

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, 2021  
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  
(State or other jurisdiction of  
incorporation or organization)  
2210 Faraday Ave.,  
Suite 100, Carlsbad, CA  
(Address of principal executive offices)

45-1306615  
(I.R.S. Employer  
Identification No.)  
  
92008  
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  NO

The aggregate market value of the common stock held by non-affiliates of the Registrant, based on the closing price of \$16.98 per share of the Registrant's common stock on June 30, 2021, 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 \$304.1 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. The Registrant had no non-voting common equity as of June 30, 2021.

On March 28, 2022, there were 28,279,065 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 2022 Annual Meeting of Stockholders to be filed within 120 days of the Registrant's fiscal year ended December 31, 2021 (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 may not realize expected benefits from our refocused commercial strategy, cost reduction or restructuring efforts, which could have a material adverse effect on our ability to drive adoption of our core technology, results of operations, cash flows or financial condition.
- 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 have been, and will continue to be, adversely impacted by the COVID-19 pandemic, nurse and hospital staffing shortages and intermittent cancellations of elective procedures in the United States and the rest of the world.
- 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.

## 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, transseptal crossing tools, 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 2021, we received U.S. Food and Drug Administration, or FDA, clearance and Conformité Européenne Mark, or CE Mark, for our innovative suite of mapping software upgrades and algorithms, collectively called AcQMap 8. In addition to workflow enhancements, AcQMap 8 offers a unique-in-the-industry capability to automatically identify regions of interest, allowing physicians to better tailor therapy for each patient, leading to predictable procedures and better outcomes.

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, our transseptal crossing device 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 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 commenced 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 the first half of 2021 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 fourth quarter of 2022 or early 2023. The AcQBlate FORCE ablation catheter can deliver both radiofrequency (RF) as well as Pulsed Field Ablation (PFA) energy to ablate cardiac tissue. We initiated the AcQForce PFA-CE trial in Europe in November 2021 and treated the first cohort of patients with the Acutus PFA system integrated into the AcQMap mapping system. 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 seeking approval for additional labeled indications as well as expanding our product portfolio to further improve and simplify the entire procedural experience. Our near-term pipeline includes products that broaden our commercial portfolio, 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 470,000 cardiac ablation procedures globally for atrial fibrillation in 2020.

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 410,000 ablation procedures worldwide for SVTs in 2020. 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 92,000 ablation procedures globally for ventricular arrhythmias in 2020.

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 can only map one rhythm from each data collection session and are not capable of quickly and reliably mapping unstable or complex arrhythmias such as AF, certain VTs, PVCs or many types of SVTs, 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 software platform, which we introduced in the second half of 2021, offers a unique-in-the-industry capability to automatically identify regions of interest, allowing physicians to better tailor therapy for each patient.

### **Key Benefits of AcQMap**

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

*Allows for an 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**

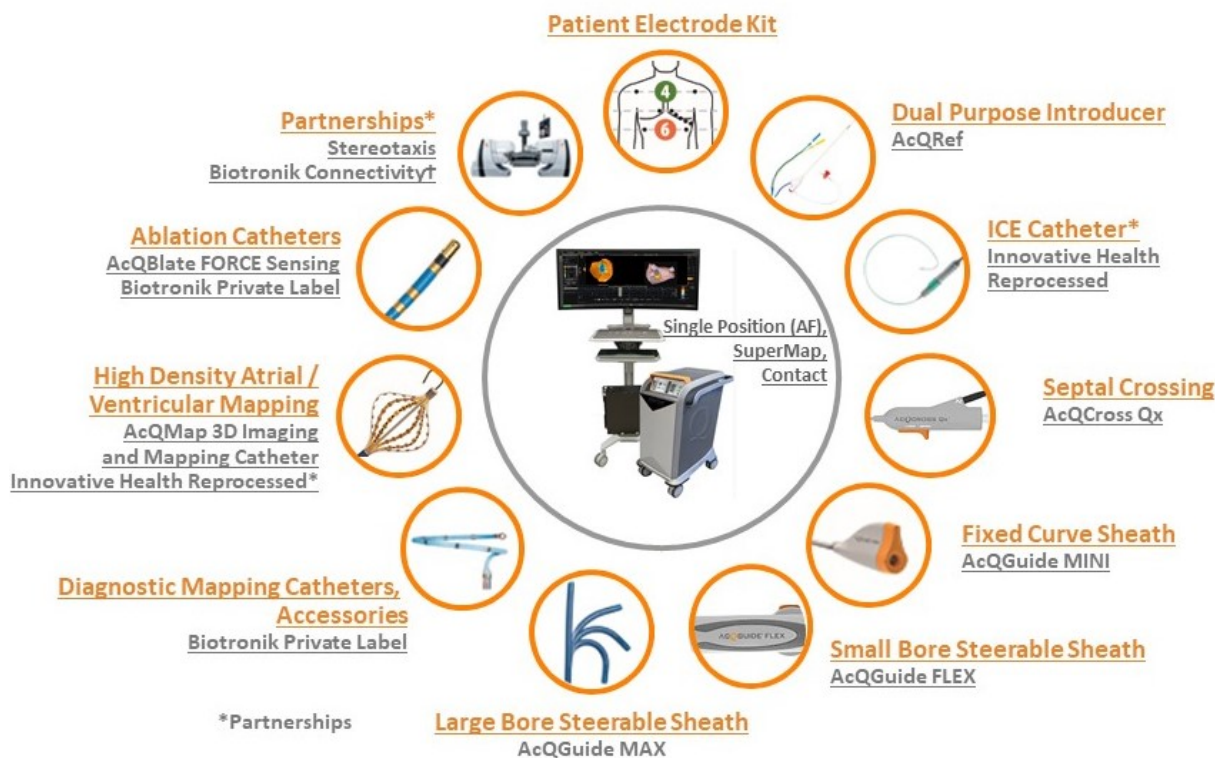
We have established a broad portfolio of electrophysiology products that complements our AcQMap System. In addition to our AcQMap System, our commercial product portfolio includes a suite of access devices, our transeptal crossing device and full product lines of diagnostic and, in our European markets, 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 commenced enrollment in an IDE trial for FDA



PMA in the United States in the first half of 2021. We currently anticipate FDA PMA, and the U.S. commercial launch, of our AcQBlate Force Sensing Ablation Catheter and System in the fourth quarter of 2022 or early 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.

The figure below shows our current portfolio of products.



## 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**

Beginning in early March 2020, the COVID-19 pandemic and the measures imposed to contain this pandemic disrupted and are expected to continue to impact our business. Moreover, beginning in March 2020 and continuing through the filing of this Form 10-K, access to hospitals and other customer sites was restricted, which negatively impacted our ability to install our AcQMap consoles and workstations in new accounts and for our sales representatives and mappers to promote the use of our products with physicians. Over the past 12 months, we have continued to observe intermittent suspension of many elective procedures, as well as nursing and staffing shortages associated with the resurgence of COVID-19 in geographies where we sell, market and distribute our products. In addition, the impact of COVID-19 has varied by region and by healthcare facility, hampering our ability to forecast the sustained impact on our business from COVID-19. 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 the pandemic, associated restrictions and other measures designed to prevent the spread of COVID-19 and on our ability to conduct business in the ordinary course. Quarantines, shelter-in-place and similar government orders, and capacity restrictions have also impacted, and may continue to impact, our third-party manufacturers and suppliers, and could in turn adversely impact the availability or cost of materials, which could disrupt our supply chain. The markets we serve are likely to 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.

