capitalized companies. We must continue to successfully compete considering our competitors' existing and future products and related pricing and their resources to successfully market to the physicians who could use our products. Publication of clinical results by us, our competitors and other third parties can also have a significant influence on whether, and the degree to which, we are able to gain market share and increase utilization of our products.

COVID-19 Pandemic

The markets we serve could see continued impacts from COVID-19 for the foreseeable future, and the emergence of new variants of COVID-19 creates significant uncertainty as to how long COVID-19 will continue to impact our business. The magnitude of the impact of the COVID-19 pandemic on our productivity, results of operations and financial position, and its disruption to our business and our clinical programs and timelines, will depend, in part, on the length and severity of outbreaks, restrictions and other measures designed to prevent the spread of COVID-19 and on our ability to conduct business in the ordinary course.

Global Supply Chain Disruption

Our costs are subject to fluctuations, particularly due to change in the price of raw and packing materials and the cost of labor, transportation and operating supplies. In addition, it is possible that we may be negatively affected from unexpected delays resulting from global supply-chain disruptions and other adverse global conditions, including supply shortages of key electronic components and other raw materials, vendor disruptions related to COVID-19, extended lead times for raw material procurement, or geopolitical factors that could restrict the manufacturing and delivery of raw materials or other components.

Variability in Operating Results

In addition, we may experience meaningful variability in our yearly revenue and gross profit/loss as a result of a number of factors, including, but not limited to: inventory write-offs and write-downs; costs, benefits and timing of new product introductions; the availability and cost of components and raw materials; fluctuations in foreign currency exchange rates, inflation rates and interest rates; and our ability to realize the benefits of our recent corporate restructuring. Additionally, we may experience quarters in which our costs and operating expenses, in particular our research and development expenses, fluctuate depending on the stage and timing of product development.

While certain of these factors may present significant opportunities for us, they also pose significant risks and challenges that we must address. See the section titled "Risk Factors" for more information.

Components of Results of Operations

Revenue

Our revenue consists primarily of revenue from: (i) the sale of our disposable products; (ii) the sale, rental or leasing of systems; and (iii) service/other revenue. In the United States and select markets in Western Europe where we have developed a direct selling presence, we install our AcQMap console and workstation with our customer accounts and then generate revenue from the sale of our disposable products to these accounts for use with our system. We also generate revenue from the direct sale of our AcQMap console into hospital accounts as well as revenue through long-term customer commitments on disposable purchases. In addition, we generate revenue under our Distribution Agreement with Medtronic, as Medtronic's exclusive OEM

supplier of the left-heart access products sold to Medtronic under the Asset Purchase Agreement. In other international markets, we leverage our partnership with Biotronik to install our AcQMap console and workstation with customer accounts and then generate revenue from Biotronik's sale of our disposable products to these accounts for use with our system. Our currently marketed disposable products include access sheaths, diagnostic and mapping catheters, ablation catheters and accessories.

For the years ended December 31, 2022 and 2021, approximately 47% and 52%, respectively, of our sales were sold outside of the United States. Additionally, for the years ended December 31, 2022 and 2021, approximately 21% and 27%, respectively, of our sales were denominated in currencies other than U.S. dollars, primarily in Euros and the British Pound Sterling. Our revenue is subject to fluctuation based on the foreign currency in which our products are sold. For the year ended December 31, 2022, changes in foreign currency rates negatively impacted sales growth compared to the prior year by an estimated $0.5 million, and adversely impacted growth by 3%.

Costs and Operating Expenses

Cost of Products Sold

Cost of products sold consist primarily of raw materials, direct labor, manufacturing overhead associated with the production and sale of our disposable products and, to a more limited extent, production and depreciation of our AcQMap console and workstation that we install with our customer accounts. We depreciate equipment over a three-year period. Cost of products sold also includes expenditures for warranty, field service, freight, royalties and inventory reserve provisions. We expect cost of products sold to increase in absolute dollars in future periods as our revenue increases.

Research and Development Expenses

Research and development expenses consist primarily of salaries and employee-related costs (including stock-based compensation) for personnel directly engaged in research and development activities, clinical trial expenses, equipment costs, materials costs, allocated rent and facilities costs and depreciation.

Research and development expenses related to possible future products are expensed as incurred. We also accrue and expense costs for activities associated with clinical trials performed by third parties as incurred. All other costs relative to setting up clinical trial sites are expensed as incurred. Clinical trial site costs related to patient enrollment are accrued as patients are entered into the trials.

To align resources with our current strategic direction, we implemented an organizational workforce reduction and other cost reduction measures. Due to this strategic realignment, we expect our research and development expenses to moderate in absolute dollars in the upcoming years.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and employee-related costs (including stock-based compensation) for personnel in sales, executive, finance and other administrative functions, allocated rent and facilities costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services, marketing costs and insurance costs.

To align resources with our current strategic direction, we implemented an organizational workforce reduction and are implementing additional cost reduction measures. Due to this on-going strategic realignment, we expect our selling, general and administrative expenses to decrease in absolute dollars in the upcoming years.

Goodwill Impairment

During the year ended December 31, 2022, our management assessed qualitative factors and determined it was more likely than not that the fair value of the goodwill was less than its carrying amount. In performing a quantitative impairment test, we determined that goodwill was fully impaired. Consequently, a one-time expense was recorded to goodwill impairment reflecting the elimination of goodwill from the consolidated balance sheets. Refer to *Note 9 - Goodwill and Intangible Assets* for additional details.

Restructuring Expenses

In 2022 we undertook an organizational workforce reduction and have implemented additional cost reduction measures. Our restructuring expenses consist of severance expenses related to employees affected by the organizational workforce reduction.

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration relates to our June 2019 acquisition of Rhythm Xience. The acquisition included potential earn-out considerations based on the achievement of certain regulatory and revenue milestones. The value of such contingencies is estimated and recorded on the consolidated balance sheets and are adjusted to fair value each period with increases and decreases of in the estimated fair value of the contingent consideration earn-out recognized in the statement of operations and comprehensive loss.

Gain on Sale of Business

Gain on sale of business consists of the value of consideration received by us in excess of the book value of assets transferred to the buyer and net of direct selling costs. In 2022, we completed the sale of certain assets to Medtronic whereby the value received was in excess of the book value of the assets transferred, resulting in a recognized gain of $79.5 million.

Gain on the sale of business also consists of consideration contingent upon the satisfaction of certain contractual conditions. Associated with the sale and included in the above recognized gain, in the current year we achieved both an OEM Earnout entitling us to $20.0 million in contingent consideration and a Transfer Earnout entitling us to $17.0 million. Additionally, over the next four years, we expect to receive a percentage of Medtronic's quarterly commercial sales of our product related to the sale of business, ranging from 100% in the first year to 50% in the fourth year. Refer to *Note 4 - Sale of Business* for more information.

Other Income (Expense)

Loss on Debt Extinguishment

Loss on debt extinguishment represents the one-time loss recognized upon the June 30, 2022 extinguishment of our 2019 Credit Agreement. Refer to *Note 11 - Debt* for more information.

Change in Fair Value of Warrant Liability

Warrants meeting specific conditions are required to be recorded as liabilities at fair value on the consolidated balance sheets. We issued warrants associated with various recorded transactions, some of which meet these specific conditions. The change in fair value of warrant liability recorded on our consolidated results of operations and comprehensive loss reflect changes in the fair value of these recorded liabilities.

Under the terms of our 2022 Credit Agreement effective June 30, 2022, we issued warrants meeting the conditions for treatment as a liability. The recorded fair value of the liability associated with such warrants is adjusted each reporting period with an entry to the consolidated statements of operations and comprehensive loss. Refer to *Note 14 - Warrants* for more information.

Interest Income

Interest income consists primarily of interest earned on our cash, cash equivalents and marketable securities.

Interest Expense

Interest expense for the six months ended June 30, 2022 primarily relates to interest paid on our 2019 Credit Agreement, which was fully repaid on June 30, 2022. Interest expense for the six months ended December 31, 2022 primarily relates to our 2022 Credit Agreement. Refer to *Note 11 - Debt* for more information.

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

The results of operations presented below should be reviewed in conjunction with our consolidated financial statements and related notes. The following table sets forth our results of operations for the years ended December 31, 2022 and 2021 (dollars in thousands):

	Year Ended December 31,		Change	
	2022	2021	$	%
Revenue	$ 16,363	$ 17,263	$ (900)	(5)%
Costs and operating expenses (income):				
Costs of products sold	31,910	32,925	(1,015)	(3)%
Research and development	28,153	36,683	(8,530)	(23)%
Selling, general and administrative	47,654	63,523	(15,869)	(25)%
Goodwill impairment	12,026	—	12,026	100 %
Restructuring	2,371	—	2,371	100 %
Change in fair value of contingent consideration	1,053	(3,746)	4,799	*
Gain on sale of business	(79,465)	—	(79,465)	100 %
Total costs and operating expenses	43,702	129,385	(85,683)	(66)%
Loss from operations	(27,339)	(112,122)	84,783	(76)%
Other income (expense):				
Loss on debt extinguishment	(7,947)	—	(7,947)	100 %
Change in fair value of warrant liability	33	—	33	*
Interest income	868	116	752	648 %
Interest expense	(5,149)	(5,677)	528	(9)%
Total other expense, net	(12,195)	(5,561)	(6,634)	119 %
Loss before income taxes	(39,534)	(117,683)	78,149	(66)%
Income tax expense	82	—	82	*
Net loss	(39,616)	(117,683)	78,067	(66)%
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities	39	(37)	76	*
Foreign currency translation adjustment	(691)	(460)	(231)	50 %
Comprehensive loss	**$ (40,268)**	**$ (118,180)**	**$ 77,912**	(66)%

* Not meaningful

Loss from Operations

Our operations resulted in a loss, however our loss from operations improved (decreased) by $84.8 million from a loss of $117.7 million for the year ended December 31, 2021 to a loss of $39.6 million in the year ended December 31, 2022. This improvement was primarily the result of the recognized gain on the sale of business assets to Medtronic of $79.5 million and cost savings from restructuring, offset by a $12.0 million write-off of goodwill, and supplemented with a mix of other factors discussed below.

Revenue

Our revenue was $16.4 million for the year ended December 31, 2022, compared to $17.3 million for the year ended December 31, 2021. This decrease of $0.9 million, or 5% is due to factors described below.

Revenue by Product

The following table sets forth our revenue for disposables, systems and service/other for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,		Change	
	2022	2021	$	%
Disposables	$ 12,922	$ 11,938	$ 984	8 %
Systems	1,750	4,058	(2,308)	(57)%
Service/Other	1,691	1,267	424	33 %
Total revenue	$ 16,363	$ 17,263	$ (900)	(5)%

Total revenue decreased $0.9 million. The decrease was primarily attributable to a decrease in the volume of system sales of $2.3 million from $4.1 million in the year ended December 31, 2021 to $1.8 million in the year ended December 31, 2022. This decrease resulted from our strategic shift in relocating low usage consoles to new sites. Otherwise, and despite the decrease in system sales, our revenue from disposables and services improved by $1.4 million from increases in procedure volumes.

Revenue by Geographic Source

The following table sets forth the geographic source of our revenue for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,		Change	
	2022	2021	$	%
United States	$ 8,707	$ 8,325	$ 382	5 %
Outside the United States	7,656	8,938	(1,282)	(14)%
Total revenue	$ 16,363	$ 17,263	(900)	(5)%

United States revenue grew by 5% primarily attributable to growth in disposables sales due to increases in procedure volumes. Revenue outside the US declined from prior year, primarily due to a decrease in capital sales.

Our revenue attributable to the United States represented 53% of our total revenue for the year ended December 31, 2022, compared to 48% for the year ended December 31, 2021. Variations in sales in insubstantial amounts may be expected and are attributable to the timing and recognition inherent in the sales cycle.

Costs and Operating Expenses (Income)

Costs and operating expenses were $43.7 million for the year ended December 31, 2022, compared to $129.4 million for the year ended December 31, 2021. This decrease of $85.7 million, or 66%, was attributable to factors described below.

Stock-Based Compensation

The following table sets forth the stock-based compensation expense included in our results of operations for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,		Change	
	2022	2021	$	%
Cost of products sold	$ 669	$ 864	$ (195)	(23)%
Research and development	1,736	2,181	(445)	(20)%
Selling, general and administrative	6,986	10,709	(3,723)	(35)%
Total stock-based compensation	$ 9,391	$ 13,754	$ (4,363)	(32)%

Our stock-based compensation decreased 32%, to $9.4 million for the year ended December 31, 2022 from $13.8 million for the year ended December 31, 2021. This was primarily the result of our planned reduction in workforce. The savings in stock-based compensation expense from our reduction in headcount during 2022 was partially offset by $0.3 million of additional

stock-based compensation from vested options associated with the re-pricing of our stock options to our employees. We expect to realize continued cost saving in future years, however, those savings will be partially offset by an additional $0.3 million in stock-based compensation expense expected over the period from the date of the modification through 2025.

Cost of Products Sold

Cost of products sold was $31.9 million for the year ended December 31, 2022, compared to $32.9 million for the year ended December 31, 2021. This decrease of $1.0 million, or 3% was primarily the result of a decrease in costs associated with our reduction in workforce and a reduction in capital sales. Gross margin was negative 95% for the year ended December 31, 2022, and negative 91% for the year ended December 31, 2021. This decrease in gross margin was attributable to several factors including product and geographic mix and reduction in capitalized manufacturing variances carried from 2021.

Research and Development Expense

Research and development expense was $28.2 million for the year ended December 31, 2022, compared to $36.7 million for the year ended December 31, 2021. This decrease of $8.5 million, or 23%, was primarily attributable to $4.9 million in decreased compensation and related costs from our planned reduction in workforce.

Selling, General and Administrative Expense

Selling, general and administrative expense was $47.7 million for the year ended December 31, 2022, compared to $63.5 million for the year ended December 31, 2021. This decrease of $15.9 million, or 25%, was primarily attributable to $13.0 million in decreased compensation and related costs from lower headcount.

Goodwill Impairment

Goodwill impairment expense was $12.0 million for the year ended December 31, 2022, which consisted of a full impairment of our goodwill balance.

Restructuring

Restructuring expenses were $2.4 million for the year ended December 31, 2022. This one-time expense resulted from our planned 2022 organizational workforce reduction and represents severance payments and other costs associated with employee terminations. We have realized and expect to continue realizing future cost savings as a result of our headcount reduction.

Change in Fair Value of Contingent Consideration

For the years ended December 31, 2022 and 2021, we recorded a change in fair value of contingent consideration consisting of an increase of $1.1 million and a decrease of $3.7 million, respectively, associated with the contingent consideration in the acquisition of Rhythm Xience. The increase in 2022 was primarily attributable to an increased in the expected term used for calculating its future value. The decrease in 2021 was primarily attributable to a decrease in projected net revenue along with a decrease to the expected term.

Gain on Sale of Business

During the year ended December 31, 2022, we completed the sale of certain assets to Medtronic resulting in a gain of $79.5 million.

The terms of our Asset Purchase Agreement with Medtronic provided for additional consideration upon our achievement of certain milestones related to our operational condition and regulatory approvals. During the year ended December 31, 2022, we achieved both the contingent OEM Earnout entitling us to $20.0 million in consideration and the contingent Transfer Earnout entitling us to $17.0 million of consideration. We received payment for the OEM Earnout in the fourth quarter of 2022 and the Transfer Earnout in January 2023.

Over the next four years, we expect to receive a percentage of Medtronic's quarterly commercial sales of product related to the sale of business, ranging from 100% in the first year to 50% in the fourth year.

Other Expense, Net

Other expense, net was $12.2 million for the year ended December 31, 2022 compared to $5.6 million for the year ended December 31, 2021. This increase of $6.6 million, or 119% was primarily attributable to the one-time loss of $7.9 million recorded as a result of the extinguishment of our 2019 Credit Agreement, and other factors, partially offset by a $0.5 million reduction in interest expense.

Loss on Debt Extinguishment

During 2022, we renegotiated our 2019 Credit Agreement, replacing it with the 2022 Credit Agreement. The extinguishment of the 2019 Credit Agreement debt resulted in our recording a one-time loss of $7.9 million.

Change in Fair Value of Warrant Liability

For the year ended December 31, 2022, we recognized a favorable change in fair value of our warrant liability that was not material. The variability in the fair value of our warrants is primarily attributable to the change in market price of the Company's common shares from the date of initial recognition of the warrant liability to December 31, 2022.

During the year ended December 31, 2021, no warrants were recognized as liabilities on our consolidated balance sheets and, therefore, no change in fair value was recorded.

Determination of fair value based upon several factors including price volatility, the price of the underlying warrant, the strike price of the warrant, the time until expiration of the warrants and the risk-free interest rate. As some factors are a reflection of market volatility, future amounts recorded are subject to market conditions and are therefore unpredictable.

Interest Income and Interest Expense, Net

Our interest income and interest expense are a direct reflection of amounts we hold for investment and amounts we owe to debtholders, respectively, both of which change according to our cash requirements. Additionally, as both our holdings and our debt bear interest at variable market rates, both are subject to market factors outside our immediate control. During the year ended December 31, 2022 interest income increased by $0.8 million resulting from increased cash balances and higher interest rates. The $0.5 million decrease in interest expense was primarily the result of a reduction in the amount of our long-term debt from 2021 to 2022, partially offset by increased interest rates.

Liquidity and Capital Resources

Our Company has limited revenue, and, since inception, we have incurred significant operating losses and negative cash flows from operations. We anticipate that we will incur significant losses for at least the next several years. As of December 31, 2022 and 2021, we had cash, cash equivalents and marketable securities of $70.4 million and $107.9 million, respectively. For the years ended December 31, 2022 and 2021, our net losses were $39.6 million and $117.7 million, respectively, and our net cash used in operating activities was $85.0 million and $99.7 million, respectively. As of December 31, 2022 and 2021, we had accumulated deficits of $518.3 million and $478.7 million, respectively, and working capital of $98.0 million and $107.8 million, respectively.

Since raising $166.3 million from our IPO in August 2020, we have issued additional shares of common stock. From time to time, the Company's Board of Directors authorizes the issuance of common stock for our stock-based compensation plans and for our ESPP. Additionally, in July 2021, we issued 6,325,000 shares of common stock in a public offering, which included 825,000 shares of common stock issued upon the underwriter's exercise in full of an option to purchase additional shares of common stock. The price to the public for each share was $14.00. We received gross proceeds of $88.6 million from the offering. Net of underwriting discounts and commission and other offering expenses, we received proceeds of $82.7 million.

On June 30, 2022, Medtronic paid us $50.0 million at the First Closing of the sale of our left-heart access portfolio to Medtronic, of which $4.0 million was paid into an indemnity escrow account for a period of 18 months to secure our indemnification obligations under the Asset Purchase Agreement. We achieved a $20.0 million OEM Earnout as set forth in the Asset Purchase Agreement on October 31, 2022, which was paid to us in the fourth quarter of 2022. Additionally, we achieved a $17.0 million Transfer Earnout as set forth under the Asset Purchase Agreement on December 21, 2022. Accordingly, $17.0 million was recorded as a receivable for the year ended December 31, 2022 and payment was received in January 2023.

Since inception, we have recorded no impairments to or write-offs of our accounts receivable. Accounts receivable for the years ended December 31, 2022 and 2021 consists of the following (in thousands):

	December 31, 2022	December 31, 2021
Trade accounts receivable	$ 4,085	$ 3,633
Transfer Earnout receivable	17,000	—
Total accounts receivable	$ 21,085	$ 3,633

Our management believes our current cash, cash equivalents, receivables, and marketable securities are sufficient to fund operations for at least the next 12 months. To ensure that we have sufficient resources to fund operations, management continues to review cost improvement opportunities and pathways to reduce expenses and cash burn, while preserving the resources to invest in future growth.

In the future, we may need to raise additional funds through the issuance of debt and/or equity securities or otherwise. Until such time, if ever, that we can generate revenue sufficient to achieve profitability, we expect to finance our operations through equity or debt financings, which may not be available to us on the timing needed or on terms that we deem to be favorable. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected. We may be required to delay, limit, reduce or terminate our product discovery and development activities or future commercialization efforts.

Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our revenue growth;
- our research and development efforts;
- our sales and marketing activities;
- our success in leveraging our strategic partnerships, including with Biotronik, as well as entrance into any other strategic partnerships or strategic transactions in the future;
- Medtronic's success in selling Products and their payment of royalties under their continuing obligation in the Asset Purchase Agreement;
- our ability to raise additional funds to finance our operations;
- the outcome, costs and timing of any clinical trial results for our current or future products;
- the emergence and effect of competing or complementary products;
- the availability and amount of reimbursement for procedures using our products;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management and sales, scientific and medical personnel;
- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- debt service requirements;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the impact of the COVID-19 pandemic.

Our primary uses of capital are, and we expect will continue to be, investment in our commercial organization and related expenses, clinical research and development services, laboratory and related supplies, legal and other regulatory expenses, general administrative costs and working capital. In addition, we have acquired, and may in the future seek to acquire or invest

in, additional businesses, products or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities.

Pursuant to the Biotronik License Agreement, we paid Biotronik a $3.0 million upfront fee as well as a technology transfer fee consisting of a total of $7.0 million in cash and $5.0 million in shares of our Series D convertible preferred stock. We may owe the Biotronik Parties up to $10.0 million, of which $2.0 million has been paid as of December 31, 2022, based upon the achievement of various regulatory and sales-related milestones. On an on-going basis, we agreed to pay a unit-based royalty on sales of force sensing catheters.

We continue to make improvements in both operating expenses and cash burn. During 2022, we completed restructuring plans that helped strengthen our financial position and extend our cash runway. Our tangible actions, as well as achievements of the milestones related to the Medtronic Asset Purchase Agreement have set us up to be in an improved cash and liquidity position.

Under Accounting Standards Codification Subtopic 205-40, Presentation of Financial Statements—Going Concern, we have the responsibility to evaluate whether conditions and/or events could raise substantial doubt about our ability to meet our future financial obligations as they become due within one year after the date that the financial statements are issued. Going concern matters are more fully discussed in *Note 1 - Organization and Description of Business – Liquidity, Capital Resources and Going Concern* of our condensed consolidated financial statements attached hereto.

Debt Obligations

On June 30, 2022, we entered into the 2022 Credit Agreement, which provided us with a term loan facility in an aggregate principal amount of $35.0 million. The 2022 Credit Agreement bears an annual interest of 9% plus the one-month adjusted term Secured Overnight Financing Rate (as defined in the 2022 Credit Agreement) with a 2.5% minimum. The principal amount of the term loan will be paid in installments with the final principal payment due on June 30, 2027. The 2022 Credit Agreement can be prepaid but is subject to prepayment penalties. The 2022 Credit Agreement provides for final payment fees of an additional $1.8 million that are due upon prepayment, on the maturity date or upon acceleration. Proceeds from the 2022 Credit Agreement, along with cash on hand, were used to extinguish amounts owed under the 2019 Credit Agreement and to pay related fees and expenses and for working capital purposes.

The 2022 Credit Agreement contains certain customary negative covenants, including, but not limited to, restrictions on our ability and that of our subsidiaries to merge and consolidate with other companies, incur indebtedness, grant liens or security interests on assets, pay dividends or make other restricted payments, sell or otherwise transfer assets or enter into transactions with affiliates. The 2022 Credit Agreement provides that, upon the occurrence of certain events of default, our obligations thereunder may be accelerated. Such events of default include payment defaults to the lenders, material inaccuracies of representations and warranties, covenant defaults, cross-defaults to certain other indebtedness, voluntary and involuntary bankruptcy proceedings, certain money judgments, change of control events and other customary events of default.

Our obligations under the 2022 Credit Agreement are secured by substantially all of our assets, including our intellectual property.

In connection with the 2022 Credit Agreement, we entered into a warrant purchase agreement (the "2022 Warrant Purchase Agreement") with certain affiliates of Deerfield Management Company (collectively referred to as "Deerfield"), pursuant to which we issued warrants to purchase up to an aggregate 3,779,018 shares of our common stock, par value $0.001 per share common stock, at an exercise price of $1.1114 per warrant share for a period of eight years following the issuance thereof (the "2022 Warrants").

Cash Flows

The following table shows a summary of our cash flows for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
Net cash used in operating activities	$ (85,032)	$ (99,682)
Net cash provided by investing activities	104,750	19,066
Net cash (used in) provided by financing activities	(12,116)	79,569
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(475)	(116)
Net change in cash, cash equivalents and restricted cash	$ 7,127	$ (1,163)

As of December 31, 2022 and 2021, cash, cash equivalents and restricted cash totaled $31.3 million and $24.2 million, respectively. During the year ended December 31, 2022, cash, cash equivalents and restricted cash increased $7.1 million. During the year ended December 31, 2021, the total of those items decreased $1.2 million.

Operating Activities

During the year ended December 31, 2022, operating activities used $85.0 million of cash, cash equivalents and restricted cash, a decrease of $14.7 million from the $99.7 million cash used in the year ended December 31, 2021.

The $85.0 million cash used in operating activities the year ended December 31, 2022 was primarily the result of our cash-basis net loss from operations for the year of $86.4 million, computed as net loss from operations before the gain on sale of business and by adding back the non-cash items of stock based compensation and goodwill impairment and subtracting the non-cash gain recognized from the increase in value of contingent consideration.

The $99.7 million cash used in operating activities for the year ended December 31, 2021 was primarily the result of our cash-basis net loss from operations for the year of $94.6 million, computed as net loss from operation and adding back non-cash stock based compensation and the non-cash loss in fair value of contingent consideration.

Investing Activities

Total cash provided by investing activities was $104.8 million for the year ended December 31, 2022 and total cash provided by investing activities was $19.1 million for the year ended December 31, 2021.

Cash provided by investing activities of $104.8 million during 2022 resulted from proceeds of $70.0 million from the sale of business to Medtronic and $38.7 million netted from the sale and maturity of marketable securities in excess of purchases, offset by our $4.0 million purchase of fixed assets.

Cash provided by investing activities was $19.1 million during 2021. Sales and maturities of marketable securities netted against purchases provided $29.1 million, which was partially offset by purchases of property and equipment of $10.0 million.

We intend to continue to invest in the purchase of fixed assets to improve and maintain our current level of customer support and our ability to efficiently manufacture and distribute our products.

Financing Activities

Cash used in financing activities was $12.1 million for the year ended December 31, 2022 and cash provided by financing activities was $79.6 million for the year ended December 31, 2021, a decrease of $91.7 million.

Cash used in financing activities during 2022 was $12.1 million, primarily due to repayment and fees of the old term loan of $45.6 million and payment of contingent consideration of $0.9 million, offset by net proceeds from new term loan of $34.2 million.

Cash provided by financing activities during 2021 was $79.6 million. $83.8 million was provided by the issuance of common and preferred stock and the purchase of stock by the ESPP. Proceeds from common stock sales were offset by the payment of $3.7 million of contingent consideration and $0.6 million of deferred offering costs.

Contractual Obligations and Commitments

We enter into agreements in the normal course of business with contract research organizations for clinical trials and with vendors for preclinical trials and other services and products for operating purposes which are cancellable at any time by us, generally upon 30 days prior written notice.

Rhythm Xience

The agreement to acquire Rhythm Xience requires us to pay the former owners of Rhythm Xience up to $17.0 million in additional cash earn-out consideration based on the achievement of certain regulatory and revenue milestones, of which $7.2 million was paid as of December 31, 2022.

Biotronik

Pursuant to the Biotronik License Agreement, we are required to pay the Biotronik Parties up to $10.0 million of additional consideration, of which $2.0 million was paid as of December 31, 2022. Payments are contingent upon the achievement of various regulatory and sales-related milestones. Additionally, we are obligated to pay a unit-based royalty on sales of force sensing catheters on a continuing basis.

Off-Balance Sheet Arrangements

As of December 31, 2022 and 2021, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined in the SEC rules and regulations.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which were prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue and expenses. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions, and any such differences may be material.

While our significant accounting policies are more fully described in *Note 2—Summary of Significant Accounting Policies* of the Notes to Consolidated Financial Statements included in *Item 8, Financial Statements and Supplementary Data* of 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 which require our most difficult, subjective and complex judgments.

Revenue from Contracts with Customers

We account for revenue earned from contracts with customers under ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), and ASC 842, *Leases* ("ASC 842"). The core principle of ASC 606 is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer.
- Step 2: Identify the performance obligations in the contract.
- Step 3: Determine the transaction price.
- Step 4: Allocate the transaction price to the performance obligations in the contract.
- Step 5: Recognize revenue when, or as, the company satisfies a performance obligation.

ASC 842 provides guidance on determining if an agreement contains a lease. ASC 842 defines a lease as a contract, or part of a contract, that conveys the right to control the use of identified property, plant or equipment for a period of time in exchange for consideration.

We usually place our AcQMap System at customer sites under evaluation agreements and we generate revenue from the sale of disposable products used with the AcQMap System. Disposable products primarily include AcQMap Catheters and AcQGuide Steerable Sheaths. Outside of the U.S., we also have the Qubic Force Device which generates revenue from the sale of the AcQBlate FORCE Ablation Catheters. We provide the disposable products in exchange for consideration, which occurs when a customer submits a purchase order and the Company provides disposables at the agreed upon prices in the invoice. Generally, customers purchase disposable products using separate purchase orders after the equipment has been provided to the customer for free with no binding agreement or requirement to purchase any disposable products. We have elected the practical expedient and accounting policy election to account for the shipping and handling as activities to fulfill the promise to transfer the disposable products and not as a separate performance obligation.

We sell the AcQMap System to customers along with software updates on a when-and-if-available basis, as well as the Qubic Force Device and a transseptal crossing line of products which can be used in a variety of heart procedures and does not need to be accompanied with an AcQMap System or Qubic Force Device.

We also enter into deferred equipment agreements that are generally structured such that we agree to provide an AcQMap System at no up-front charge, with title of the device transferring to the customer at the end of the contract term, in exchange for the customer's commitment to purchase disposables at a specified price over the term of the agreement, which generally ranges from two to four years. We have determined that the deferred equipment agreements include an embedded sales-type lease. We allocate contract consideration under deferred equipment agreements containing fixed annual disposable purchase commitments to the underlying lease and non-lease components at contract inception. We expense the cost of the device at the inception of the agreement and record a financial lease asset equal to the gross consideration allocated to the lease. The lease asset will be reduced by payments for minimum disposable purchases that are allocated to the lease.

Lastly, we enter into short-term operating leases, for the rental of the system after an evaluation. These lease agreements impose no requirement on the customer to purchase the equipment and the equipment is not transferred to the customer at the end of the lease term. The short-term nature of the lease agreements does not result in lease payments accumulating to an amount that equals the value of the equipment nor is the lease term reflective of the economic life of the equipment.

In addition to our AcQMap System and Disposable sales, we manufacture and sell left-heart access transseptal crossing products to Medtronic under a Distribution Agreement. Under our Distribution Agreement with Medtronic, we expect to produce and sell these products to Medtronic for a period of up to four years. Revenue is recognized when the title to the products are transferred to Medtronic, which occurs when the products are shipped from our facility (FOB shipping point).

Stock-Based Compensation

We account for all stock-based payments to employees and non-employees, including grants of stock options, restricted stock awards ("RSAs") and restricted stock units ("RSUs") to be recognized in the consolidated financial statements based on their respective grant date fair values. We estimate the fair value of stock option grants using the Black-Scholes option pricing model. The RSAs and RSUs are valued based on the fair value of the Company's common stock on the date of grant. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The Company expenses stock-based compensation related to stock options, RSAs and RSUs over the requisite service period.

All stock-based compensation costs are recorded in cost of products sold, research and development expense or selling, general, and administrative expense in the consolidated statements of operations and comprehensive loss based upon the respective employee's or non-employee's roles within the Company. Forfeitures are recorded as they occur.

In addition, we have an employee stock purchase plan, or ESPP, which has an offering period commencing on the first trading day on or after February 1 and August 1 of each year and terminating on the last trading day on or before July 31 and January 31, respectively. In November 2021, we amended our ESPP offering periods beginning in 2022 after the January 31 purchase, to commence on the first trading day on or after May 15 and November 15 of each year and terminating on the last trading day on or before November 14 and May 14, respectively. On each purchase date, which falls on the last date of each offering period, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the offering date or (2) the fair market value of the common stock on the purchase date. We recognizer an expense in the amount equal to the estimated fair value of the discount.