### **Corporate Restructuring**

On January 19, 2022, we announced a corporate restructuring to reduce our operating expenses and to optimize our cash resources, pursuant to which we undertook a reduction in force, or RIF, and implemented additional cost reduction measures. 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 plc. 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, preserve the confidentiality of our trade secrets, operate without infringing, misappropriating or otherwise violating the intellectual property rights of others and 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, 2021, our patent portfolio included 32 solely owned or exclusively licensed U.S. patents and 26 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 60 issued patents and 59 pending patent applications in jurisdictions outside the United States. Of our 85 pending patent applications (U.S. and outside the U.S.), three have been allowed. Of our 32 owned and exclusively licensed U.S. patents, 30 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, Innovative Health for reprocessed diagnostic catheters and MedFact for robotic navigation enabled ablation catheters.

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, we must submit a premarket notification to the FDA demonstrating that our 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 we intend to market a device, and we must receive 510(k) clearance from the FDA before we actually market 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, has valid marketing authorization from the appropriate authority and 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 the MDD. The MDD sets 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 MDD 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, similar to the U.S. system. 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 are carried out as required by the MDD. 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 Mark is 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.

In 2017, the European Parliament passed the Medical Devices Regulation, which repeals and replaces the EU Medical Devices Directive. The Medical Devices Regulation, among other things, establishes a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and in vitro diagnostic devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation:

- strengthened the rules on placing devices on the market and reinforce surveillance once they are available;
- established explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improved the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthened 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.

To the extent that any of our products were already certified under the existing regulatory framework, the Medical Devices Regulation allows us to market them provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid. Under article 120(2) of the Medical Devices Regulation, certificates issued by Notified Bodies before May 25, 2017 will remain valid until their indicated expiry dates. By contrast, certificates issued after May 25, 2017 will be void at the latest by May 27, 2024. Accordingly, before that date, we will need to obtain new CE Certificats de Conformité.

#### *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.

### ***California Consumer Privacy Act***

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. One such law is the California Consumer Privacy Act, or 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 bring enforcement actions for violations beginning July 1, 2020. The CCPA has been amended from time to time, and most recently a new privacy law, the California Privacy Rights Act, or CPRA, was approved by California voters in the November 3, 2020 election. Effective starting January 1, 2023, the CPRA will significantly modify the CCPA, including 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.

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.”

### ***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, or the Anti-Kickback Statute, prohibits, subject to certain safe harbors set forth in the Anti-Kickback Statute, 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 to, 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, more commonly, as “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, is for an item or service that was not provided as claimed or is false or fraudulent.

### ***Open Payments***

The Affordable Care Act also included 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 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 affected medical device manufacturers significantly. The Affordable Care Act imposed, among other things, a 2.3% federal excise tax, with limited exceptions, on any entity that manufactures or imports Class I, II and III medical devices offered for sale in the United States that began on January 1, 2013. Although this excise tax was in effect during the years 2013–2015, there was in effect a moratorium on the medical device excise tax through the end of 2019. The excise tax was repealed effective January 1, 2020. The Affordable Care Act also provided incentives to programs that increase the federal government’s comparative effectiveness research and implemented 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.

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, 2021, we had 338 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:

- Accountable to patients, physicians and each other;
- Courageously pursuing continuous improvement;
- United as one team achieving excellence;
- Tenacious about innovation;
- Uncompromising in integrity; and
- Science 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, 2021, 133 employees, or 39% 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](http://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, “AcQCross,” the “AcQCross” 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 \$1.07 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.

## Item 1A. Risk Factors.

*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, 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 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, reduce the cost of products sold, broaden our commercial portfolio offerings and obtain FDA 510(k) clearance or PMA for, and 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 response 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, 2021, 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, 2021 and 2020, 52% and 43%, 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 an expansive bi-lateral distribution agreement with Biotronik, 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, suppliers and 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, fail to manage, train or incentivize distributors effectively, or 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, 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 plc. 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, broaden our product portfolio and 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 or compete in 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.

***We may not realize expected benefits from our cost reduction and restructuring efforts, which could have a material adverse effect on our competitive position, results of operations, cash flows or financial condition.***

On January 19, 2022, we announced a corporate restructuring to reduce our operating expenses and optimize our cash resources, pursuant to which we undertook a RIF, and implemented additional cost reduction measures. 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. These activities are complex and may involve or require significant changes to our operations. If we do not successfully manage these activities, expected efficiencies and benefits might be delayed or not realized. Risks associated with these actions and other workforce management issues include: unfavorable political responses and reputational harm; unforeseen delays in the implementation of the restructuring activities; additional costs; adverse effects on employee morale; the failure to meet operational targets due to the loss of employees or work stoppages; and difficulty managing our operations, any of which may impair our ability to achieve anticipated cost reductions, harm our business or reputation, or have a material adverse effect on our competitive position, results of operations, cash flows or financial condition.

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

We have experienced substantial growth in our operations, and we expect to experience continued substantial growth in our business. For example, in 2021, our headcount increased by 16%, and we released multiple new disposable and hardware products as well as multiple software updates. This growth has placed, and will continue to place, significant demands on our management and our operational infrastructure. 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 reporting systems and procedures. If we are unable to manage our

growth effectively, including by failing to implement necessary procedures, transition to new processes or 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 than we do, may be able to respond more quickly and effectively than we can 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, successfully commercialized or 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, timely completion and delivery, competitive pricing and 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;
- 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;
- 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;
- 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, in response to an outbreak of COVID-19, the single-source supplier of flex circuits for one of our products temporarily suspended production for a period of approximately one week in the first quarter of 2020. 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 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 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. For example, in February 2020, we initiated a voluntary recall of a total of 120 of our AcQGuide Flex and AcQGuide Mini sheaths due to product defects that we determined arose during the manufacturing process by one of our contract manufacturers. Although this issue has been corrected and did not cause any patient injury, as the recalled products had not been placed into service, customer satisfaction problems early in a product's launch can have a lasting negative impact on our reputation or on our ability to sell such product. 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 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, product recalls or market withdrawals.

We are required to file adverse event reports under MDR regulations with the FDA, which reports 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 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 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, to 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 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 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 have been, and will continue to be, adversely impacted by the COVID-19 pandemic in the United States and the rest of the world.***

In December 2019, COVID-19 was reported to have surfaced in Wuhan, China, resulting in significant disruptions to Chinese manufacturing and travel. COVID-19 has now spread to virtually all other countries, including the United States, resulting in the World Health Organization characterizing COVID-19 as a pandemic. As a result of measures imposed by the governments in affected regions, many commercial activities, businesses and schools have been suspended as part of quarantines, shelter-in-place orders and other measures intended to contain this pandemic.