Fair Value Measurements

Accounting guidance regarding fair value measurements addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under GAAP, and provides a common definition of fair value to be used throughout GAAP. It defines fair value as the price that would be received when selling an asset or paid to transfer a liability in an orderly fashion between market participants at the measurement date. In addition, it establishes a three-level valuation hierarchy for the disclosure of fair value measurements. The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability as of the measurement date. The level in the hierarchy within which a given fair value measurement falls is determined based on the lowest level input that is significant to the measurement (Level 1 being the highest and Level 3 being the lowest).

In connection with certain of our acquisitions, additional contingent consideration can be earned by the sellers upon achievement of certain milestones and revenue-based targets in certain years. We classify our contingent consideration liability as Level 3. The initial fair value of the revenue-based contingent consideration was therefore calculated through the use of a Monte Carlo simulation utilizing revenue projections for the respective earn-out period, corresponding targets and approximate timing of payments as outlined in the purchase agreement. The analyses used the following assumptions: (i) expected term; (ii) risk-adjusted net sales; (iii) risk-free interest rate; and (iv) expected volatility of net sales.

Estimated contingent consideration payments, as determined through the respective model, were further discounted by a credit spread assumption to account for credit risk. The fair value of the milestones-based contingent consideration was determined by probability weighting and discounting to the respective valuation date at our cost of debt. Our cost of debt was determined by performing a synthetic credit rating for us and selecting yields based on companies with a similar credit rating. The contingent consideration is revalued to fair value each period, and any increase or decrease is recorded in operating loss. The fair value of the contingent consideration may be impacted by certain unobservable inputs, most significantly with regard to discount rates, expected volatility and historical and projected performance. Significant changes to these inputs in isolation could result in a significantly different fair value measurement.

Warrant Liability

We account for certain common stock warrants outstanding as a liability, in accordance with ASC 815, *Derivatives and Hedging*, at fair value and adjust the instruments to fair value at each reporting period. On June 30, 2022, we issued warrants in connection with the 2022 Credit Agreement, which were determined to be liability classified warrants. The stock warrant liability was estimated using a Black-Scholes model.

The warrant liability is subject to re-measurement at each reporting period or upon conversion, and any change in fair value is recognized in our consolidated statements of operations and comprehensive loss.

Goodwill

Goodwill is not amortized but is subject to periodic impairment testing. Goodwill is assigned to a reporting unit and the reporting unit's goodwill is tested for impairment at least on an annual basis and between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount. In the evaluation of goodwill for impairment, which we perform annually during the fourth quarter, we first assess qualitative factors to determine whether the existence of events or circumstances could lead to a determination that it was more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, we determine that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, we perform a quantitative goodwill impairment test. We could also elect to perform a quantitative impairment test without first assessing qualitative factors.

During the year ended December 31, 2022, our management assessed qualitative factors and determined it was more likely than not that the fair value of the goodwill was less than its carrying amount. This required us to perform a quantitative impairment test prior to our standard year-end testing. In performing a quantitative impairment test, we determined that goodwill was fully impaired. We took a charge against the goodwill asset on the consolidated balance sheets and recorded a concurrent expense on the statements of operations and comprehensive loss for the full recorded balance of goodwill.

Recent Accounting Pronouncements

For a description of recently issued and adopted accounting pronouncements, including the respective dates of adoption and expected effects on our results of operations and financial condition, see *Note 2—Summary of Significant Accounting Policies* of the Notes to Consolidated Financial Statements included in *Item 8, Financial Statements and Supplementary Data* of this Annual Report on Form 10-K, which is incorporated by reference in response to this item.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the JOBS Act. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation, and an exemption from the requirements to obtain a non-binding advisory vote on executive compensation or golden parachute arrangements. We have elected to take advantage of certain of the reduced disclosure obligations and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We elected to avail ourselves of this provision of the JOBS Act. As a result, we will not be subject to new or revised accounting standards at the same time as other public companies that are not emerging growth companies. Therefore, our consolidated financial statements may not be comparable to those of companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of: (i) December 31, 2025; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion; (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company as defined by Item 10 of Regulation S-K, we are not required to provide the information required by this item.

INDEX TO FINANCIAL STATEMENTS

Acutus Medical, Inc.
Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Acutus Medical, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Acutus Medical, Inc. and subsidiary (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated 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 then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2015.

San Diego, California
March 23, 2023

ACUTUS MEDICAL, INC.
Consolidated Balance Sheets

(in thousands, except share and per share amounts)	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,584	$ 24,071
Marketable securities, short-term	44,863	76,702
Restricted cash	5,764	150
Accounts receivable	21,085	3,633
Inventory	13,327	16,408
Employer retention credit receivable	4,703	—
Prepaid expenses and other current assets	2,541	5,326
Total current assets	117,867	126,290
Marketable securities, long-term	—	7,120
Property and equipment, net	9,221	13,670
Right-of-use asset, net	3,872	4,521
Intangible assets, net	1,583	5,013
Goodwill	—	12,026
Other assets	897	1,152
Total assets	**$ 133,440**	**$ 169,792**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,721	$ 7,519
Accrued liabilities	9,686	9,096
Contingent consideration, short-term	1,800	1,500
Operating lease liabilities, short-term	319	395
Warrant liability	3,346	—
Total current liabilities	19,872	18,510
Operating lease liabilities, long-term	4,103	4,591
Long-term debt	34,434	40,415
Contingent consideration, long-term	—	500
Other long-term liabilities	12	50
Total liabilities	58,421	64,066
Commitments and contingencies (Note 13)		
Stockholders' equity		
Preferred stock: Series A Common Equivalent Preferred Stock, 0.001 par value; 5,000,000 shares authorized, and 6,666 shares issued and outstanding	—	—
Common stock: 0.001 par value; 260,000,000 shares authorized, 28,554,656 and 27,957,223 issued and outstanding at December 31, 2022 and 2021, respectively	29	28
Additional paid-in capital	594,173	584,613
Accumulated deficit	(518,314)	(478,698)
Accumulated other comprehensive loss	(869)	(217)
Total stockholders' equity	75,019	105,726
Total liabilities and stockholders' equity	**$ 133,440**	**$ 169,792**

The accompanying notes are an integral part of these consolidated financial statements.

ACUTUS MEDICAL, INC.
Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)	Year Ended December 31, 2022	2021
Revenue	$ 16,363	$ 17,263
Costs and operating expenses (income):		
Cost of products sold	31,910	32,925
Research and development	28,153	36,683
Selling, general and administrative	47,654	63,523
Goodwill impairment	12,026	—
Restructuring	2,371	—
Change in fair value of contingent consideration	1,053	(3,746)
Gain on sale of business	(79,465)	—
Total costs and operating expenses	43,702	129,385
Loss from operations	(27,339)	(112,122)
Other income (expense):		
Loss on debt extinguishment	(7,947)	—
Change in fair value of warrant liability	33	—
Interest income	868	116
Interest expense	(5,149)	(5,677)
Total other expense, net	(12,195)	(5,561)
Loss before income taxes	(39,534)	(117,683)
Income tax expense	82	—
Net loss	(39,616)	(117,683)
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	39	(37)
Foreign currency translation adjustment	(691)	(460)
Comprehensive loss	**$ (40,268)**	**$ (118,180)**
Basic and diluted net loss per common share	$ (1.40)	$ (4.11)
Basic and diluted weighted average shares outstanding	28,322,753	28,654,313

The accompanying notes are an integral part of these consolidated financial statements.

ACUTUS MEDICAL, INC.
Consolidated Statements of Stockholders' Equity

(in thousands, except share amounts)	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2020	**—**	**$ —**	**27,991,425**	**$ 28**	**$ 487,290**	**$ (361,015)**	**$ 280**	**$ 126,583**
Unrealized loss on marketable securities	—	—	—	—	—	—	(37)	(37)
Foreign currency translation adjustment	—	—	—	—	—	—	(460)	(460)
Issuance of common stock for cash, net of issuance costs of $5,893	—	—	6,325,000	6	82,651	—	—	82,657
Stock option exercises	—	—	111,804	—	711	—	—	711
Stock-based compensation	—	—	134,236	—	13,515	—	—	13,515
Employee stock purchase plan shares issued	—	—	33,641	—	440	—	—	440
Issuance of common stock for cashless warrant exercise	—	—	26,958	—	—	—	—	—
Exchange of common stock for Series A Common Equivalent Preferred Stock	6,666	—	(6,665,841)	(6)	6	—	—	—
Net loss	—	—	—	—	—	(117,683)	—	(117,683)
Balance as of December 31, 2021	**6,666**	**$ —**	**27,957,223**	**$ 28**	**$ 584,613**	**$ (478,698)**	**$ (217)**	**$ 105,726**

(in thousands, except share amounts)	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2021	**6,666**	**$ —**	**27,957,223**	**$ 28**	**$ 584,613**	**$ (478,698)**	**$ (217)**	**$ 105,726**
Unrealized gain on marketable securities	—	—	—	—	—	—	39	39
Foreign currency translation adjustment	—	—	—	—	—	—	(691)	(691)
Stock option exercises	—	—	35,478	1	66	—	—	67
Stock-based compensation	—	—	412,628	—	9,280	—	—	9,280
Employee stock purchase plan shares issued	—	—	149,327	—	214	—	—	214
Net loss	—	—	—	—	—	(39,616)	—	(39,616)
Balance as of December 31, 2022	**6,666**	**$ —**	**28,554,656**	**$ 29**	**$ 594,173**	**$ (518,314)**	**$ (869)**	**$ 75,019**

The accompanying notes are an integral part of these consolidated financial statements.

ACUTUS MEDICAL, INC.
Consolidated Statements of Cash Flows

(in thousands)	Year Ended December 31, 2022	2021
Cash flows from operating activities		
Net loss	$ (39,616)	$ (117,683)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	6,060	5,754
AcQMap Systems converted to sales	605	2,182
Sales-type lease loss (gain)	(87)	28
Amortization of intangible assets	420	640
Non-cash stock-based compensation expense	9,391	13,754
Amortization of premiums (accretion of discounts) on marketable securities, net	(24)	1,277
Amortization of debt issuance cost	850	1,404
Amortization of operating lease right-of-use assets	649	496
Goodwill impairment	12,026	—
Loss on extinguishment of debt	7,947	—
Gain on sale of business, net	(79,465)	—
Direct costs paid for sale of business	(4,027)	—
Change in fair value of warrant liability	(33)	—
Loss on disposal of fixed assets	825	—
Change in fair value of contingent consideration	1,053	(3,746)
Changes in operating assets and liabilities:		
Accounts receivable	(452)	(1,473)
Inventory	3,081	(3,872)
Employer retention credit receivable	(4,703)	—
Prepaid expenses and other current assets	2,804	1,133
Other assets	475	304
Accounts payable	(2,852)	(871)
Accrued liabilities	605	1,549
Operating lease liabilities	(526)	(608)
Other long-term liabilities	(38)	50
Net cash used in operating activities	(85,032)	(99,682)
Cash flows from investing activities		
Proceeds from sale of business	70,000	—
Purchases of available-for-sale marketable securities	(54,508)	(87,258)
Sales of available-for-sale marketable securities	18,599	8,590
Maturities of available-for-sale marketable securities	74,642	107,707
Purchases of fixed assets	(3,983)	(9,973)
Net cash provided by investing activities	104,750	19,066
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	—	82,657
Proceeds from the exercise of stock options	67	711
Repurchase of common shares to pay employee withholding taxes	(111)	—
Proceeds from employee stock purchase plan	214	440
Payment of contingent consideration	(872)	(3,435)
Payment of deferred offering costs	—	(580)
Payment of contingent consideration into escrow	—	(224)
Repayment of old term loan	(44,550)	—
Prepayment penalty fees	(1,063)	—
Borrowing under new term loan	34,825	—
Payment of debt issuance costs for new loan	(626)	—
Net cash (used in) provided by financing activities	(12,116)	79,569
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(475)	(116)
Net change in cash, cash equivalents and restricted cash	7,127	(1,163)
Cash, cash equivalents and restricted cash at the beginning of the period	24,221	25,384
Cash, cash equivalents and restricted cash at the end of the period	**$ 31,348**	**$ 24,221**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 4,231	$ 4,259
Supplemental disclosure of noncash investing and financing activities:		
Amount of debt proceeds allocated to warrant liability	$ 3,379	$ —
Accounts receivable from sale of business	$ 17,000	$ —
Change in unrealized loss on marketable securities	$ (39)	$ 37
Right-of-use assets exchanged for operating lease liabilities	$ —	$ 3,527

(in thousands)	Year Ended December 31, 2022	2021
Contingent consideration escrow release	$ 381	$ 119
Change in unpaid purchases of property and equipment	$ 54	$ 124
Net book value on AcQMap system sales-type leases	$ 244	$ 1,104

The accompanying notes are an integral part of these consolidated financial statements.

Note 1—Organization and Description of Business

Acutus Medical, Inc. (the "Company") is an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated. The Company designs, manufactures and markets a range of tools for catheter-based ablation procedures to treat various arrhythmias. The Company's product portfolio includes novel access sheaths, diagnostic and mapping catheters, ablation catheters, mapping and imaging consoles and accessories, as well as supporting algorithms and software programs. The Company was incorporated in the state of Delaware on March 25, 2011, and is located in Carlsbad, California.

Liquidity and Capital Resources

The Company has limited revenue and has incurred significant operating losses and negative cash flows from operations since its inception, and anticipates that it will incur significant losses for at least the next several years. As of December 31, 2022 and 2021, the Company had cash, cash equivalents and marketable securities of $70.4 million and $107.9 million, respectively. For the years ended December 31, 2022 and 2021, net losses were $39.6 million and $117.7 million, respectively, and net cash used in operating activities was $85.0 million and $99.7 million respectively. As of December 31, 2022 and 2021, the Company had an accumulated deficit of $518.3 million and $478.7 million, respectively, and working capital of $98.0 million and $107.8 million, respectively.

Since raising $166.3 million from its IPO in August 2020, the Company has issued additional shares of common stock. From time to time, the Company's Board of Directors issues common stock for its stock-based compensation plans and for its ESPP. Additionally, in July 2021, the Company issued 6,325,000 shares of common stock in a public offering, which included 825,000 shares of common stock issued upon the underwriter's exercise in full of an option to purchase additional shares of common stock. The price to the public for each share was $14.00. The Company received gross proceeds of $88.6 million from the offering. Net of underwriting discounts and commission and other offering expenses, the Company received proceeds of $82.7 million.

On June 30, 2022, Medtronic, Inc. ("Medtronic") paid the Company $50.0 million at the First Closing of the sale of its left-heart access portfolio to Medtronic, of which $4.0 million was paid into an indemnity escrow account for a period of 18 months following the First Closing to secure the Company's indemnification obligations under the Asset Purchase Agreement. The OEM Earnout under the Asset Purchase Agreement with Medtronic was achieved on October 31, 2022, with $20.0 million paid in November 2022. Additionally, the Transfer Earnout under the Asset Purchase Agreement with Medtronic was achieved on December 21, 2022. Accordingly, cash consideration of $17.0 million payable to the Company for the satisfaction of the Transfer Earnout conditions was received from Medtronic on January 13, 2023.

Management believes the Company's current cash, cash equivalents and marketable securities are sufficient to fund operations for at least the next 12 months from the date of this filing. To ensure that the Company has sufficient resources to fund operations, management continues to review cost improvement opportunities and pathways to reduce expenses and cash burn, while preserving the resources to invest in future growth.

In the future, the Company may need to raise additional funds through the issuance of debt and/or equity securities or otherwise. Until such time, if ever, that the Company can generate revenue sufficient to achieve profitability, the Company expects to finance its operations through equity or debt financings, which may not be available to it on the timing needed or on terms that it deems to be favorable. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interest of its stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting the Company's ability to take specific actions such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If the Company is unable to maintain sufficient financial resources, its business, financial condition, and results of operations will be materially and adversely affected. The Company may be required to delay, limit, reduce or terminate its product discovery and development activities or future commercialization efforts.

Note 2—Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Principles of Consolidation

The consolidated financial statements include the accounts of Acutus Medical, Inc. and its wholly-owned subsidiary Acutus Medical NV ("Acutus NV"), which was incorporated under the laws of Belgium in August 2013. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates and Assumptions

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and disclosures of contingent assets and liabilities. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenue and expenses that are not readily apparent from other sources. Actual results could differ from those estimates.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating and reportable segment.

Cash and Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. All of the Company's cash equivalents have liquid markets and high credit ratings. The Company maintains its cash in bank deposits and other accounts, the balances of which, at times and as of December 31, 2022 and 2021, exceeded federally insured limits.

Restricted cash consists of (i) deposited cash collateral for the Company's corporate credit card program and (ii) cash received for the sale of business to Medtronic held in an indemnity escrow account until certain terms of sale are met.

The following table reconciles cash and restricted cash in the consolidated balance sheets to the totals shown on the consolidated statements of cash flows (in thousands).

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 25,584	$ 24,071
Restricted cash	5,764	150
Total cash, cash equivalents and restricted cash	$ 31,348	$ 24,221

Marketable Securities

The Company's marketable securities portfolio consists of investments in money market funds, commercial paper, U.S. treasury securities and Yankee debt securities.

The Company considers its debt securities to be available-for-sale securities. Available-for-sale securities are initially classified as cash equivalents, short-term marketable securities or long-term marketable securities based on the maturity date at time of purchase and their availability to meet current operating requirements. Marketable securities that mature in three months or less from the date of purchase are classified as cash equivalents. Marketable securities excluding cash equivalents that mature in one year or less are classified as short-term available-for-sale securities and are reported as a component of current assets.

Securities that are classified as available-for-sale are measured at fair value with temporary unrealized gains and losses reported in other comprehensive loss and as a component of stockholders' equity until their disposition or maturity. The Company reviews all available-for-sale securities at each period end to determine if they remain available-for-sale based on the Company's current intent and ability to sell the security if it is required to do so. Realized gains and losses from the sale of marketable securities, if any, are calculated using the specific-identification method.

Marketable securities are subject to a periodic impairment review. The Company may recognize an impairment charge when a decline in the fair value of investments below the cost basis is determined to be other-than-temporary. In determining whether a decline in market value is other-than-temporary, various factors are considered including the cause, duration of time and severity of the impairment, any adverse changes in the investees' financial condition and the Company's intent and ability to hold the security for a period of time sufficient to allow for an anticipated recovery in market value. Declines in value judged to be other-than-temporary are included in the Company's consolidated statements of operations and comprehensive loss. The Company recorded no other-than-temporary impairments related to marketable securities in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2022 and 2021.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to credit risk consist principally of cash, cash equivalents, restricted cash, accounts receivable and marketable securities. Cash and restricted cash are maintained in accounts with financial institutions, which, at times may exceed the Federal depository insurance coverage of $0.25 million. The Company has not experienced losses on these accounts and management believes, based upon the quality of the financial institutions, that the credit risk with regard to these deposits is not significant.

Revenue from Contracts with Customers

The Company accounts for revenue earned from contracts with customers under ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), and ASC 842, *Leases* ("ASC 842"). The core principle of ASC 606 is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer.
- Step 2: Identify the performance obligations in the contract.
- Step 3: Determine the transaction price.
- Step 4: Allocate the transaction price to the performance obligations in the contract.
- Step 5: Recognize revenue when, or as, the company satisfies a performance obligation.

ASC 842 provides guidance on determining whether an agreement contains a lease. ASC 842 defines a lease as a contract, or part of a contract, that conveys the right to control the use of identified property, plant or equipment for a period of time in exchange for consideration.

For new customers, the Company places its medical diagnostic equipment, the AcQMap System, at customer sites under evaluation agreements, and generates revenue from the sale of disposable products used with the AcQMap System. Disposable products primarily include AcQMap Catheters and AcQGuide Steerable Sheaths. Outside of the U.S., the Company also has the Qubic Force Device which generates revenue from the sale of the AcQBlate FORCE Ablation Catheters. The Company provides the disposable products in exchange for consideration, which occurs when a customer submits a purchase order and the Company provides disposables at the agreed upon prices in the invoice. Generally, the AcQMap System is provided to the customer for free with no binding agreement or requirement to purchase any disposable products, and customers thereafter purchase disposable products using separate purchase orders. The Company has elected the practical expedient and accounting policy election to account for the shipping and handling as activities to fulfill the promise to transfer the disposable products and not as a separate performance obligation.

Additionally, the Company sells the AcQMap System to customers along with software updates on a when-and-if-available basis, as well as the Qubic Force Device and a transseptal crossing line of products which can be used in a variety of heart procedures and does not need to be accompanied with an AcQMap System or Qubic Force Device. Included in the transseptal crossing line of products are primarily the AcQRef introducer sheath, the AcQGuide sheaths and the AcQCross Transseptal Dilator/Needle.

The Company also enters into deferred equipment agreements that are generally structured such that the Company agrees to provide an AcQMap System at no up-front charge, with title of the device transferring to the customer at the end of the contract term in exchange for the customer's commitment to purchase disposables at a specified price over the term of the agreement, which generally ranges from two to four years. The Company has determined that such deferred equipment agreements include an embedded sales-type lease. The Company allocates contract consideration under deferred equipment agreements containing fixed annual disposable purchase commitments to the underlying lease and non-lease components at contract inception. The Company expenses the cost of the device at the inception of the agreement and records a financial lease asset equal to the gross consideration allocated to the lease. The lease asset is reduced by payments for minimum disposable purchases that are allocated to the lease.

Lastly, the Company enters into short-term operating leases for the rental of the AcQMap System after an evaluation. These lease agreements impose no requirement on the customer to purchase the equipment, and the equipment is not transferred to the customer at the end of the lease term. The short-term nature of the lease agreements does not result in lease payments accumulating to an amount that equals the value of the equipment nor is the lease term reflective of the economic life of the equipment.

The Company's contracts primarily include fixed consideration. Generally, there are no discounts, rebates, returns or other forms of variable consideration. Customers are generally required to pay within 30 to 60 days.

The delivery of disposable products are performance obligations satisfied at a point in time. The disposable products are shipped free on board ("FOB") shipping point or FOB destination. For disposable products that are shipped FOB shipping point, the customer has the significant risks and rewards of ownership and legal title to the assets when the disposable products leave the Company's shipping facilities, thus the customer obtains control and revenue is recognized at that point in time. Revenue is recognized on delivery for disposable products shipped via FOB destination.

For direct customers, the installation and delivery of the AcQMap System is satisfied at a point in time when the installation is complete, which is when the customer can benefit and has control of the system. For AcQMap System sales sold to Biotronik, the installation is not a performance obligation as it is performed by Biotronik, and therefore, the AcQMap System is satisfied at a point in time when they have control of the system. The Company's software updates and equipment service performance obligations are satisfied evenly over time as the customer simultaneously receives and consumes the benefits of the Company's performance for these services throughout the service period.

The Company allocates the transaction price to each performance obligation identified in the contract based on the relative standalone selling price ("SSP"). The Company determines SSP for the purposes of allocating the transaction price to each performance obligation based on the adjusted market assessment approach that maximizes the use of observable inputs, which include, but are not limited to, sales transactions where the specific performance obligations are sold separately, company list prices and specific offers to customers.

Except for the deferred equipment agreements noted above, the Company's contracts with customers generally have an expected duration of one year or less, and therefore, the Company has elected the practical expedient in ASC 606 to not disclose information about its remaining performance obligations. Any incremental costs to obtain contracts are recorded as selling, general and administrative ("SG&A") expense as incurred due to the short duration of the Company's contracts. The Company's contract balances consisted solely of accounts receivable as of December 31, 2022 and 2021.

In May 2020, the Company entered into Bi-Lateral Distribution Agreements with Biotronik. Pursuant to the Bi-Lateral Distribution Agreements, the Company obtained a non-exclusive license to distribute a range of Biotronik's products and accessories in the United States, Canada, China, Hong Kong and multiple Western European countries under the Company's private label. Moreover, if an investigational device exemption ("IDE") clinical trial is required for these products to obtain regulatory approval in the United States, or a clinical trial is required for these products to obtain regulatory approval in China, the Company will obtain an exclusive distribution right in such territories for a term of up to five years commencing on the date of regulatory approval if the Company covers the cost of the IDE or other clinical trial and the Company conducts such study within a specified period. Biotronik also agreed to distribute the Company's products and accessories in Germany, Japan, Mexico, Switzerland and multiple countries in Asia-Pacific, Eastern Europe, the Middle East and South America. The Company also granted Biotronik a co-exclusive right to distribute these products in Hong Kong. Each party will pay a specified transfer price on the sale of the other party's products and, accordingly, will earn a distribution margin on the sale of the other party's products.

In 2022, the Company sold the left-heart access transseptal crossing business to Medtronic. Under a Distribution Agreement, the Company will act as the OEM supplier of these products. The Company will produce and sell the products to Medtronic for

a period of up to four years. Revenue is recognized when the title to the products are transferred to Medtronic, which occurs when the products are shipped from our facility (FOB shipping point).

The following table sets forth the Company's revenue for disposables, systems, and service/other for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
Disposables	$ 12,922	$ 11,938
Systems	1,750	4,058
Service/Other	1,691	1,267
Total revenue	$ 16,363	$ 17,263

The following table provides revenue by geographic location for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
United States	$ 8,707	$ 8,325
Outside the United States	7,656	8,938
Total revenue	$ 16,363	$ 17,263

Inventory

Inventory is stated at the lower of cost (first-in, first-out basis) or net realizable value. The Company recorded write-downs for excess and obsolete inventory of $3.8 million and $1.3 million for the years ended December 31, 2022 and 2021, respectively, based on management's review of inventories on hand, comparisons to estimated future usage and sales, observed shelf-life and assumptions about the likelihood of obsolescence.

Accounts Receivable

Trade accounts receivable are recorded net of allowances for uncollectible accounts. The Company evaluates the collectability of its accounts receivable based on various factors including historical experience, the length of time the receivables are past due and the financial health of the customer. The Company reserves specific receivables if collectability is no longer reasonably assured. Based upon the assessment of these factors, the Company did not record an allowance for uncollectible accounts as of December 31, 2022 or 2021.

Pursuant to the Asset Purchase Agreement with Medtronic (see *Note 4 - Sale of Business)*, the Company is eligible to receive contingent cash consideration of $17.0 million (the "Transfer Earnout") upon the Company's initial submission for CE Mark certification. The Company met this condition as of December 31, 2022 and recorded a receivable on the consolidated balance sheets for the year then ended. Medtronic provided full payment in January 2023.

Accounts receivable recorded on the consolidated balance sheets for the years ended December 31, 2022 and 2021 consists of the following (in thousands):

	December 31, 2022	December 31, 2021
Trade accounts receivable	$ 4,085	$ 3,633
Transfer earnout receivable	17,000	—
Total accounts receivable	$ 21,085	$ 3,633

Employee Retention Credit Receivable

The Employee Retention Credit is a refundable U.S. tax credit separate from tax based on income for businesses that continued to pay employees while shut down due to the COVID-19 pandemic or had significant declines in gross receipts from March 13, 2020 to December 31, 2021. The Company is an eligible employer qualifying under the program, applied for the tax credit in 2022 and is expecting receipt in the early part of 2023.

Property and Equipment, Net

Property and equipment is recorded at cost. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets, generally three to five years, or, in the case of leasehold improvements, over the lesser of the useful life of the related asset or the lease term.

Intangible Assets

Intangible assets consist of acquired developed technology and customer-related intangible assets acquired as part of the acquisition of Rhythm Xience. The Company's intangible assets also include a license agreement with Biotronik. The Company determines the appropriate useful life of its finite-lived intangible assets by performing an analysis of expected cash flows of the acquired assets. Finite-lived intangible assets are amortized over their estimated useful lives using the straight-line method, which approximates the pattern in which the economic benefits are consumed. Acquired in-process technology is classified as a finite-lived intangible and amortized accordingly. Indefinite-lived intangible assets are tested for impairment at least annually and are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Indefinite-lived intangible assets are impaired if their estimated fair values are less than their carrying value. During the year ended December 31, 2022, the Company disposed of intangible assets related to the sale of the left-heart access business to Medtronic. These intangible assets consisted of its developed technology and its customer-related intangible assets. See *Note 4 - Sale of Business* and *Note 9 - Goodwill and Intangible Assets* for additional details.

Goodwill

Goodwill represents the excess of the purchase price of an entity over the estimated fair value of the assets acquired and liabilities assumed. Under ASC 350, *Intangibles – Goodwill and Other* ("ASC 350"), goodwill is not amortized but is subject to periodic impairment testing. ASC 350 requires that an entity assign its goodwill to reporting units and test each reporting unit's goodwill for impairment at least on an annual basis and between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount. In the evaluation of goodwill for impairment, which is performed annually during the fourth quarter, the Company first assesses qualitative factors to determine whether the existence of events or circumstances led to a determination that it was more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, it is determined that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, the Company is required to perform a quantitative goodwill impairment test. The Company could also elect to perform a quantitative impairment test without first assessing qualitative factors. For the year ended December 31, 2021, the quantitative testing indicated no impairment for the carrying amount of goodwill.

For the year ended December 31, 2022, the Company identified a triggering event prior to its annual assessment and determined a quantitative goodwill impairment test was required. The test indicated the fair value of goodwill recorded on the Company's consolidated balance was zero. Consequently, the Company fully impaired the carrying amount of $12.0 million and recorded a corresponding charge on the consolidated statements of operations and comprehensive loss. Refer to *Note 9 - Goodwill and Intangible Assets* for additional details.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment and finite-lived intangible assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss is recognized when the asset's carrying value exceeds the total undiscounted cash flows expected from its use and eventual disposition. The amount of the impairment loss is determined as the excess of the carrying value of the asset over its fair value. For the years ended December 31, 2022 and 2021, the Company determined that there was no impairment of property and equipment or intangible assets other than goodwill.

Foreign Currency Translation and Transactions

The assets, liabilities and results of operations of Acutus NV are recorded using the Euro as the designated functional currency, which is the currency of the primary economic environment in which Acutus NV operates. Consequently, transactions in currencies other than Euro are measured and recorded in Euro. Upon consolidation with the Company, its assets and liabilities are translated to U.S. dollars at currency exchange rates as of the balance sheet date and its revenues and expenses are translated at the weighted-average currency exchange rates during the applicable reporting periods. Translation adjustments resulting from the process of translating this entity's financial statements are reported in accumulated other comprehensive income (loss) in the

consolidated balance sheets and foreign currency translation adjustment in the consolidated statements of operations and comprehensive loss.

Lease Property

The Company leases office space in Carlsbad, CA as its corporate headquarters and for manufacturing operations. Additionally, it leases office space in Zaventem, Belgium for international operations. The Company accounts for its lease property under ASC 842. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases, and are recorded on the consolidated balance sheet as both a right-of-use asset and a lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate, which is the rate for collateralized borrowings based on the current economic environment, credit history, credit rating, value of leases, currency in which the lease obligation is satisfied, rate sensitivity, lease term and materiality. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset results in straight-line rent expense over the lease term. Variable lease expenses are recorded when incurred.

In calculating the right-of-use asset and lease liability, the Company elected to combine lease and non-lease components. The Company adopted the policy election to exclude short-term leases having initial terms of twelve months from the initial recognition provisions of ASC 842. See *Note 12 - Operating leases* for additional details.

Cost of Products Sold

Cost of products sold includes raw materials, direct labor, manufacturing overhead, shipping and receiving costs and other less significant indirect costs related to the production of the Company's products.

Research and Development

The Company is actively engaged in new product research and development efforts. Research and development expenses consist primarily of salaries and employee-related costs (including stock-based compensation) for personnel directly engaged in research and development activities, clinical trial expenses, equipment costs, material costs, allocated rent and facilities costs and depreciation.

Research and development expenses relating to possible future products are expensed as incurred. The Company also accrues and expenses costs for activities associated with clinical trials performed by third parties as incurred. All other costs relative to setting up clinical trial sites are expensed as incurred. Clinical trial site costs related to patient enrollment are accrued as patients are entered into the trials.

Selling, General and Administrative

SG&A consist primarily of salaries and employee-related costs (including stock-based compensation) for personnel in sales, executive, finance and other administrative functions, allocated rent and facilities costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services, marketing costs and insurance costs. The Company expenses all SG&A costs as incurred.