The COVID-19 pandemic and the measures imposed to contain this pandemic disrupted and are expected to continue to impact our business. Beginning in early March 2020, the COVID-19 pandemic and the measures imposed to contain this pandemic disrupted and are expected to continue to impact our business. Moreover, beginning in March 2020 and continuing through the filing of this Form 10-K, access to hospitals and other customer sites was restricted, which negatively impacted our ability to install our AcQMap consoles and workstations in new accounts and for our sales representatives and mappers to promote the use of our products with physicians. As the COVID-19 pandemic continues to spread around the globe, the impact may be prolonged and we may experience additional disruptions that 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 of the COVID-19 pandemic 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, due to 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 continuously assessing the ongoing impact that COVID-19 may have on our ability to effectively conduct our business operations as planned and there can be no assurance that we will be able to avoid a material impact on our business from the spread of COVID-19 or its consequences, including disruption to our business and downturns in business sentiment generally or in our industry. 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 over time, will depend, in part, on the length and severity of these continuing restrictions and on our ability to conduct business in the ordinary course. The global outbreak of COVID-19 continues to evolve. Over the past 12-months, we have continued to observe intermittent suspension of many elective procedures, as well as nursing and staffing shortages associated with the resurgence of COVID-19 in geographies where we sell, market and distribute our products. In addition, the impact of COVID-19 has varied by region and by healthcare facility, hampering our ability to forecast the sustained impact on our business from COVID-19. We cannot assure you that we will not experience similar, or even more sustained, access restrictions or decreases in procedural activities as hospitals continue to deal with the COVID-19 pandemic. If cases of COVID-19 increase and hospitals again prioritize those patients, additional restrictions may be implemented which would adversely impact our business and financial results.

Additionally, certain third parties with whom we engage, including our strategic partners, third-party manufacturers, suppliers, clinical trial sites, regulators and other third parties with whom we conduct business are similarly adjusting their operations and assessing their capacity in light of the COVID-19 pandemic. If these third parties experience shutdowns or continued business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. Quarantines, shelter-in-place, and capacity restrictions and similar government orders may continue to impact our third-party manufacturers and suppliers and could in turn adversely impact the availability or cost of materials, which could disrupt our supply chain. The markets we serve are likely to 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.

***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 start of the military conflict between Russia and Ukraine. On February 24, 2022, a full-scale military invasion of Ukraine by Russian troops was reported. 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 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, developing our technologies and 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, financial condition and 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 these 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 (v) 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 to adopt, 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 2021 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 five customers accounted for 37% and 44% of our revenue in 2021, 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, inability to hire personnel with sufficient technical skills, a lack of other research and development resources or 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, need to be redesigned, enroll an adequate number of patients on time or 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 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, deviating from the protocol or 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 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, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate safety and effectiveness, changes in governmental regulations or administrative actions or 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, 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, slow down our product development and approval process and 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 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 the 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, incur unanticipated liabilities and 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 obtain the expected benefits of any acquisition or investment. In addition, under our Credit Agreement, dated as of May 20, 2019, with the lenders from time to time party thereto, Wilmington Trust, National Association, as administrative agent, and OrbiMed Royalty Opportunities II, LP, or ORO II, as origination agent, or the 2019 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, the use of our available cash, or the incurrence of debt, whether to fund the upfront purchase price of the transaction or deferred or contingent payments we agree to 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 2019 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 May 20, 2019, we entered into the 2019 Credit Agreement. The 2019 Credit Agreement provided us with a senior term loan facility in aggregate principal amount of \$70.0 million, of which \$40.0 million in aggregate principal amount is outstanding as of December 31, 2021. Of the remaining \$30.0 million, none is available for borrowing. We could also incur additional indebtedness in the future.

Our payment obligations under the 2019 Credit Agreement reduce cash available to fund working capital, capital expenditures, research and development and general corporate needs. In addition, indebtedness under the 2019 Credit Agreement bears 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 2019 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 2019 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 \$5.0 million. Failure to comply with the covenants in the 2019 Credit Agreement, including the minimum liquidity covenant, could result in the acceleration of our obligations under the 2019 Credit Agreement, and, if such acceleration were to occur, it 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 2019 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, ORO II 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 2019 Credit Agreement also provides for final payment fees of an additional \$4.6 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, 2021 and 2020, approximately 27% and 29%, 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 U.S. dollars, 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, 2021, we had U.S. federal and state net operating loss, or NOL, carryforwards of approximately \$415.3 million and \$105.7 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 and used in taxable years beginning after 2020 is 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 income, rather than losses, 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 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, insurance will continue to be available to us on economically reasonable terms, or at all, or 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 customer's 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, others with authorized access to our systems or unauthorized persons could negatively impact operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential



information stored in our or our third-party providers' systems, portable media or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. We are investing in protections and monitoring practices of our data and IT to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems that could 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 bring enforcement actions for violations beginning as early as July 1, 2020. The CCPA has been amended from time to time, and recently a new privacy law, the CPRA, was approved by California voters in the November 3, 2020 election. Effective starting January 1, 2023, the CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates 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, state officers and 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, require additional investment of resources in compliance programs, 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 €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, restrictions on data processing and other administrative penalties.

Further, following a referendum in June 2016 in which voters in the UK approved an exit from the EU, the United Kingdom government initiated a process to leave the EU known as Brexit. Brexit has created uncertainty with regard to the regulation of data protection in the United Kingdom. In January 2021, following its exit from the EU, the UK 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, diversion of internal resources and 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 UK 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 UK 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 UK. This adequacy determination will automatically expire in June 2025 unless the European Commission renews or extends it and 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, failed to comply with data

protection laws, or 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, 2021 and 2020, we had a net loss of \$117.7 million and \$102.0 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, 2021 and 2020, we had an accumulated deficit of \$478.7 million and \$361.0 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 will 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 several 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 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.

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 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, 2021 and 2020, we had \$107.9 million and \$139.8 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 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 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 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 of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting 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 had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and

regulatory requirements, which may also impact our business and which could have a material adverse effect on our business, financial condition and results of operations.

***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 changed, 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 ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation will only become applicable three years after publication. The effective date was further postponed by the European Commission for one year due to the COVID-19 pandemic, to May 2021. The new regulations, among other things:

- strengthens the rules on placing devices on the market and reinforce 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 or 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, and modify and clarify 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 also will be 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 otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state beneficiary inducement laws, which are state 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. Most recently, 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, effective January 1, 2019, 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, effective January 1, 2019, 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. The U.S. Supreme Court is currently reviewing the case, although it is unclear when a decision will be made or how the Supreme Court will rule. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the Affordable Care Act. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the Affordable Care Act, 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, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. 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 2030 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. 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 is 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, anticorruption, 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 allegations 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, 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, premarket approvals or 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 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 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 divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition and results of operations.