Fair Value Measurements

Financial Instruments

Fair value measurements are based on the premise that fair value is an exit price representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the following three-tier fair value hierarchy is used in determining the inputs for measuring fair value:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3—Unobservable inputs which are supported by little or no market activity and consist of financial instruments valued using pricing models, discounted cash flow methodologies or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. Management's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed or initial amounts recorded may not be indicative of the amount that the Company or holders of the instruments could realize in a current market exchange. There were no transfers made among the three levels in the fair value hierarchy for the years ended December 31, 2022 and 2021.

As of December 31, 2022 and 2021, the Company's cash (excluding cash equivalents which are recorded at fair value on a recurring basis), restricted cash, accounts receivable, accounts payable and accrued expenses were carried at cost, which approximates the fair values due to the short-term nature of each instrument. The carrying amount of the Company's long-term debt approximates fair value due to its variable market interest rate and management's opinion that current rates and terms that would be available to the Company with the same maturity and security structure would be essentially equivalent to that of the Company's long-term debt.

The following tables classify the Company's financial assets and liabilities measured at fair value on a recurring basis into the fair value hierarchy as of December 31, 2022 and 2021 (in thousands):

As of December 31, 2022	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets included in:				
Cash and cash equivalents				
Money market securities	$ 22,700	$ —	$ —	$ 22,700
Marketable securities at fair value				
U.S. treasury securities	—	26,897	—	26,897
Commercial paper	—	14,764	—	14,764
Yankee debt securities	—	3,202	—	3,202
Total fair value	$ 22,700	$ 44,863	$ —	$ 67,563
Liabilities included in:				
Warrant liability	$ —	$ —	$ 3,346	$ 3,346
Contingent consideration	—	—	1,800	1,800
Total fair value	$ —	$ —	$ 5,146	$ 5,146

As of December 31, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets included in:				
Cash and cash equivalents				
Money market securities	$ 21,893	$ —	$ —	$ 21,893
Marketable securities at fair value				
Corporate debt securities	—	18,860	—	18,860
U.S. treasury securities	—	5,064	—	5,064
Commercial paper	—	36,759	—	36,759
Yankee debt securities	—	3,932	—	3,932
Supranational	—	3,051	—	3,051
Asset-backed securities	—	16,156	—	16,156
Total fair value	$ 21,893	$ 83,822	$ —	$ 105,715
Liabilities included in:				
Contingent consideration	$ —	$ —	$ 2,000	$ 2,000
Total fair value	$ —	$ —	$ 2,000	$ 2,000

The fair value of the Company's money market funds is determined using quoted market prices in active markets for identical assets.

The fair value for the available-for-sale marketable securities is determined based on valuation models using inputs that are observable either directly or indirectly (Level 2 inputs) such as quoted prices for similar assets, yield curve, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instruments, broker and dealer quotes, as well as other relevant economic measures.

Financial Obligations

The following table presents changes in Level 3 liabilities measured at fair value for the years ended December 31, 2022 and 2021 (in thousands):

	Contingent Consideration	Warrant Liability
Balance, December 31, 2020	$ 9,300	
Payment of contingent consideration	(3,435)	
Escrow release [1]	(119)	
Change in fair value	(3,746)	
Balance, December 31, 2021	$ 2,000	$ —
Payment of contingent consideration	(872)	—
Escrow release [1]	(381)	—
Issuance of common stock warrants [2]	—	3,313
Change in fair value	1,053	33
Balance, December 31, 2022	$ 1,800	$ 3,346

[1] As part of the Rhythm Xience acquisition (see *Note 3 - Asset Acquisition and Business Combination)*, the first $0.5 million earned related to revenue success payments was paid at the end of the first month following the end of the quarter in which the revenue success payments were earned, into an escrow account until the expiration of an additional 18 month hold-back period commencing with the end of the quarter during which such revenue success payment amounts were earned. Amounts noted above were released from the escrow account.

[2] Common stock warrants issued to lenders under the 2022 Credit Agreement (see *Note 11 - Debt* and *Note 14 - Warrants*).

Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs.

Contingent Consideration

The fair value of the contingent consideration from the acquisition of Rhythm Xience represents the estimated fair value of future payments due to the sellers of Rhythm Xience based on the achievement of certain milestones and revenue-based targets in certain years. The initial fair value of the revenue-based contingent consideration was calculated through the use of a Monte Carlo simulation using revenue projections for the respective earn-out period, corresponding targets and approximate timing of payments as outlined in the purchase agreement. The analyses used the following assumptions: (i) expected term; (ii) risk-adjusted net sales; (iii) risk-free interest rate; and (iv) expected volatility of net sales (see table below). Estimated payments as determined through the respective model were further discounted by a credit spread assumption to account for credit risk. The fair value of the milestones-based contingent consideration was determined by probability weighting and discounting to the respective valuation date at the Company's cost of debt. The Company's cost of debt was determined by performing a synthetic credit rating for the Company and selecting yields based on companies with a similar credit rating. The contingent consideration is revalued to fair value each period on the consolidated balance sheets, and any increase or decrease is recorded on the consolidated statements of operations and comprehensive loss. The fair value of the contingent consideration may be impacted by certain unobservable inputs, most significantly with regard to discount rates, expected volatility and historical and projected performance. Significant changes to these inputs in isolation could result in a significantly different fair value measurement.

The weighted-average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the contingent consideration from the acquisition of Rhythm Xience as of December 31, 2022 and December 31, 2021 were as follows:

	December 31, 2022	December 31, 2021
Risk-free interest rate	4.8%	0.6%
Expected term in years	1.0 - 2.0	1.0 - 2.0
Expected volatility	28.0%	28.8%

Warrants

As of December 31, 2022, the fair value of the common stock warrants was estimated using the Black-Scholes option pricing model. The fair value was estimated to be $0.8853 per warrant as of December 31, 2022 and the significant inputs used in the estimation of the fair value were as follows:

Risk-free interest rate	3.96%
Expected term in years	7.5
Expected volatility	80.0%

Stock-Based Compensation

The Company accounts for all stock-based payments to employees and non-employees, including grants of stock options, RSU, and RSAs, to be recognized in the consolidated financial statements based on their respective grant date fair values. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. The RSUs and RSAs, are valued based on the fair value of the Company's common stock on the date of grant. The Company expenses stock-based compensation related to stock options, RSUs and RSAs over the requisite service period. All stock-based compensation costs are recorded in cost of products sold, research and development expense or SG&A expense in the consolidated statements of operations and comprehensive loss based upon the respective employee's or non-employee's roles within the Company. Forfeitures are recorded as they occur. See *Note 16—Stock-Based Compensation* for additional details.

Income Taxes

Income taxes are recorded in accordance with ASC 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse, and NOL carryforwards and R&D tax

credit carryforwards. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits. See *Note 19—Income Taxes* for additional details.

Warrant Liability

The Company accounts for certain common stock warrants outstanding as a liability at fair value, determined using the Black-Scholes option pricing model, on the consolidated balance sheets in accordance with ASC 815, *Derivatives and Hedging* ("ASC 815"). The liability is subject to re-measurement at each reporting period and any change in fair value is recognized in the consolidated statements of operations and comprehensive loss. See *Note 14—Warrants* for additional details.

Business Combinations

The Company accounts for business acquisitions using the acquisition method of accounting based on ASC 805, *Business Combinations* ("ASC 805"), which requires recognition and measurement of all identifiable assets acquired and liabilities assumed at their fair value as of the date control is obtained. The Company determines the fair value of assets acquired and liabilities assumed based upon its best estimates of the acquisition-date fair value of assets acquired and liabilities assumed in the acquisition. Goodwill is calculated as the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired. See *Note 3 - Asset Acquisition and Business Combination* for additional details.

Recently Adopted Accounting Pronouncements

In May 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2021-05, *Leases (Topic 842), Lessors – Certain Leases with Variable Lease Payments* ("ASU 2021-05"), which clarifies that lessors should classify and account for a lease with variable lease payments that do not depend on a reference index or a rate as an operating lease. This ASU is effective for smaller reporting companies in 2022. The Company adopted ASU 2021-05 in the first quarter of 2022 with no material impact on the consolidated financial statements.

In April 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt Modifications and Extinguishments (Subtopic 470-50), Compensation Stock Compensation (Topic 718), and Derivatives and Hedging Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2021-04"), which provides clarification on how to account for a modification or exchange of free-standing equity-classified written call options that remain equity classified after the modification or exchange. ASU 2021-04 is effective for smaller reporting companies in 2022. The Company adopted the guidance in the first quarter of 2022 with no material impact on the consolidated financial statements.

Accounting Pronouncements to Be Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)* ("ASU 2016-13"). ASU 2016-13 sets forth a "current expected credit loss" model which requires the Company to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost, available-for-sale debt securities and applies to certain off-balance sheet credit exposures. ASU 2016-13 is effective for smaller reporting companies in 2023. The Company is currently assessing the impact of the adoption of ASU 2016-13 on the consolidated financial statements, however it has recognized no credit losses since inception and expects the adoption to have minimal, if any, impact.

Note 3—Asset Acquisition and Business Combination

Biotronik Asset Acquisition

In July 2019, the Company entered into a License and Distribution Agreement with Biotronik and VascoMed GmbH (collectively, the "Biotronik Parties") whereby the Company acquired certain manufacturing equipment and obtained a license under certain patents and technology to develop, commercialize, distribute and manufacture the AcQBlate FORCE ablation catheters and Qubic Force Device. In accordance with ASC 805, the Biotronik Asset Acquisition was accounted for as an asset

acquisition, as substantially all of the $15.0 million value transferred to Biotronik was allocated to intellectual property and charged to research and development expense - license acquired in the consolidated statements of operations and comprehensive loss.

The agreement provides for additional milestone payments of up to $10.0 million contingent upon certain regulatory approvals and first commercial sale, of which $2.0 million has been paid as of December 31, 2022. upon regulatory approval of the Company's force sensing ablation catheter in Europe. The Company determined that payment of the remaining $8.0 million of contingent milestones is not probable and estimable, and therefore the potential liability is not recorded as of December 31, 2022 and December 31, 2021.

In further consideration of the rights granted, beginning with the Company's first commercial sale of the first force sensing ablation catheter within the licensed product line, the agreement specifies per-unit royalty payments to the Biotronik Parties. As sales of catheters are recognized, royalties are recorded as cost of products sold on the statements of operations and comprehensive loss. As of December 31, 2022, less than $0.1 million has been included within accrued liabilities for these royalties.

Rhythm Xience Business Combination

On June 18, 2019, the Company acquired an integrated family of transseptal crossing and steerable introducer systems through its acquisition of Rhythm Xience for $3.0 million in cash in exchange for all of the stock of Rhythm Xience (the "Rhythm Xience Acquisition"). The purchase agreement included a potential of $17.0 million in earn-out consideration to be paid based on the achievement of certain regulatory milestones and revenue milestones, of which $7.2 million has been paid as of December 31, 2022. In accordance with ASC 805, the Rhythm Xience Acquisition was accounted for as a business combination.

Additionally as part of the Rhythm Xience Acquisition, the Company recorded a contingent consideration liability of $13.4 million for potential payments if certain regulatory approval and revenue milestones are achieved. During the year ended December 31, 2020, the Company issued 119,993 shares of Series D convertible preferred stock (since converted to common stock) and paid $2.5 million of contingent consideration. The Company paid $0.9 million and $3.4 million of contingent consideration in the years ended December 31, 2022 and 2021, respectively.

The contingent consideration liability is recorded on the consolidated balance sheets at fair value. For the years ended December 31, 2022 and 2021, the Company recorded a $1.1 million increase and $3.7 million decrease, respectively, for the change in fair value of contingent consideration in the consolidated statements of operations and comprehensive loss. As of December 31, 2022, the fair value of the contingent consideration liability on the consolidated balance sheets is $1.8 million.

Note 4—Sale of Business

On June 30, 2022, the Company completed the First Closing in accordance with the Asset Purchase Agreement with Medtronic, pursuant to which the Company agreed to sell to Medtronic certain transseptal access and sheath assets which make up the Company's left-heart access portfolio (and which comprised the Rhythm Xience product line acquired as part of the Rhythm Xience Acquisition). The assets transferred to Medtronic upon the First Closing (the "Assets") include patents, trademarks, patent and trademark applications, know-how, copyrights, prototypes and other intellectual property owned or licensed by the Company, business records and documents (including regulatory and clinical materials) and manufacturing equipment related to the AcQCross® line of sheath-compatible septal crossing devices, AcQGuide® MINI integrated crossing device and sheath, AcQGuide® FLEX Steerable Introducer with integrated transseptal dilator and needle and AcQGuide® VUE steerable sheaths .

Pursuant to the Asset Purchase Agreement, Medtronic paid $50.0 million at the First Closing, of which $4.0 million was paid into an indemnity escrow account for a period of 18 months following the First Closing to secure indemnification obligations of the Company under the Asset Purchase Agreement and recorded as restricted cash on the consolidated balance sheets as of December 31, 2022.

The Company is also eligible to receive the following contingent cash consideration pursuant to the Asset Purchase Agreement:

(i) $20.0 million upon its completion, to the reasonable satisfaction of Medtronic, of certain conditions set forth in the Asset Purchase Agreement relating to the Company becoming a qualified supplier of Medtronic for the Products, including demonstration of ISO 14971:2019 compliance, completion of certain test method validations and compliance with certain other reporting requirements (the "OEM Earnout");

(ii) $17.0 million upon the earlier of (A) the Second Closing or (B) the Company's initial submission for CE Mark certification of the Products under the European Union Medical Devices Regulation to the reasonable satisfaction of a third-party regulatory consultant, subject to certain other conditions as set forth in the Asset Purchase Agreement; and

(iii) amounts equal to 100%, 75%, 50% and 50%, respectively, of quarterly Net Sales (as defined in the Asset Purchase Agreement) from sales of the Products achieved by Medtronic over each year over four years beginning on the first full quarter after Medtronic's first commercial sale of a Product and achievement of the OEM Earnout.

The $20.0 million OEM Earnout was achieved on October 31, 2022 and payment was received in November 2022, of which $1.6 million is held in escrow and recorded as restricted cash on the consolidated balance sheets. The $17.0 million Transfer Earnout was achieved as of December 31, 2022 and recorded as a receivable on the consolidated balance sheets. Payment was received from Medtronic on January 14, 2023. No amounts under item (iii) were earned or received as of December 31, 2022.

With the achievement of the OEM Earnout Conditions (as defined in the Asset Purchase Agreement) and upon notice from Medtronic, Medtronic became the Company's exclusive distributor of the Products under the Distribution Agreement in connection with the Asset Purchase Agreement.

The Company recorded the following amounts in 2022, resulting in a net gain of $79.5 million related to the sale of business to Medtronic, calculated as the difference between the non-contingent consideration received, less direct transaction costs and the net carrying amount of the assets sold (in thousands):

Non-contingent cash consideration received under the First Closing	$	50,000
OEM Earnout received in November 2022		20,000
Transfer Earnout accrued as of December 31, 2022 and received in January 2023		17,000
Property and equipment sold, net		(498)
Intangible assets sold, net		(3,010)
Transaction costs		(4,027)
Gain on sale of business	$	79,465

The sale was accounted for as a derecognition of a group of assets that is a business pursuant to ASC 810 - *Consolidation*, with the resulting gain classified as operating income within loss from operations on the consolidated statements of operations and comprehensive loss. The sale does not represent a strategic shift having a major effect on the Company's operations and financial results and, consequently, does not qualify as a discontinued operation.

Note 5—Marketable Securities

Marketable securities consist of the following as of December 31, 2022 and 2021 (in thousands):

December 31, 2022	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale securities - short-term:				
U.S. treasury securities	$ 26,906	$ 3	$ (12)	$ 26,897
Commercial paper	3,200	2	—	3,202
Yankee debt securities	14,764	—	—	14,764
Total available-for-sale securities - short-term	44,870	5	(12)	44,863
Total available-for-sale securities	$ 44,870	$ 5	$ (12)	$ 44,863

December 31, 2021	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale securities - short-term:				
Corporate debt securities	$ 15,786	$ —	$ (6)	$ 15,780
U.S. treasury securities	5,073	—	(9)	5,064
Commercial paper	36,759	—	—	36,759
Yankee debt securities	3,941	—	(9)	3,932
Supranational	3,054	—	(3)	3,051
Asset-backed securities	12,128	—	(12)	12,116
Total available-for-sale securities - short-term	76,741	—	(39)	76,702
Available-for-sale securities - long-term				
Corporate debt securities	3,082	—	(2)	3,080
Asset-backed securities	4,044	—	(4)	4,040
Total available-for-sale securities - long-term	7,126	—	(6)	7,120
Total available-for-sale securities	$ 83,867	$ —	$ (45)	$ 83,822

As of December 31, 2022, the Company's available-for-sale securities classified as short-term of $44.9 million mature in 1 year or less and there were none held long-term. As of December 31, 2021, the Company's available-for-sale securities classified as short-term of $76.7 million were to mature in 1 year or less and the available-for-sale securities classified as long-term of $7.1 million were to mature within 2 years.

Note 6—Inventory

Inventory as of December 31, 2022 and 2021 consists of the following (in thousands):

	December 31, 2022	December 31, 2021
Raw materials	$ 9,179	$ 6,779
Work in process	2,025	1,772
Finished goods	2,123	7,857
Total inventory	$ 13,327	$ 16,408

Inventory is recorded net of write-downs and manufacturing scrap of $3.8 million and $1.3 million for the years ended December 31, 2022 and 2021.

Note 7—Lessor Sales-Type Leases

The Company recognizes revenue and costs, as well as a lease receivable, at the commencement of embedded sales-type leases within its deferred equipment agreements. Lease revenue related to sales-type leases was $0.3 million and $1.2 million for the years ended December 31, 2022 and 2021, respectively, and is included within revenue in the consolidated statements of operations and comprehensive loss. Costs related to embedded leases within the Company's deferred equipment agreements are included in cost of products sold in the consolidated statements of operations and comprehensive loss.

As of December 31, 2022 and 2021, a balance of $0.6 million and $0.9 million, respectively, is recorded for short-term leases receivable in prepaid expenses and other current assets on the consolidated balance sheets, and a balance of $0.5 million and $0.7 million, respectively, for long-term lease receivable is recorded in other assets related to sales-type leases .

The following table is an estimation of maturities of customer sales-type lease receivables for each of the following years as of December 31, 2022 (in thousands):

Year ending December 31, 2023	$ 616
Year ending December 31, 2024	368
Year ending December 31, 2025	127
Total maturities of customer sales-type leases	$ 1,111

Note 8—Property and Equipment, Net

The following table summarizes the Company's property and equipment, net, as of December 31, 2022 and 2021 (in thousands):

	December 31, 2022	December 31, 2021
Medical diagnostic equipment	$ 14,826	$ 16,759
Furniture and fixtures	432	433
Office equipment	1,556	1,538
Laboratory equipment and software	5,148	5,302
Leasehold improvements	580	582
Construction in process	2,166	958
Total property and equipment	24,708	25,572
Less: accumulated depreciation	(15,487)	(11,902)
Property and equipment, net	$ 9,221	$ 13,670

Property and equipment includes certain medical diagnostic equipment and AcQMap Systems located at customer premises. The Company retains ownership of the equipment and has the right to remove the equipment if it is not being used according to expectations. The Company records the cost of equipment to cost of sales on the consolidated statements of operations and comprehensive loss when it is subsequently sold or the Company enters into a sales-type lease agreement. See *Note 7—Lessor Sales-Type Leases* for additional details.

Depreciation expense was $6.1 million and $5.8 million for the years ended December 31, 2022 and 2021, respectively.

Note 9—Goodwill and Intangible Assets

The following table presents goodwill and intangible assets activity during the years ended December 31, 2022 and 2021 (in thousands):

	Goodwill	Intangible Assets
Balance, December 31, 2020	$ 12,026	$ 5,653
Amortization expense	—	(640)
Balance, December 31, 2021	12,026	5,013
Amortization Expense	—	(420)
Impairment	(12,026)	—
Intangible assets disposed in sale [(1)]	—	(3,010)
Balance, December 31, 2022	$ —	$ 1,583

[(1)] Intangible assets were reduced by $3.0 million related to the sale of business to Medtronic. See *Note 4 - Sale of Business*.

Goodwill Impairment

During the first quarter of 2022, the Company experienced a significant decline in stock price which reduced the market capitalization below the carrying value of the Company. The Company performed a quantitative assessment of the fair value of its reporting unit. The assessment used a combination of quoted market prices as well as present value calculations which included both the income and market approach. Based on the assessment, the Company concluded that the fair value of the reporting unit was less than its carrying amount by an amount that resulted in the Company fully impairing its goodwill balance of $12.0 million during the year ended December 31, 2022.

Intangible Assets

The tables below present the details of intangible assets as of December 31, 2022 and 2021 (dollars in thousands):

December 31, 2022	Estimated Useful Life (in years)	Weighted Average Remaining Life (in years)	Intangible Assets	Accumulated Amortization	Balance
Licensed intangibles	10.0	7.9	$ 2,000	$ (417)	$ 1,583
Total intangible assets			$ 2,000	$ (417)	$ 1,583

December 31, 2021	Estimated Useful Life (in years)	Weighted Average Remaining Life (in years)	Intangible Assets	Accumulated Amortization	Balance
Developed technology	10	7.6	$ 4,200	$ (1,020)	$ 3,180
Customer-related intangible	5	2.5	100	(50)	50
Licensed intangibles	10	8.9	2,000	(217)	1,783
Total intangible assets			$ 6,300	$ (1,287)	$ 5,013

The Company recorded amortization expense related to intangible assets of $0.4 million and $0.6 million for the years ended December 31, 2022 and 2021, respectively. For the years ended December 31, 2022 and 2021, the Company determined that there was no impairment of intangible assets. Developed technology and customer related intangibles were disposed during the year ended December 31, 2022 as part of the sale to Medtronic. See *Note 4 - Sale of Business* for additional details.

The following table presents the future amortization expense associated with amortizable intangible assets as of December 31, 2022 (in thousands):

Year ending December 31, 2023	$ 200
Year ending December 31, 2024	200
Year ending December 31, 2025	200
Year ending December 31, 2026	200
Year ending December 31, 2027	200
Thereafter	583
Total future amortization	$ 1,583

Note 10—Accrued Liabilities

The following table presents details of accrued liabilities as of December 31, 2022 and 2021 (in thousands):

	December 31, 2022	December 31, 2021
Compensation and related expenses	$ 6,919	$ 7,088
Professional fees	126	158
Deferred revenue	326	401
Sales and use tax	639	71
Clinical studies	390	541
Clinician Council payable	216	358
Accrued royalties	159	129
Accrued restructuring	45	—
Other	866	350
Total accrued liabilities	$ 9,686	$ 9,096

Note 11—Debt

Outstanding debt as of December 31, 2022 and 2021 consists of the following (in thousands):

	December 31, 2022	December 31, 2021
2022 Credit Agreement [1]	$ 36,776	$ —
2019 Credit Agreement [2]	—	44,550
Total outstanding debt under credit agreements	36,776	44,550
Less: Unamortized debt discount and fees	(2,342)	(4,135)
Total outstanding debt, long-term	$ 34,434	$ 40,415

[1] The 2022 Credit Agreement includes final payment fees of $1.8 million.

[2] The 2019 Credit Agreement includes final payment fees of $4.6 million

2019 Credit Agreement

On May 20, 2019, the Company entered into the 2019 Credit Agreement which provided the Company with a senior term loan facility in aggregate principal amount of $70.0 million, of which the Company borrowed $40.0 million upon closing. The 2019 Credit Agreement bore interest per annum at LIBOR plus 7.75% and the principal amount of the obligation was due on May 20, 2024. The 2019 Credit Agreement provided for final payment fees of an additional $4.6 million due upon prepayment, upon the maturity date or upon acceleration.

In connection with the issuance of the 2019 Credit Agreement, the Company issued liability-classified warrants (the "2019 Warrants") with a fair value of $0.9 million to purchase 419,992 shares of Series C convertible preferred stock at $16.67 per share. These warrants were subsequently automatically converted into warrants to purchase an equal number of shares of the Company's Series D convertible preferred stock at $16.67 per share and were automatically converted into warrants to purchase an equal number of shares of common stock at $16.67 per share.

The Company's obligations under the 2019 Credit Agreement were secured by substantially all of its assets, including its intellectual property, and was guaranteed by Acutus NV. The 2019 Credit Agreement contained customary affirmative and negative covenants, including with respect to the Company's ability to enter into fundamental transactions, to incur additional indebtedness, to grant liens, to pay dividends or to make distributions to its holders, to make investments and to merge or consolidate with any other person or engage in transactions with its affiliates, but did not include any financial covenants other than a minimum liquidity requirement.

On June 30, 2022, the 2019 Credit Agreement was modified and resulted in an extinguishment of the debt. This transaction resulted in a loss on extinguishment of $7.9 million. See *2022 Credit Agreement* section below for more details.

2022 Credit Agreement

On June 30, 2022, the Company amended and restated the 2019 Credit Agreement. The 2022 Credit Agreement is with new lenders consisting of certain affiliates of Deerfield Management Company and is for an aggregate principal amount of $35.0 million with a five-year term. Proceeds from the 2022 Credit Agreement, along with cash on hand, were used to repay the 2019 Credit Agreement and to pay related fees and expenses.

The 2022 Credit Agreement bears an annual interest of 9% plus the one-month adjusted term Secured Overnight Financing Rate (applying a 2.5% minimum rate). From date of closing, amortization payments are due as follows:

- 15% of the principal due at the end of month 36;
- 15% of the principal due at the end of month 48; and
- 70% due at the end of month 60.

The 2022 Credit Agreement is subject to prepayment penalties. The 2022 Credit Agreement provides for final payment fees of an additional $1.8 million due upon prepayment, on the maturity date or upon acceleration.

The 2022 Credit Agreement is secured by a first-priority perfected lien on and security interest in substantially all of the Company's existing and after-acquired tangible and intangible assets, subject to certain exceptions noted in the 2022 Credit Agreement.

The 2022 Credit Agreement is subject to certain customary affirmative covenants, representations and warranties and other terms and conditions. It contains certain customary negative covenants including, but not limited to, restrictions on the Company's ability and that of its subsidiaries to merge and consolidate with other companies, to incur indebtedness, to grant liens or security interests on assets, to pay dividends or make other restricted payments, to sell or otherwise transfer assets or to enter into transactions with affiliates. As of and for the year ended December 31, 2022, the Company was in compliance with all such covenants.

In addition, the 2022 Credit Agreement includes customary events of default and other provisions that could require all amounts due thereunder to become immediately due and payable, either automatically or at the option of the lenders, if the Company fails to comply with terms.

In connection with entering into the 2022 Credit Agreement, the Company entered into the 2022 Warrant Purchase Agreement with Deerfield, pursuant to which the Company issued to Deerfield warrants to purchase up to an aggregate 3,779,018 shares of common stock at an exercise price of $1.1114 per warrant share for a period of eight years following issuance.

The 2022 Warrants represent a freestanding financial instrument and are conditionally puttable at the holder's option upon an event that is outside of the Company's control. Therefore, the 2022 Warrants are classified as liability pursuant to ASC 480, *Distinguishing Liabilities from Equity*, initially and subsequently recognized at fair value, with changes in fair value recognized in the Company's statement of operations and comprehensive loss. Refer to Fair Value Measurements in *Note 2 - Summary of Significant Accounting Policies* and *Note 14 - Warrants* for more information.

Note 12—Operating Leases

The Company leases approximately 50,800 square feet of office space for its corporate headquarters and manufacturing facility in Carlsbad, California under a noncancelable operating lease that expires on December 31, 2027. The lease is subject to variable charges for common area maintenance and other costs that are determined annually based on actual costs. The base rent is subject to an annual increase each year. The Company has a renewal option for an additional five-year term upon the expiration date of the lease, which has been excluded from the calculation of the right-of-use asset as it is not reasonably certain to be exercised.

Additionally, the Company leases approximately 3,900 square feet of office space in Zaventem, Belgium under a noncancelable operating lease that expires on December 31, 2024. The lease is subject to variable charges that are determined annually for common area maintenance and other costs based on actual costs, and base rent is subject to an annual increase each year based on an index rate.

The following table summarizes quantitative information of the Company's operating leases for the years ended December 31, 2022 and 2021 (dollars in thousands):

	Year Ended December 31,	
	2022	2021
Cash flows from operating leases	$ 898	$ 853
Weighted average remaining lease term - operating leases	4.9 years	3.6 years
Weighted average discount rate – operating leases	7.0%	7.0%

The following table provides the components of the Company's operating lease expense for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
Operating lease cost	$ 1,013	$ 950
Variable lease cost	293	325
Total operating lease expense	$ 1,306	$ 1,275

The following table presents the future minimum payments under the non-cancelable operating leases as of December 31, 2022 (in thousands):

Year ending December 31, 2023	$	618
Year ending December 31, 2024		1,166
Year ending December 31, 2025		1,151
Year ending December 31, 2026		1,185
Year ending December 31, 2027		1,221
Total future minimum operating lease payments		5,341
Less: imputed interest		(919)
Total operating lease liability	$	4,422

Note 13—Commitments and Contingencies

The Company and certain of its current and former officers have been named as defendants in two putative securities class action lawsuits filed in the United States District Court for the Southern District of California on February 14, 2022 and March 23, 2022. On July 19, 2022, the court consolidated the two actions, appointed a lead plaintiff and appointed lead counsel for the proposed class. On September 16, 2022, the lead plaintiff filed a consolidated amended complaint. The defendant thereafter filed a motion to dismiss. Due to the complex nature of the legal and factual issues involved in these class action matters, the outcome is not presently determinable and any loss is neither probable nor reasonably estimable.

Note 14—Warrants

As of December 31, 2022 and 2021, the outstanding warrants to purchase the Company's common stock consist of the following:

	Exercise Price	Expiration Date	Warrants Outstanding as of December 31, 2022	Warrants Outstanding as of December 31, 2021
Warrants issued in 2015	$5.25	01/30/2025	3,808	3,808
Warrants issued with 2018 Convertible Notes	$0.10	06/07/2028	346,689	346,689
Warrants issued with 2018 Term Loan	$16.67	07/31/2028	26,998	26,998
2019 Warrants	$16.67	05/20/2029	419,992	419,992
2022 Warrants	$1.11	6/30/2030	3,779,018	—
Total warrants outstanding			4,576,505	797,487

The Company's warrant activity for the years ended December 31, 2022 and 2021 is as follows:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Balance - December 31, 2020	824,608	$9.10	7.9
Exercised, net	(26,958)	$0.10	6.2
Shares withheld for exercise price	(163)	$0.10	6.2
Balance - December 31, 2021	797,487	$9.41	5.9
Granted	3,779,018	$1.11	7.5
Balance - December 31, 2022	4,576,505	$2.56	7.2

The Company's warrants provide the holder the option to purchase a specified number of shares for a specified price within a specified duration or upon the occurrence of a specific event. The holder may exercise the warrant either by cash payment or by exercise pursuant to a cashless exercise whereby a calculated number of shares are withheld upon exercise to satisfy the exercise price. The warrants do not provide the holder any voting rights until the warrants are exercised.

In accordance with ASC 480, the 2022 Warrants are recorded at fair value on the consolidated balance sheets as a warrant liability. Changes in fair value are recognized as a change in fair value of warrant liability on the consolidated statements of operations and comprehensive loss. For the year ended December 31, 2022, the Company recognized a favorable change in fair value that was not material.

In connection with the Series A Common Equivalent Preferred Stock Exchange Agreements, four warrant holders are limited to exercising their warrants such that following any such exercise, the number of shares of common stock beneficially owned by such holder cannot exceed 4.9% of the outstanding common stock of the Company (two of the holders may, at their option and upon sufficient prior written notice to the Company, increase such percentage to 9.9%). In the event the common share limit has been met and the holder chooses to exercise their warrants, the holder can sell any common stock they hold. Therefore, the amendment to the warrant agreements does not restrict the holder from fully exercising the warrants under the original terms of the warrant agreements. See *Note 15 - Stockholders' Equity* for additional details.

Note 15—Stockholders' Equity

Common Stock

In July 2021, the Company issued 6,325,000 shares of common stock in a public offering, which included 825,000 shares of common stock issued upon the underwriter's exercise in full of an option to purchase additional shares of common stock. The price to the public for each share was $14.00 providing gross proceeds of $88.6 million. Net of underwriting discounts, commission and other offering expenses, the Company received $82.7 million from the offering.