***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 these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, 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, 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, construe the patent's claims narrowly or 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 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 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 our patent or trademark applications at risk, 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, allow third-party submission of prior art to the USPTO during patent prosecution and 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, if any, impact 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 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 “—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 and 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, 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, 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 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 (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. We expect the lawsuits to be consolidated. 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 financings, acquisitions, investments, our 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 a financing, acquisition, investment, our 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 2019 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:

- not being required to have 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 \$1.07 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 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, 2021, our directors, executive officers and holders of more than 5% of our common stock beneficially owned, as a group, 23.9% of our common stock. As of December 31, 2021, funds affiliated with certain of our directors also held all of the outstanding shares of our Series A Common Equivalent Preferred Stock, which are 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, 2021, we had \$40.0 million in aggregate principal amount of outstanding long-term debt under our 2019 Credit Agreement with an entity affiliated with OrbiMed Advisors LLC, or OrbiMed Advisors, one of our 5% holders. 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 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, which requires 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), then 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.

## **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.

***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 (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. We expect the lawsuits to be consolidated. 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, 2021, 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 (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. We expect the lawsuits to be consolidated. 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 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 approximate number of record holders of our common stock on March 28, 2022 was 74. 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 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 access catheters, 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 were a series of recent strategic transactions and regulatory approvals, including: FDA 510(k) clearance and CE Mark of our second-generation AcQMap console and SuperMap software suite; the addition of an integrated family of transseptal crossing and steerable introducer systems to our product portfolio through our acquisition of Rhythm Xience; and the acquisition of our AcQBlate Force sensing product line from Biotronik. Since our full launch, we have continued to enhance our product portfolio and global presence by entering into bi-lateral distribution agreements with Biotronik in May 2020, which added a full suite of diagnostic and ablation catheters to our product portfolio and significantly expanded our international distribution and market development capabilities.

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, transseptal crossing tools, 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 year ended December 31, 2021 and 2020, we generated revenue of \$17.3 million and \$8.5 million, respectively, of which 52% and 43%, respectively, was from customers located outside of the United States. Since our inception, we have generated significant losses. Our net loss was \$117.7 million and \$102.0 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021 and 2020, we had an accumulated deficit of \$478.7 million and \$361.0 million, respectively, and working capital of \$107.8 million and \$129.5 million, respectively. Prior to our IPO in August 2020, our operations were financed primarily by aggregate net proceeds from the sale of our convertible preferred stock and principal of our converted debt of \$253.9 million, as well as other indebtedness.

On January 19, 2022, we announced a corporate restructuring to reduce our operating expenses and optimize our cash resources, pursuant to which we undertook a RIF and implemented additional cost reduction measures. 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. Based on the timing of notifications under the Worker Adjustment and Retraining Notification (WARN) Act, we expect to start realizing the benefits of our restructuring plan beginning late in the first quarter of 2022.

The 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 initial public offering or incurred prior to our initial public offering 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 substantial net losses and negative cash flows from operations for at least the next several years.

### **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, 2021 and 2020 is set forth in the table below:

	Year Ended December 31,	
	2021	2020
Acutus		
U.S.	42	37
Outside the U.S.	35	21
Total Acutus net system placements	77	58

**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.

During the years ended December 31, 2021 and 2020, physicians performed 1,570 and 930 procedures, respectively, including non-contact mapping and contact mapping worldwide, and therapeutic ablations outside the U.S.

Our total procedure volumes as of December 31, 2021 and 2020 is set forth in the table below:

	Year Ended December 31,	
	2021	2020
Procedure volumes	1,570	930

**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. These factors include:

- **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, 2021, our commercial organization consisted of 97 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 have entered into strategic partnerships with Innovative Health and Stereotaxis and, most recently, we entered into our Global Alliance for Electrophysiology with Biotronik in May 2020. In addition,



we added an integrated family of transseptal crossing and steerable introducer systems to our product portfolio through our acquisition of Rhythm Xience in June 2019 and acquired our AcQBlate Force Sensing Ablation System from Biotronik in July 2019. 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 2021, 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; 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 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 AcQCross family of universal transseptal crossing devices, the next-generation AcQGuide MAX and AcQGuide VUE large bore delivery sheaths and the next-generation AcQMap mapping catheter in May 2021. We also received FDA clearance of our AcQCross family of universal transseptal crossing devices in April 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.** Beginning in early March 2020, the COVID-19 pandemic and the measures imposed to contain this pandemic disrupted and are expected to continue to impact our business. Moreover, beginning in March 2020 and continuing through the filing of this Form 10-K, access to hospitals and other customer sites was restricted, which negatively impacted our ability to install our AcQMap consoles and workstations in new accounts and for our sales representatives and mappers to promote the use of our products with physicians. Over the past 12 months, we have continued to observe intermittent suspension of many elective procedures, as well as nursing and staffing shortages associated with the resurgence of COVID-19 in geographies where we sell, market and distribute our products. In addition, the impact of COVID-19 has varied by region and by healthcare facility, hampering our ability to forecast the sustained impact on our business from COVID-19. 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 the pandemic, associated restrictions and other measures designed to prevent the spread of COVID-19 and on our ability to conduct business in the ordinary course. Quarantines, shelter-in-place and similar government orders and capacity restrictions have also impacted, and may continue to impact, our third-party manufacturers and suppliers, and could in turn adversely impact the availability or cost of materials, which could disrupt our supply chain. The markets we serve are likely to 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.

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 of: (i) revenue from the sale of our disposable products; (ii) 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 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, transseptal crossing tools, diagnostic and mapping catheters, ablation catheters and accessories.

For the years ended December 31, 2021 and 2020, approximately 27% and 29%, 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.

## **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 have undertaken a planned RIF and are implementing additional 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 have undertaken a planned RIF and are implementing additional cost reduction measures. Due to this strategic realignment, we expect our selling, general and administrative expenses to decrease in absolute dollars in the upcoming years.

### *Change in Fair Value of Contingent Consideration*

The change in fair value of contingent consideration relates to the contingent consideration associated with our June 2019 acquisition of Rhythm Xience, an entity with an integrated family of transeptal crossing and steerable introducer systems. This acquisition included potential earn out considerations based on the achievement of certain regulatory milestones and revenue milestones. Changes in the estimated fair value of the contingent consideration earn out are recognized in the statement of operations and comprehensive loss, and reflect the changes within this account.

## **Other Income (Expense)**

### *Change in Fair Value of Warrant Liability*

We accounted for certain of our freestanding warrants to purchase shares of our common stock and preferred stock as liabilities at fair value. On August 10, 2020, in connection with the closing of our IPO, the warrants no longer met the definition of a derivative. Accordingly, the fair value of the common and preferred stock warrant liability was reclassified to additional paid-in capital in the consolidated balance sheet.

### *Interest Income*

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

*Interest Expense*

Interest expense primarily relates to our 2019 Credit Agreement with OrbiMed Royalty Opportunities II, LP and Deerfield Private Design Fund II, L.P.

## Results of Operations for the Years Ended December 31, 2021 and 2020

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, 2021 and 2020:

(dollars in thousands)	Year Ended December 31,		Change	
	2021	2020	\$	%
Revenue <sup>(1)</sup>	\$ 17,263	\$ 8,464	\$ 8,799	104 %
Costs and operating expenses:				
Costs of products sold <sup>(2)</sup>	32,925	15,889	17,036	107 %
Research and development <sup>(2)</sup>	36,683	33,454	3,229	10 %
Selling, general and administrative <sup>(2)</sup>	63,523	50,357	13,166	26 %
Change in fair value of contingent consideration	(3,746)	97	(3,843)	*
Total costs and operating expenses	129,385	99,797	29,588	30 %
Loss from operations	(112,122)	(91,333)	(20,789)	23 %
Other income (expense):				
Change in fair value of warrant liability	—	(5,555)	5,555	*
Interest income	116	436	(320)	(73)%
Interest expense	(5,677)	(5,506)	(171)	3 %
Total other expense, net	(5,561)	(10,625)	5,064	(48)%
Loss before income taxes	(117,683)	(101,958)	(15,725)	15 %
Income tax expense	—	23	(23)	*
Net loss	\$ (117,683)	\$ (101,981)	\$ (15,702)	15 %
Other comprehensive income (loss)				
Unrealized loss on marketable securities	(37)	(53)	16	(30)%
Foreign currency translation adjustment	(460)	363	(823)	*
Comprehensive loss	\$ (118,180)	\$ (101,671)	\$ (16,509)	16 %

\* Not meaningful

(1) The following tables sets forth our revenue for disposables, systems and service/other for the years ended December 31, 2021 and 2020:

	Year Ended December 31,	
	2021	2020
Disposables	\$ 11,938	\$ 6,713
Systems	4,058	1,660
Service/Other	1,267	91
Total revenue	\$ 17,263	\$ 8,464

	Year Ended December 31,	
	2021	2020
United States	\$ 8,325	\$ 4,854
Outside the United States	8,938	3,610
Total revenue	\$ 17,263	\$ 8,464

(2) The following table sets forth the stock-based compensation expense included in our results of operations for the years ended December 31, 2021 and 2020:

	Year Ended December 31,	
	2021	2020
Cost of products sold	\$ 864	\$ 440
Research and development	2,181	1,002
Selling, general and administrative	10,709	10,661
Total stock-based compensation	\$ 13,754	\$ 12,103

### **Revenue**

Revenue was \$17.3 million for the year ended December 31, 2021, compared to \$8.5 million for the year ended December 31, 2020. This increase of \$8.8 million, or 104%, was attributable to a \$5.2 million increase in purchase volume of our disposable products used in electrophysiology procedures as a result of a higher installed base and increased procedures, an increase of \$2.4 million in system sales, and \$1.2 million in services/other.

### **Costs and Operating Expenses**

#### *Cost of Products Sold*

Cost of products sold was \$32.9 million for the year ended December 31, 2021, compared to \$15.9 million for the year ended December 31, 2020. This increase of \$17.0 million, or 107%, was primarily driven by an increase of \$6.8 million due to the growth in revenue and a \$7.5 million increase in depreciation and freight expense to support the higher installed base. Gross margin was negative 91% for the year ended December 31, 2021, and negative 88% for the year ended December 31, 2020. This decrease in gross margin was attributable to several factors including, product and geographic mix, higher depreciation associated with placed equipment, higher field service expenses, as well as the write-off of excess and obsolete inventory in 2021.

#### *Research and Development Expenses*

Research and development expenses were \$36.7 million for the year ended December 31, 2021, compared to \$33.5 million for the year ended December 31, 2020. This increase of \$3.2 million, or 10%, was primarily attributable to \$2.9 million in increased compensation and related costs from higher headcount.

#### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses were \$63.5 million for the year ended December 31, 2021, compared to \$50.4 million for the year ended December 31, 2020. This increase of \$13.2 million, or 26%, was primarily attributable to \$10.8 million in increased compensation and \$3.1 million in increased insurance costs in connection with our operations as a public company, partially offset by \$0.7 million in decreased consulting expenses.

#### *Change in Fair Value of Contingent Consideration*

For the years ended December 31, 2021 and 2020, we recorded a change in fair value of contingent consideration of a decrease of \$3.7 million and an increase of \$0.1 million, respectively, for the change in the fair value of the contingent consideration for the acquisition of Rhythm Xience. The decrease in 2021 was primarily attributable to a decrease in projected net revenue, along with a decrease to the expected term.

#### **Other Income (Expense)**

Other expense, net was \$5.6 million for the year ended December 31, 2021, compared to \$10.6 million for the year ended December 31, 2020. This decrease of \$5.1 million, or 48%, was primarily attributable to a prior year change of \$5.6 million in the fair value of the warrant liability.

### **Liquidity and Capital Resources**

The Company has limited revenue, has incurred significant operating losses and negative cash flows from operations since our inception, and we anticipate that we will incur significant losses for at least the next several years. As of December 31, 2021 and 2020, we had cash, cash equivalents and marketable securities of \$107.9 million and \$139.8 million, respectively. For the years ended December 31, 2021 and 2020, our net losses were \$117.7 million and \$102.0 million, respectively, and our net cash

used in operating activities was \$99.7 million and \$85.2 million respectively. As of December 31, 2021 and 2020, we had an accumulated deficit of \$478.7 million and \$361.0 million, respectively, and working capital of \$107.8 million and \$129.5 million, respectively.

Prior to our IPO in August 2020, our operations had been financed primarily by aggregate net proceeds from the sale of our convertible preferred stock and principal of our converted debt of \$253.9 million, as well as other indebtedness. On August 10, 2020, we issued 10,147,058 shares of common stock in our IPO, which included 1,323,529 shares of common stock issued upon the exercise in full by the underwriters of an option to purchase additional shares of our common stock, at the public offering price less underwriting discounts and commissions. The price to the public was \$18.00 per share, for net proceeds to us of \$166.3 million.

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 from the offering.

With the closing of the Company's IPO in August 2020 and follow on offering in July 2021 and the January 2022 RIF, we believe the Company's current cash, cash equivalents and marketable securities are sufficient to fund operations for at least the next 12 months. However, the Company may need to raise additional funds through the issuance of additional debt, equity or both. 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 the Company on the timing needed or on terms that the Company 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.

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

- our revenue growth;
- our ability to drive improved manufacturing efficiency;
- 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 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;

- our ability to realize the anticipated benefits of our corporate restructuring; 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. For example, in June 2019, we acquired Rhythm Xience, a medical device company specializing in the design and manufacture of transseptal crossing and steerable introducer systems, for \$3.0 million in cash. The cash payment did not include the potential \$17.0 million in earn out consideration to be paid based on the achievement of certain regulatory milestones and revenue milestones. In February 2020, we issued to the former owners of Rhythm Xience 119,993 shares of our Series D convertible preferred stock and paid them \$2.5 million in connection with the regulatory and revenue milestones earned to date. In addition, pursuant to the Biotronik License Agreement, we paid Biotronik a \$3.0 million upfront fee at the time the agreement was signed, as well as a technology transfer fee consisting of \$7.0 million in cash in December 2019 and \$5.0 million in shares of our Series D convertible preferred stock in February 2020. We are required to pay the Biotronik Parties up to \$10.0 million, of which \$2.0 million has been paid as of December 31, 2021, upon the achievement of various regulatory and sales-related milestones, as well as unit-based royalties on any sales of force sensing catheters. We also incur costs as a public company that we did not incur prior to our IPO or incurred prior to our IPO at lower rates.