During the year ended December 31, 2022 and 2021, stock options to acquire 35,478 shares and 111,804 shares, respectively, were exercised for shares of the Company's common stock with proceeds of $0.1 million and $0.7 million, respectively. Additionally in conjunction with the 2020 Employee Stock Purchase Plan, during the year ended December 31, 2022 and 2021 149,327 shares and 33,641 shares, respectively, of common stock were issued for consideration of $0.2 million and $0.4 million, respectively. During the year ended December 31, 2022 and 2021, the Company issued 412,628 shares and 134,050 shares, respectively, of common stock upon vesting of RSUs, and the Company issued no shares and 186 shares, respectively, of common stock for RSAs. See *Note 16 - Stock-Based Compensation* for additional details.

Series A Common Equivalent Preferred Stock

In August 2021, the Company entered into exchange agreements (the "Exchange Agreements") with four investors pursuant to which the investors exchanged 6,665,841 shares of the Company's common stock for 6,666 shares of a new series of non-voting convertible preferred stock of the Company designated as "Series A Common Equivalent Preferred Stock," par value $0.001 per share (the "Preferred Stock"). In connection with the issuance of the Preferred Stock pursuant to the Exchange Agreements, on August 23, 2021, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of the Series A Common Equivalent Preferred Stock of the Company with the Secretary of State of the State of Delaware. The Preferred Stock ranks senior to the common stock with respect to rights on the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company, having a liquidation preference equal to its par value of $0.001 per share. The Preferred Stock will participate equally and ratably on an as-converted basis with the holders of common stock in all cash dividends paid on the common stock. The Preferred Stock is non-voting.

Upon election, each holder may convert each share of Preferred Stock into 1,000 shares of common stock, except to the extent that following such conversion the number of shares of common stock held by such holder, its affiliates and any other persons whose beneficial ownership of common stock would be aggregated with such holder's for purposes of Section 13(d) of the Exchange Act including shares held by any "group" (as defined in Section 13(d) of the Exchange Act and applicable regulations of the Securities and Exchange Commission) of which such holder is a member, but excluding shares beneficially owned by virtue of the ownership of securities or rights to acquire securities that have limitations on the right to convert, exercise or purchase similar to the limitation set forth in the Series A Certificate of Designation, exceeds 4.9% (or, at the election of the holders, OrbiMed Private Investments IV, LP or OrbiMed Royalty Opportunities II, LP, made by delivering at least 61 days advance written notice to the Company of its intention to increase the beneficial ownership cap applicable to such holder, 9.9%) of the total number of shares of common stock then issued and outstanding.

Note 16—Stock-Based Compensation

2022 Inducement Equity Incentive Plan

The 2022 Inducement Equity Incentive Plan (the "2022 Plan"), permitting the granting of nonstatutory stock options, RSUs, RSAs, stock appreciation rights, performance share units ("PSUs"), performance shares and other equity-based awards to employees, directors and consultants, became effective on March 30, 2022. As of December 31, 2022, 6,000,000 shares of common stock were authorized for issuance under the 2022 Plan, of which 5,928,500 shares remain available for issuance.

2020 Equity Incentive Plan

The 2020 Equity Incentive Plan (the "2020 Plan"), permitting the granting of non-statutory stock options, RSAs, RSUs, stock appreciation rights, PSUs, performance shares and other equity-based awards to employees, directors and consultants, became effective on August 5, 2020. As of December 31, 2022, 4,431,305 shares of common stock were authorized for issuance under the 2020 Plan including 1,118,288 shares that were authorized during the year ended 2022. As of December 31, 2022, 2,037,630 shares remain available for issuance under the 2020 Plan including shares that became available under the 2011 Equity Incentive Plan.

2011 Equity Incentive Plan

The 2011 Equity Incentive Plan (the "2011 Plan") permits the granting of incentive stock options, non-statutory stock options, restricted stock, RSUs and other stock-based awards to employees, directors, officers and consultants. As of December 31, 2022, 1,319,968 shares of common stock were authorized for issuance under the 2011 Plan and no shares remain available for issuance. No additional awards will be granted under the 2011 Plan. Shares that become available for issuance from the outstanding awards under the 2011 Plan due to forfeiture or otherwise will become available for issuance of future awards under the 2020 Plan.

Stock Options

The stock options generally vest over four years and have a ten-year contractual term. The fair value of each employee and non-employee stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. As the Company's common stock began public trading in August 2020, the Company lacks company-specific historical and implied volatility information required for valuation. Consequently, the Company estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. Due to the lack of historical exercise history, the expected term of the Company's stock options was determined using the "simplified method" for awards. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant for time periods approximately equal to the expected term of the award. Expected dividend yield is zero as the Company has never paid nor does it expect to pay any cash dividend in the foreseeable future.

The following assumptions were used to estimate the fair value of stock option for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
Risk-free interest rate	1.76 % - 3.39%	0.76 % - 1.39%
Expected dividend yield	—%	—%
Expected term in years	5.5 - 6.0	5.5 - 7.0
Expected volatility	75 % - 90%	60 % - 75%

The following table summarizes stock option activity during the years ended December 31, 2022 and 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	3,403,607	$13.32	8.1	$ 52,866
Options granted	1,196,281	$12.89		
Options exercised	(111,804)	$6.36		$ 2,799
Options forfeited	(706,448)	$14.76		
Outstanding as of December 31, 2021[(1)]	3,781,636	$13.12	7.6	$ 93
Options granted	782,430	$1.48		
Options exercised	(35,478)	$1.85		
Options forfeited	(1,629,767)	$11.14		
Outstanding as of December 31, 2022	2,898,821	$6.83	6.9	$ 79
Options vested and expected to vest December 31, 2022	2,898,821	$6.83	6.9	$ 79
Options exercisable December 31, 2022	1,744,253	$8.53	5.8	$ —

[(1)] The weighted average exercise price of stock options outstanding was $13.12 as of December 31, 2021. However, those same options after the July 15, 2022 stock option repricing have a weighted average exercise price of $9.75.

The aggregate intrinsic year-end values in the table above reflects a value for options "in the money," which are options exercisable for a value less than the Company's common stock price on the last day of the fiscal period of $1.15, $3.41 and $11.58 as of December 31, 2022, 2021 and 2020, respectively. The Company calculates the aggregate intrinsic value for such options as the product of the number of options outstanding multiplied by the difference between the per share fair value and the exercise price. The aggregate intrinsic value for options exercised in the above table represents the product of the number of options exercised multiplied by the difference between the per share fair value of the Company's stock on the date of exercise and the exercise price. The weighted-average grant date fair value per share for the stock option grants during the years ended December 31, 2022, 2021 and 2020 was $1.33, $8.46 and $11.58, respectively. As of December 31, 2022, the total unrecognized compensation related to unvested stock option awards granted was $6.6 million, which the Company expects to recognize over a weighted-average period of approximately 1.5 years.

Restricted Stock Units (RSUs)

The following table summarizes the Company's RSU activity for the years ended December 31, 2022 and 2021:

	Number of Shares	Weighted Average Grant Price
Unvested as of December 31, 2020	545,466	$16.53
Granted	718,567	$12.25
Forfeited	(117,430)	$17.22
Vested	(151,512)	$15.77
Unvested as of December 31, 2021	995,091	$13.47
Granted	1,863,156	$1.76
Forfeited	(690,059)	$6.71
Vested	(508,290)	$10.11
Unvested as of December 31, 2022	1,659,898	$4.17

As of December 31, 2022, unrecognized compensation related to unvested RSUs was $5.1 million, which the Company expects to recognize over a weighted-average period of approximately 1.6 years.

Restricted Stock Awards (RSAs)

The following table summarizes the Company's Restricted Stock Award ("RSA") activity for the year ended December 31, 2021 and the Company recorded no RSA activity for the year ended December 31, 2022:

	Number of Shares	Weighted Average Grant Price
Unvested as of December 31, 2020	—	—
Granted	186	$14.75
Vested	(186)	$14.75
Unvested as of December 31, 2021	—	—

Employee Stock Purchase Plan (ESPP)

The Company's 2020 ESPP permits individual employees to purchase shares of the Company's common stock from amounts accumulated under payroll deductions. The ESPP became effective on August 5, 2020 wherein 645,105 shares of common were been authorized. Additional shares of common stock are allocated to the 2020 ESPP by the determination of the Compensation Committee of the Company's Board of Directors, in its sole discretion, and by evergreen provisions in the plan authorization. Automatically authorized were 258,042 shares during 2022 under the plan's evergreen provision. As of December 31, 2022, 462,137 shares are available for purchase under the Company's 2020 ESPP.

The 2020 ESPP is implemented in consecutive offering periods, with a new offering period commencing on the first trading day on or after February 1 and August 1 of each year and terminating on the last trading day on or before July 31 and January 31, respectively. For the current year, offering periods began on February 1 and August 1. In November 2021, the Company amended its ESPP offering periods, for those beginning after the January 31, 2022 purchase, to commence on the first trading day on or after May 15 and November 15 of each year and terminating on the last trading day on or before November 14 and May 14, respectively. On each purchase date which falls on the last date of each offering period, 2020 ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the offering date or (2) the fair market value of the common stock on the purchase date. The occurrence and duration of offering periods under the 2020 ESPP are subject to the determination of the Compensation Committee of the Company's Board of Directors, in its sole discretion.

The fair value of the 2020 ESPP shares used in determining compensation expense is estimated using the Black-Scholes option pricing model.

Stock Option Repricing

On July 15, 2022, and in accordance with the terms of the Company's 2011 Plan and 2020 Plan, the Company's Board of Directors approved a stock option repricing (the "2022 Repricing") wherein the exercise price of each Designated Option was to be reduced to the price of the Company's common stock as of the market close on July 25, 2022. As of that date, the closing price of the Company's common stock was $1.34 per share. "Designated Option" is defined as all outstanding stock options to acquire shares of the Company's common stock that were issued to active employees of the Company (not a non-employee member of the Board or a consultant) as of July 25, 2022. All outstanding options remain outstanding in accordance with their current terms and conditions. Upon modification, the Company recognized $0.3 million of additional stock-based compensation from vested options. As unvested options continue to vest, the Company anticipates the recognition of an additional $0.3 million of stock-based compensation expense from the date of the modification through 2025.

Total Stock-Based Compensation

The following table summarizes the total stock-based compensation expense for the stock options, RSUs, RSAs and ESPP expense recorded in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
Cost of products sold	$ 669	$ 864
Research and development	1,736	2,181
Selling, general and administrative	6,986	10,709
Total stock-based compensation	$ 9,391	$ 13,754

Note 17—Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. Diluted net loss per common share excludes the potential impact of the Company's convertible preferred stock, common stock options, RSUs, RSAs, intended ESPP purchases and warrants because the Company's net losses would cause such shares to be anti-dilutive. Therefore, as the Company recorded net losses loss in the periods presented, basic and diluted net loss per common share are the same.

The table below provides potentially dilutive securities not included in the calculation of the diluted net loss per common share because to do so would be anti-dilutive:

	Year Ended December 31,	
	2022	2021
Shares issuable upon:		
Conversion of Series A Common Equivalent Preferred Stock	6,665,841	6,665,841
Exercise of common stock warrants	4,576,505	797,487
Exercise of stock options	1,744,253	3,781,636
Vesting of RSUs and RSAs	1,659,898	995,091
Issuance of shares under 2020 ESPP	51,730	—
Total potentially dilutive securities	14,698,227	12,240,055

Note 18—401(k) Retirement Plan

The Company has a 401(k) retirement savings plan that provides retirement benefits to substantially all full-time U.S. employees. Eligible employees may contribute a percentage of their annual compensation, subject to Internal Revenue Service limitations. The Company provided no contributions to the 401(k) retirement savings plan for the years ended December 31, 2022 and 2021.

Note 19—Income Taxes

The components of pretax loss from operations for the years ended December 31, 2022 and 2021 are as follows:

	December 31,	
	2022	2021
U.S.	$ (39,346)	$ (117,868)
Foreign	(188)	185
Pretax loss from operations	$ (39,534)	$ (117,683)

The components of income tax expense for continuing operations are as follows:

	December 31,	
	2022	2021
Federal	$ —	$ —
State	15	—
Foreign	67	—
Total provision for income taxes	$ 82	$ —

A provision for state and foreign income taxes was less than $0.1 million for the year ended December 31, 2022 and there was no provision for the year ended December 31, 2021. Current income taxes are based upon the year's income taxable for federal, state and foreign tax reporting purposes. Deferred income taxes are provided for certain income and expenses which are recognized in different periods for tax and financial reporting purposes. Deferred tax assets and liabilities are computed for differences between the consolidated financial statements and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the period in which the differences are expected to affect taxable income, and NOL carryforwards and R&D tax credit carryforwards. The Company adopted ASU 2019-12 in the first quarter of 2021 and has recorded franchise taxes not based on income outside of income tax expense.

The following table presents a reconciliation of income tax computed at the U.S. federal statutory tax rate to the total income tax expense for the years ended December 31, 2022 and 2021 (dollars in thousands):

	Year Ended December 31,			
	2022		2021	
	Amount	Tax Rate	Amount	Tax Rate
Income tax benefit at federal statutory rate	$ (8,302)	21.0 %	$ (24,714)	21.0 %
Adjustments for tax effects of:				
State taxes, net	(847)	2.1 %	(2,343)	2.0 %
Permanent adjustments	917	(2.3)%	352	(0.3)%
Goodwill impairment	2,525	(6.4)%	—	— %
Stock based compensation expense	2,525	(6.4)%	—	— %
Research and development credit	(2,099)	5.3 %	(2,255)	1.9 %
Unrecognized tax benefit	630	(1.6)%	676	(0.6)%
Rate change	—	— %	532	(0.5)%
Return to provision	534	(1.3)%	—	— %
Other	—	— %	817	(0.6)%
Valuation allowance	4,199	(10.6)%	26,935	(22.9)%
Income tax expense	$ 82	(0.2)%	$ —	— %

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2022 and 2021 are as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating losses	$ 94,437	$ 93,668
Stock-based compensation	1,678	2,468
Research and development credit	10,273	8,803
Capitalized research costs	9,473	—
Accrued compensation	1,161	432
Accrued expenses	—	446
Intangible assets	92	3,564
Lease liability	1,019	1,114
Inventory	655	202
Other	35	11
Total gross deferred tax assets	118,823	110,708
Valuation allowance	(110,907)	(106,717)
Net deferred tax asset	7,916	3,991
Deferred tax liabilities:		
Deferred installment gain	(5,315)	—
Property and equipment	(1,105)	(1,986)
Right of use assets	(891)	(1,009)
Prepaid expenses	(105)	(593)
Other	(461)	(313)
Debt	(39)	(90)
Total deferred tax liabilities	(7,916)	(3,991)
Net deferred tax assets (liabilities)	$ —	$ —

In assessing the realizability of deferred tax assets as of December 31, 2022 and 2021, management considered whether it is more likely than not that some portion or all of the deferred tax assets will 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 or the NOL carryforwards and R&D credit carryforwards will be used. The Company determined it is more likely than not that its net deferred tax assets will not be realized. Accordingly, a valuation allowance was recorded as of December 31, 2022 and 2021 to fully offset the net deferred tax assets of $110.9 million and $106.7 million, respectively.

The following table presents NOLs and tax credit carryforwards as of December 31, 2022 (in thousands):

	Amount	Expiration Years
NOLs, federal (post-December 31, 2017)	$ 309,325	Indefinite [1]
NOLs, federal (pre-January 1, 2018)	$ 108,165	2031 - 2037
NOLs, state	$ 96,361	2026 - 2042
NOLs, state (post-December 31, 2017)	$ 14,725	Indefinite [1]
Research and development tax credits, federal	$ 9,503	2031 - 2042
Research and development tax credits, California	$ 6,548	Indefinite

[1] NOL carryforwards generated after 2017 can be carried forward indefinitely and can generally be used to offset up to 80% of future taxable income.

NOL carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be used annually to offset future taxable income and tax, respectively. In general, an "ownership

change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders. The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company's formation due to the complexity and cost associated with such study, and the fact that there may be additional such ownership changes in the future. Any limitation may result in expiration of a portion of the NOL carryforwards or research and development tax credit carryforwards before utilization; however, such limitation, if any, would not have an impact on the Company's financial statement due to the full valuation.