Under Accounting Standards Codification, or ASC, 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. We believe management’s plans sufficiently alleviate the risk of substantial doubt about our ability to continue as a going concern for at least twelve months from the date that the accompanying consolidated financial statements included elsewhere in this Form 10-K were issued. Going concern matters are more fully discussed in Note 1, “Organization and Description of Business - Liquidity and Capital Resources” of our consolidated financial statements. Additionally, we will need to raise additional funds through the issuance of debt and/or equity securities or otherwise, 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. To raise sufficient additional funds, we may be required to delay, limit, reduce or terminate our product discovery and development activities or future commercialization efforts. There can be no assurance that we will be able to obtain the needed financing on acceptable terms or at all. In addition, our recent corporate restructuring is intended to reduce our operating expenses and optimize our cash resources. Based on the timing of notifications under the WARN Act, we expect to start realizing the benefits of our restructuring plan beginning late in the first quarter of 2022; however, there can be no assurance that we realize the benefits of the restructuring on the anticipated timeline, or at all.

### **Debt Obligations**

On May 20, 2019, we entered into the 2019 Credit Agreement. The 2019 Credit Agreement provided us with a senior term loan facility in aggregate principal amount of \$70.0 million, of which we borrowed \$40.0 million upon closing. Of the remaining \$30.0 million, none is available for borrowing. The 2019 Credit Agreement bears interest per annum at 7.75% plus LIBOR for such interest period, and the principal amount of term loans outstanding under the 2019 Credit Agreement is due on May 20, 2024. The 2019 Credit Agreement can be prepaid but is subject to prepayment penalties. The 2019 Credit Agreement provides for final payment fees of an additional \$4.6 million that are due upon prepayment, on the maturity date or upon acceleration.

Upon the occurrence and during an event of default, which includes but is not limited to payment default, covenant default or the occurrence of a material adverse change, the lenders may declare all outstanding principal and accrued and unpaid interest immediately due and payable, there would be an increase in the applicable interest rate by 10% per annum and the lenders would be entitled to exercise their other rights and remedies provided for under the 2019 Credit Agreement. Additionally, the lenders may request repayment of a portion of obligations outstanding under the 2019 Credit Agreement to the extent of the Company’s receipt of any (i) net casualty proceeds or (ii) net asset sales proceeds, as defined.

Our obligations under the 2019 Credit Agreement are secured by substantially all of our assets, including our intellectual property, and is guaranteed by our subsidiary. The 2019 Credit Agreement contains customary affirmative and restrictive



covenants, including with respect to our ability to enter into fundamental transactions, incur additional indebtedness, grant liens, pay any dividend or make any distributions to our holders, make investments and merge or consolidate with any other person or engage in transactions with our affiliates, but does not include any financial covenants, other than a minimum liquidity requirement.

### **Cash Flows**

The following table shows a summary of our cash flows for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
Net cash used in operating activities	\$ (99,682)	\$ (85,169)
Net cash provided by / (used in) investing activities	19,066	(63,824)
Net cash provided by financing activities	79,569	164,433
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(116)	342
Net change in cash, cash equivalents and restricted cash	<u>\$ (1,163)</u>	<u>\$ 15,782</u>

### *Operating Activities*

During the year ended December 31, 2021, operating activities used \$99.7 million of cash, an increase of \$14.5 million from the year ended December 31, 2020. This increase was attributable to higher net losses of \$15.7 million and a decrease in non-cash items of \$1.1 million, including a decrease in the fair value of warrant liability of \$5.6 million and a decrease in the change in fair value of contingent consideration of \$3.8 million, offset by an increase in depreciation expense of \$3.0 million, an increase in AcQMap Systems converted to sales of \$2.2 million, an increase in stock-based compensation expense of \$1.7 million, an increase in the amortization of premiums on marketable securities of \$0.8 million, and an increase in amortization of debt issuance costs of \$0.6 million, partially offset by favorable changes in working capital of \$2.3 million.

### *Investing Activities*

Total cash provided by investing activities was \$19.1 million and used in investing activities was \$63.8 million for the years ended December 31, 2021 and 2020, respectively.

Cash provided by investing activities during 2021 was related to proceeds from maturities of marketable securities of \$107.7 million and sales of marketable securities of \$8.6 million. These inflows were partially offset by purchases of marketable securities of \$87.3 million and purchases of property and equipment of \$10.0 million.

Cash used in investing activities during 2020 was related to purchases of marketable securities of \$114.7 million and purchases of property and equipment of \$11.2 million. These outflows were partially offset by proceeds from maturities of marketable securities of \$45.0 million and sales of marketable securities of \$17.1 million.

### *Financing Activities*

Total cash provided by financing activities was \$79.6 million and \$164.4 million for the years ended December 31, 2021 and 2020, respectively. The decrease of \$84.9 million is primarily related to the difference in proceeds from our follow on offering in the current year and our IPO in the prior year of \$83.6 million.

### **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

Further, the agreement to acquire Rhythm Xience requires us to pay the former owners of Rhythm Xience up to \$15.0 million in additional cash earn out consideration based on the achievement of certain regulatory and revenue milestones, of which \$5.9 million has been paid as of December 31, 2021. In February 2020, we issued to the former owners of Rhythm Xience 119,993 shares of our Series D convertible preferred stock valued at \$2.2 million. In addition, pursuant to the Biotronik License Agreement, we issued to Biotronik \$5.0 million in shares of our Series D convertible preferred stock in February 2020, and we

are required to pay the Biotronik Parties up to \$10.0 million, of which \$2.0 million has been paid as of December 31, 2021, upon the achievement of various regulatory and sales-related milestones, as well as unit-based royalties on any sales of force sensing catheters.

### **Off-Balance Sheet Arrangements**

As of December 31, 2021 and 2020, 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 have been 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 to our consolidated financial statements, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

### **Revenue from Contracts with Customers**

We account for revenue earned from contracts with customers under ASC 606, *Revenue from Contracts with Customers*, or ASC 606, and ASC 842, *Leases*, or 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. Included in the transseptal crossing line of products are primarily the AcQRef introducer sheath, the AcQGuide sheaths and the AcQCross Transseptal Dilator/Needle.

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.

### ***Stock-Based Compensation***

We account for all stock-based payments to employees and non-employees, including grants of stock options, restricted stock awards, or RSAs, restricted stock units, or RSUs, and restricted stock units with non-market performance and service conditions, or PSUs, 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, RSUs and PSUs 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. As the PSUs have a performance condition, compensation expense was recognized for each vesting tranche over the respective requisite service period of each tranche upon the registration statement used in connection with the Company's IPO being declared effective on August 5, 2020, when the Company's management deemed it probable that the performance conditions were satisfied. The Company recognized a cumulative true-up adjustment related to PSUs once the conditions became probable of being satisfied as the related service period had been completed in a prior 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 recognize 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 to sell 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). We classify our contingent consideration liability, discussed below, as Level 3.