The Company conducts intensive research and experimentation activities, generating R&D tax credits for federal and state purposes under Section 41 of the Code. The Company has not performed a formal study validating these credits claimed in the tax returns. Once a study is prepared, the amount of R&D tax credits available could vary from what was originally claimed on the tax returns.

The following table summarizes the changes to unrecognized tax benefits as of December 31, 2022 and 2021 (in thousands):

	December 31,	
	2022	2021
Balance at beginning of year	$ 4,128	$ 3,397
Gross increases – tax positions in current period	683	731
Gross decreases – tax positions in prior period	(16)	—
Balance at end of year	$ 4,795	$ 4,128

As of December 31, 2022, the Company has unrecognized tax benefits of $4.8 million of which $4.4 million will affect the effective tax rate if recognized when the Company no longer has a valuation allowance offsetting its deferred tax assets.

The Company does not anticipate that there will be a significant change in unrecognized tax benefits over the next 12 months.

The Company is subject to U.S. federal and various state tax as well as Belgium tax jurisdictions. Since the Company formed in 2011, all filed tax returns are subject to examination. Generally, the tax years remain open for examination by the federal statute under a three-year statute of limitation; however, states generally keep their statutes open between three and four years. However, the Company's tax years from inception are subject to examination by the United States and various state taxing authorities due to the carry forward of unused NOLs and R&D credits.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest and penalties on its consolidated balance sheets and has not recognized interest and/or penalties in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2022 and 2021.

The Tax Cuts and Jobs Act enacted in 2017 requires taxpayers to capitalize and amortize R&D expenditures for tax purposes incurred in tax years beginning after December 31, 2021. The rule resulted in the Company's capitalization of R&D expenditures of approximately $25.3 million incurred during 2022. For R&D performed in the U.S., the Company will amortize costs capitalized for tax purposes over 5 years and for R&D performed outside the U.S, the Company will amortize costs capitalized for tax purposes over 15 years.

The Inflation Reduction Act 2022 incorporating a Corporate Alternative Minimum Tax ("CAMT") was signed into law on August 16, 2022. The changes will affect tax years beginning after December 31, 2022. The CAMT will require companies to make a new minimum tax calculation for federal income tax purposes and pay the greater of the new minimum tax or the regular tax liability. The Company is currently evaluating the provisions of the CAMT, however it is not expected to have any material impact for the Company.

The Creating Helpful Incentives to Produce Semiconductors Act of 2022 ("CHIPS Act") was signed into law on August 9, 2022 to boost domestic semiconductor manufacturing and encourage U.S. research activities. The CHIPS Act provides for a 25% investment credit intended to promote the domestic production of semiconductors. The CHIPS Act is not expected to have any material impact for the Company.

Note 20—Related Party Transactions

Grant and Vesting of Performance Share Units

The August 2020 completion of the Company's IPO satisfied performance conditions for certain PSUs granted to the chairman of the Company's board of directors. The Company recorded $4.6 million of stock-based compensation expense in the year ended December 31, 2021 related to the grant.

Series A Common Equivalent Preferred Stock

In August 2021, the Company entered into the Exchange Agreements with related parties Deerfield Private Design Fund III, L.P., Deerfield Partners, L.P., OrbiMed Private Investments IV, LP and OrbiMed Royalty Opportunities II, LP pursuant to which the investors exchanged 6,665,841 shares of the Company's common stock for 6,666 shares of Series A Common Equivalent Preferred Stock, par value $0.001 per share. See *Note 15 - Stockholders' Equity* for additional details.

Consulting Agreement

The Company entered into a consulting agreement with the chairman of the Company's board of directors. The Company recorded $0.2 million and $0.1 million of expense related to the agreement during the years ended December 31, 2022 and 2021, respectively.

Credit Agreements

The 2019 Credit Agreement was between the Company and related parties OrbiMed Royalty Opportunities II, LP and Deerfield Private Design Fund II, L.P., and provided for a loan of up to $70.0 million with a maturity date of May 20, 2024. On June 30, 2022, the loan balance of $40.0 million was repaid in full out of the proceeds of the 2022 Credit Agreement. The 2022 Credit Agreement with related parties Deerfield Private Design Fund III, L.P. and Deerfield Partners, L.P. replaced the 2019 Credit Agreement and provides for an aggregate principal amount of $35.0 million and a maturity date five years from the closing of the loan. Refer to *Note 11 - Debt* for additional details.

The liability for the loan balance related to the 2022 Credit Agreement and the 2019 Credit Agreement recorded on the Company's consolidated balance sheets was $34.4 million and $40.4 million as of December 31, 2022 and 2021, respectively. The Company recorded interest expense related to the debt on the consolidated statement of operations and comprehensive loss of $5.1 million and $5.7 million for the years ended December 31, 2022 and 2021, respectively.

Warrants

In connection with the 2022 Credit Agreement, the Company entered into the 2022 Warrant Purchase Agreement with Deerfield, pursuant to which the Company issued warrants for the purchase up to an aggregate 3,779,018 shares of the Company's common stock at an exercise price of $1.1114 per share for a period of eight years following issuance. Refer to *Note 14 - Warrants* for additional details.

Note 21—Subsequent Events

On January 10, 2023, the Company received a letter from The Nasdaq Stock Market LLC notifying the Company that it had regained compliance with Listing Rule 5450(a)(1), which requires that listed securities maintain a minimum closing bid price of at least $1.00 per share (the "Minimum Bid Requirement"). The Company regained compliance with the Minimum Bid Requirement based on the closing bid price of the Company's common stock on the Nasdaq Global Select Market between December 23, 2022 and January 9, 2023. The Company had previously been notified of its non-compliance with the Minimum Bid Requirement on November 2, 2022, as described in the Company's Current Report on Form 8-K filed on November 4, 2022.

On March 10, 2023, the Company conducted an analysis of its financial exposure stemming from the failure of Silicon Valley Bank ("SVB") and subsequent appointment of the Federal Deposit Insurance Corporation (the "FDIC") as receiver and had assessed the Company's exposure to be immaterial. On March 12, 2023, the Department of the Treasury, Board of Governors of the Federal Reserve System and the FDIC approved actions enabling the FDIC to complete its resolution of SVB in a manner that fully protects all depositors. We are confident that the Company will have full access to its cash and investments. Additionally, the Company is evaluating its financial business partners to ensure long-term security of its assets.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

As of December 31, 2022, there were no material changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarterly period ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Control Processes

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. 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, 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 is also 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.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company (as defined in Exchange Act Rule 13a-15(f)). Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2022.

Attestation Report of Independent Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered independent public accounting firm regarding internal control over financial reporting due to an exemption established by the JOBS Act for emerging growth companies.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our Proxy Statement.

Item 11. Executive Compensation.

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

1. The following consolidated financial statements of Acutus Medical, Inc. included in Item 8 are filed as part of this Annual Report on Form 10-K:

   Report of Independent Registered Public Accounting Firm

   Consolidated Balance Sheets as of December 31, 2022 and 2021

   Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2022 and 2021

   Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2022 and 2021

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

   Notes to the Consolidated Financial Statements for the Years Ended December 31, 2022 and 2021

2. Financial Statement Schedule: All schedules have been omitted because they are not required or because the required information is given in the consolidated financial statements or notes thereto.

3. Exhibits: The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

Item 16. Form 10-K Summary

None.

Exhibit Index

Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit	Filing Date
2.1	Acquisition Agreement, dated May 31, 2019, among the Registrant, Rhythm Xience, Inc., the sellers listed on Schedule I thereto and Harold Wodlinger, as the Sellers' Agent	S-1	333-239873	2.1	July 15, 2020
2.2+	Asset Purchase Agreement, dated April 26, 2022, among the Registrant and Medtronic, Inc.	8-K	001-39430	2.1	April 27, 2022
3.1	Amended and Restated Certificate of Incorporation	8-K	001-39430	3.1	August 10, 2020
3.2	Amended and Restated Bylaws	8-K	001-39430	3.2	August 10, 2020
3.3	Certificate of Designation of Preferences, Rights and Limitations of the Series A Common Equivalent Preferred Stock, par value $0.001 per share, of the Company.	8-K	001-39430	3.1	August 23, 2021
4.1	Specimen Common Stock Certificate	S-1/A	333-239873	4.2	July 30, 2020
4.2	Amended and Restated Investors' Rights Agreement	S-1	333-239873	4.1	July 15, 2020
4.3*	Description of the Registrant's Securities				
4.4	Form of warrant to purchase common stock dated January 30, 2015, issued by the Registrant to various parties, together with a schedule of material differences	S-1	333-239873	4.3	July 15, 2020
4.5	Form of warrant to purchase common stock dated June 7, 2018, issued by the Registrant to various parties, together with a schedule of material differences	S-1	333-239873	4.4	July 15, 2020
4.6	Form of warrant to purchase common stock dated July 31, 2018, issued by the Registrant to various parties, together with a schedule of material differences	S-1	333-239873	4.5	July 15, 2020
4.7	Form of warrant to purchase common stock dated May 20, 2019, issued by the Registrant to various parties, together with a schedule of material differences	S-1	333-239873	4.6	July 15, 2020
4.8+	Form of warrant for the issuance of warrants dated June 30, 2022	8-K	001-39430	10.3	July 1, 2022
10.1+	Amended and Restated Credit Agreement, dated June 30, 2022, among the Registrant, the lenders from time to time party thereto, Wilmington Trust, National Association, as Administrative Agent	8-K	001-39430	10.1	July 1, 2022
10.2+	Warrant Purchase Agreement, dated June 30, 2022, among the Registrant and the purchasers named therein	8-K	001-39430	10.2	July 1, 2022
10.3+	Registration Rights Agreement, dated June 20, 2022, among the Registrant, Deerfield Partners, L.P. and Deerfield Private Design Fund III	8-K	001-39430	10.4	July 1, 2022
10.4	License and Distribution Agreement, dated July 2, 2019, among the Registrant, Biotronik SE & Co. KG and VascoMed GmbH	S-1	333-239873	10.3	July 15, 2020
10.5	Bi-Lateral Distribution Agreement, dated May 11, 2020, between the Registrant and Biotronik SE & Co. KG (Acutus as distributor)	S-1	333-239873	10.4	July 15, 2020

Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit	Filing Date
10.6	Bi-Lateral Distribution Agreement, dated May 11, 2020, between the Registrant and Biotronik SE & Co. KG (Biotronik as distributor)	S-1	333-239873	10.5	July 15, 2020
10.7	License Agreement, dated May 10, 2011, between the Registrant and Dr. Christoph Scharf	S-1	333-239873	10.6	July 15, 2020
10.8	First Amendment to License Agreement, dated September 30, 2011, between the Registrant and Dr. Christoph Scharf	S-1	333-239873	10.7	July 15, 2020
10.9	Master License Agreement, dated March 11, 2014, between the Registrant and Biotectix, LLC	S-1	333-239873	10.8	July 15, 2020
10.1	Exclusive Patent License Agreement, dated April 21, 2014, between the Registrant and Regents of the University of Minnesota	S-1	333-239873	10.9	July 15, 2020
10.11	First Amendment to Exclusive Patent License Agreement, dated October 20, 2014, between the Registrant and Regents of the University of Minnesota	S-1	333-239873	10.10	July 15, 2020
10.12+	Distribution Agreement, dated June 30, 2022, among the Registrant and Medtronic, Inc.	8-K	01-39430	10.1	December 5, 2022
10.13	Lease Agreement, dated January 22, 2015, as amended, between the Registrant and Carlsbad 2210, LLC	S-1	333-239873	10.11	July 15, 2020
10.14†	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers	S-1	333-239873	10.12	July 15, 2020
10.15†	2011 Equity Incentive Plan, as amended, and forms of agreement thereunder	S-1	333-239873	10.13	July 15, 2020
10.16†	2020 Equity Incentive Plan and forms of agreement thereunder	S-1/A	333-239873	10.14	July 30, 2020
10.17†	2020 Employee Stock Purchase Plan	S-1/A	333-239873	10.15	July 30, 2020
10.18†	Executive Incentive Compensation Plan	S-1	333-239873	10.16	July 15, 2020
10.19†	Executive Chairman Agreement between the Registrant and Scott Huennekens	S-1	333-239873	10.17	July 15, 2020
10.20†	Restricted Stock Unit Award Agreement between the Registrant and Scott Huennekens	S-1	333-239873	10.18	July 15, 2020
10.21†	Employment Agreement between Registrant and David Roman	10-K	001-39430	10.22	March 19, 2021
10.22†	Amendment No. 1 to Employment Agreement between Registrant and David Roman	8-K	001-39430	10.1	July 21, 2022
10.23†	Employment Agreement by and between Registrant and Takeo Mukai	8-K	001-39430	10.1	January 8, 2023
10.24†	Separation Agreement between Registrant and Vince Burgess	8-K	001-39430	10.1	May 12, 2022
10.25†	Consulting Agreement between Registrant and Vince Burgess	8-K	001-39430	10.2	May 12, 2022
10.26†	Consulting Agreement between Registrant and Steve McQuillan	10-Q	001-39430	10.2	November 11, 2022

Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit	Filing Date
10.27	Limited Consent, dated April 26, 2022, between the Registrant, the lenders party to the Credit Agreement and Wilmington Trust, National Association, as Administrative Agent	8-K	001-39430	10.1	April 27, 2022
10.28	Commitment Letter, dated April 26, 2022, between the Registrant and the Commitment Parties	8-K	001-39430	10.2	April 27, 2022
10.29	2nd Amendment to the Global Alliance for Product Distribution Agreement, dated April 25, 2022, between the Registrant and Biotronik SE & Co.	8-K	001-39430	10.3	April 27, 2022
10.30	Amendment No. 2 and Waiver to the Credit Agreement, dated October 21, 2020	10-K	001-39430	10.25	March 19, 2021
10.31	Exchange Agreement, dated as of August 23, 2021, by and among the Company, Deerfield Private Design Fund III, L.P. and Deerfield Partners, L.P.	8-K	001-39430	10.1	August 23, 2021
10.32	Exchange Agreement, dated as of August 23, 2021, by and among the Company, OrbiMed Private Investments IV, LP and OrbiMed Royalty Opportunities II, LP	8-K	001-39430	10.2	August 23, 2021
10.33	Feasibility and Development Agreement, by and between Biotronik SE & Co. KG and Acutus Medical, Inc.	S-1	333-257844	10.24	July 12, 2021
10.34	2022 Inducement Equity Plan and forms of agreement thereunder	S-8	333-264004	99.1	March 31, 2022
21.1*	Subsidiaries of the Registrant				
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm				
24.1*	Power of Attorney (included on signature page)				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1**	Certification 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**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				

Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit	Filing Date
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data File (formatted as iXBRL with applicable taxonomy extension information contained in Exhibit 101)				

* Filed herewith.

** These certifications are being furnished solely to accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Acutus Medical, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

† Indicates management contract or compensatory plan.

+ The schedules and exhibits to the exhibited agreements have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish copies of any such schedules and exhibits to the Securities and Exchange Commission upon request.

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in Carlsbad, State of California, on March 23, 2023**.**

Acutus Medical, Inc.

Date: March 23, 2023

By: /s/ David Roman

David Roman

President, Chief Executive Officer and Director

POWER OF ATTORNEY AND SIGNATURES

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David Roman and Takeo Mukai, and each of them, his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agents full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or either of them or their or his or her substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ David Roman David Roman	President, Chief Executive Officer and Director (Principle Executive Officer)	March 23, 2023
/s/ Takeo Mukai Takeo Mukai	Senior Vice President & Chief Financial Officer (Principal Financial and Accounting Officer)	March 23, 2023
/s/ R. Scott Huennekens R. Scott Huennekens	Chairman of the Board	March 23, 2023
/s/ David Bonita David Bonita, M.D.	Director	March 23, 2023
/s/ Andrew ElBardissi Andrew ElBardissi, M.D.	Director	March 23, 2023
/s/ Jason Garland Jason Garland	Director	March 23, 2023
/s/ Niamh Pellegrini Niamh Pellegrini	Director	March 23, 2023
/s/ Shaden Marzouk Shaden Marzouk	Director	March 23, 2023
/s/ John Sheridan John Sheridan	Director	March 23, 2023

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