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. The initial fair value of the revenue-based contingent consideration was 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 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 accounted for certain common stock warrants and convertible preferred stock warrants outstanding as a liability, in accordance with ASC 815, *Derivatives and Hedging*, at fair value and adjusted the instruments to fair value at each reporting period. On August 10, 2020 when the warrants were converted and became equity classified warrants, the fair value of the common and preferred stock warrant liability was estimated using a Black-Scholes model. The underlying equity included in the Black-Scholes model was based on the IPO share price of \$18.00.

This liability was subject to re-measurement at each reporting period and upon conversion to equity-classified warrants, and any change in fair value was recognized in our consolidated statements of operations and comprehensive loss. In connection with the IPO on August 10, 2020, the common stock warrants and convertible preferred stock warrants that had been liability-classified, were automatically converted into an equal number of warrants to purchase common stock and became equity-classified. The fair value of the outstanding liability on the conversion date was reclassified to additional paid-in capital in our consolidated balance sheet.

### **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 could first assess 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, 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.

### **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 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 \$1.07 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.

**Item 8. Financial Statements and Supplementary Data.**

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**Acutus Medical, Inc.  
Consolidated Financial Statements**

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## 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, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), 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, 2021 and 2020, 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 30, 2022

**ACUTUS MEDICAL, INC.**  
**Consolidated Balance Sheets**

(in thousands, except share and per share amounts)	December 31,	
	2021	2020
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 24,071	\$ 25,234
Marketable securities, short-term	76,702	105,839
Restricted cash	150	150
Accounts receivable	3,633	2,160
Inventory	16,408	12,958
Prepaid expenses and other current assets	5,326	5,047
<b>Total current assets</b>	<b>126,290</b>	<b>151,388</b>
Marketable securities, long-term	7,120	8,726
Property and equipment, net	13,670	12,356
Right-of-use asset, net	4,521	1,669
Intangible assets, net	5,013	5,653
Goodwill	12,026	12,026
Other assets	1,152	717
<b>Total assets</b>	<b>\$ 169,792</b>	<b>\$ 192,535</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,519	\$ 8,266
Accrued liabilities	9,096	7,308
Contingent consideration, short-term	1,500	5,400
Operating lease liabilities, short-term	395	933
<b>Total current liabilities</b>	<b>18,510</b>	<b>21,907</b>
Operating lease liabilities, long-term	4,591	1,134
Long-term debt	40,415	39,011
Contingent consideration, long-term	500	3,900
Other long-term liabilities	50	—
<b>Total liabilities</b>	<b>64,066</b>	<b>65,952</b>
<b>Commitments and contingencies (Note 12)</b>		
<b>Stockholders' equity</b>		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized December 31, 2021 and 2020; 6,666 shares of preferred stock, designated as Series A Common Equivalent Preferred Stock, are issued and outstanding as of December 31, 2021, no shares issued and outstanding as of December 31, 2020	—	—
Common stock, \$0.001 par value; 260,000,000 shares authorized as of December 31, 2021 and 2020; 27,957,223 and 27,991,425 shares issued and outstanding as of December 31, 2021 and 2020, respectively	28	28
Additional paid-in capital	584,613	487,290
Accumulated deficit	(478,698)	(361,015)
Accumulated other comprehensive (loss) income	(217)	280
<b>Total stockholders' equity</b>	<b>105,726</b>	<b>126,583</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 169,792</b>	<b>\$ 192,535</b>

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



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

<i>(in thousands, except share and per share amounts)</i>	Year Ended December 31,	
	2021	2020
<b>Revenue</b>	\$ 17,263	\$ 8,464
<b>Costs and operating expenses:</b>		
Cost of products sold	32,925	15,889
Research and development	36,683	33,454
Selling, general and administrative	63,523	50,357
Change in fair value of contingent consideration	(3,746)	97
Total costs and operating expenses	129,385	99,797
<b>Loss from operations</b>	(112,122)	(91,333)
<b>Other income (expense):</b>		
Change in fair value of warrant liability	—	(5,555)
Interest income	116	436
Interest expense	(5,677)	(5,506)
Total other expense, net	(5,561)	(10,625)
Loss before income taxes	(117,683)	(101,958)
Income tax expense	—	23
<b>Net loss</b>	\$ (117,683)	\$ (101,981)
<b>Other comprehensive income (loss):</b>		
Unrealized loss on marketable securities	(37)	(53)
Foreign currency translation adjustment	(460)	363
<b>Comprehensive loss</b>	\$ (118,180)	\$ (101,671)
Net loss per common share, basic and diluted	\$ (4.11)	\$ (8.94)
Weighted average shares outstanding, basic and diluted	28,654,313	11,407,542

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

**ACUTUS MEDICAL, INC.**  
**Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**

(in thousands, except share amounts)	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
	<b>Balance as of December 31, 2019</b>	391,210	\$ 3,059	3,088,444	\$ 40,685	4,499,921	\$ 74,575	8,200,297	\$ 135,039	695,902				
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	(53)	(53)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	—	363	363
Issuance of Series D convertible preferred stock for the Biotronik Asset Purchase	—	—	—	—	—	—	273,070	5,000	—	—	—	—	—	—
Issuance of Series D convertible preferred stock for the contingent consideration related to the Rhythm Xience Acquisition	—	—	—	—	—	—	119,993	2,197	—	—	—	—	—	—
Conversion of convertible preferred stock into common stock upon IPO	(391,210)	(3,059)	(3,088,444)	(40,685)	(4,499,921)	(74,575)	(8,593,360)	(142,236)	16,572,935	17	260,538	—	—	260,555
Issuance of common stock for cash, net of issuance costs of \$16,361	—	—	—	—	—	—	—	—	10,147,058	10	166,276	—	—	166,286
Reclassification of warrant liability to stockholders' equity	—	—	—	—	—	—	—	—	—	—	14,474	—	—	14,474
Stock option exercises	—	—	—	—	—	—	—	—	124,938	—	634	—	—	634
Stock-based compensation	—	—	—	—	—	—	—	—	319,420	—	12,103	—	—	12,103
Warrant exercises	—	—	—	—	—	—	—	—	131,172	—	13	—	—	13
Net loss	—	—	—	—	—	—	—	—	—	—	—	(101,981)	—	(101,981)
<b>Balance as of December 31, 2020</b>	—	\$ —	—	\$ —	—	\$ —	—	\$ —	27,991,425	\$ 28	\$ 487,290	\$ (361,015)	\$ 280	\$ 126,583

(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				
<b>Balance as of December 31, 2020</b>	—	\$ —	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)
<b>Balance as of December 31, 2021</b>	<b>6,666</b>	<b>\$ —</b>	<b>27,957,223</b>	<b>\$ 28</b>	<b>\$ 584,613</b>	<b>\$ (478,698)</b>	<b>\$ (217)</b>	<b>\$ 105,726</b>

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,	
	2021	2020
<b>Cash flows from operating activities</b>		
Net loss	\$ (117,683)	\$ (101,981)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	5,754	2,763
AcQMap Systems converted to sales	2,182	—
Sales-type lease loss	28	—
Amortization of intangible assets	640	457
Non-cash stock-based compensation expense	13,754	12,103
Amortization of premiums/(accretion of discounts) on marketable securities, net	1,277	484
Amortization of debt issuance costs	1,404	767
Amortization of right-of-use assets	496	684
Change in fair value of warrant liability	—	5,555
Change in fair value of contingent consideration	(3,746)	97
Changes in operating assets and liabilities:		
Accounts receivable	(1,473)	(1,897)
Inventory	(3,872)	(3,891)
Prepaid expenses and other current assets	1,133	(3,383)
Other assets	304	(622)
Accounts payable	(871)	2,283
Accrued liabilities	1,549	2,232
Operating lease liabilities	(608)	(820)
Other long-term liabilities	50	—
Net cash used in operating activities	(99,682)	(85,169)
<b>Cash flows from investing activities</b>		
Purchases of available-for-sale marketable securities	(87,258)	(114,694)
Sales of available-for-sale marketable securities	8,590	17,095
Maturities of available-for-sale marketable securities	107,707	45,000
Purchases of property and equipment	(9,973)	(11,225)
Net cash provided by (used in) investing activities	19,066	(63,824)
<b>Cash flows from financing activities</b>		
Payment of deferred offering costs	(580)	—
Payment of contingent consideration	(3,435)	(2,500)
Payment of contingent consideration into escrow	(224)	—
Proceeds from employee stock purchase plan	440	—
Proceeds from warrants exercises	—	13
Proceeds from issuance of common stock, net of issuance costs	82,657	166,286
Proceeds from stock options exercises	711	634
Net cash provided by financing activities	79,569	164,433
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(116)	342
Net change in cash, cash equivalents and restricted cash	(1,163)	15,782
Cash, cash equivalents and restricted cash, at the beginning of the period	25,384	9,602
<b>Cash, cash equivalents and restricted cash, at the end of the period</b>	<b>\$ 24,221</b>	<b>\$ 25,384</b>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 4,259	\$ 4,676
<b>Supplemental disclosure of noncash investing and financing activities:</b>		
Issuance of Series D convertible preferred stock for Biotronik asset purchase	\$ —	\$ 5,000
Issuance of Series D convertible preferred stock for Rhythm Xience Acquisition	\$ —	\$ 2,197
Change in unrealized loss on marketable securities	\$ 37	\$ 53
Right-of-use assets exchanged for operating lease liabilities	\$ 3,527	\$ —
Accrued licensed intangibles assets	\$ —	\$ 2,000
Change in unpaid purchases of property and equipment	\$ 124	\$ 101
Unpaid deferred offering costs	\$ —	\$ 643
Net book value of AcQMap System sales-type leases	\$ 1,104	\$ —
Conversion of convertible preferred stock into common stock upon IPO	\$ —	\$ 260,555
Reclassification of warrant liability to additional paid-in capital	\$ —	\$ 14,474

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

**Acutus Medical, Inc.**  
**Notes to 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, transseptal crossing tools, 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, 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, 2021 and 2020, the Company had cash, cash equivalents and marketable securities of \$107.9 million and \$139.8 million, respectively. For the years ended December 31, 2021 and 2020, net losses were \$117.7 million and \$102.0 million, respectively, and net cash used in operating activities was \$99.7 million and \$85.2 million respectively. As of December 31, 2021 and 2020, the Company had an accumulated deficit of \$478.7 million and \$361.0 million, respectively, and working capital of \$107.8 million and \$129.5 million, respectively.

Prior to the Company’s initial public offering (“IPO”) in August 2020, operations had been financed primarily by aggregate net proceeds from the sale of convertible preferred stock and principal of converted debt of \$253.9 million, as well as other indebtedness. On August 10, 2020, the Company issued 10,147,058 shares of common stock in its IPO, which included 1,323,529 shares of common stock issued upon the exercise in full by the underwriters of an option to purchase additional shares of common stock, at the public offering price less underwriting discounts and commissions. The price to the public was \$18.00 per share, for net proceeds of \$166.3 million.

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 from the offering.

With the closing of the Company’s IPO in August 2020, the follow on offering in July 2021 and the January 2022 reduction in force, management believes the Company’s current cash, cash equivalents and marketable securities are sufficient to fund operations for at least the next 12 months. Under Accounting Standard Codification (“ASC”) Subtopic 205-40, *Presentation of Financial Statements—Going Concern* (“ASC 205-40”), the Company has the responsibility to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the date that the consolidated financial statements are issued. As required under ASC 205-40, management’s evaluation should initially not take into consideration the potential mitigating effects of management’s plans that have not been fully implemented as of the date the consolidated financial statements are issued. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern.

**Substantial Doubt Raised**

In performing the first step of the evaluation, the Company concluded that the following conditions raised substantial doubt about its ability to continue as a going concern:

- History of net losses of \$117.7 million and \$102.0 million for the years ended December 31, 2021 and December 31, 2020, respectively;
- Accumulated deficit of \$478.7 million and \$361.0 million as of December 31, 2021 and December 31, 2020, respectively;
- Disruptions in elective procedure volumes related to unanticipated impacts from COVID-19; and
- History of negative gross margins.

### *Consideration of Management's Plans*

In performing the second step of this assessment, the Company is required to evaluate whether it is probable that its plans will be effectively implemented within one year after the consolidated financial statements are issued and whether it is probable those plans will alleviate the substantial doubt about its ability to continue as a going concern.

The Company has identified several potential actions to strengthen liquidity and optimize resources in the event actual results and other planned activities differ materially from projections. The Company is prepared to rapidly implement these actions as required by business and market conditions. These actions would improve the available cash balances, liquidity and cash flows generated from operations over the twelve-month period from the date the consolidated financial statements are issued, as follows:

- Reduction in force that would be intended to extend the cash runway necessary to fund operations;
- Total compensation reductions for senior executives to strengthen liquidity and to preserve key research and development, commercial and functional roles;
- Identification of efficiencies within corporate functions to reduce certain external consulting and business support spend; and
- Deferral and reprioritization of certain research and development programs that would involve reduced program and headcount spend.

### *Management Assessment of Ability to Continue as a Going Concern*

The Company has a history of operating losses and negative cash flows from operations. However, despite these conditions, the Company believes management's plans, as described more fully above, will provide sufficient liquidity to meet its financial obligations and maintain levels of liquidity as specifically required under the 2019 Credit Agreement, as defined below. Therefore, management concluded these plans alleviate the substantial doubt that was raised about the Company's ability to continue as a going concern for at least twelve months from the date that the consolidated financial statements were issued.

### *Future Plans and Considerations*

Although not considered for purposes of the Company's assessment of whether substantial doubt was alleviated, the Company has retained several specialized third-party consultants and advisors to review its strategy as well as a range of options to fund the long-term growth of the Company, including non-dilutive financing, partnerships, licensing, and distribution agreements.

The Company's plans are subject to inherent risks and uncertainties, which become significantly magnified when the effects of the current pandemic and related financial crisis are included in the assessment. Accordingly, there can be no assurance that the Company's plans can be effectively implemented and, therefore, that the conditions can be effectively mitigated.

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 the Company on the timing needed or on terms that the Company 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. The most significant estimates and assumptions in the Company’s consolidated financial statements include, but are not limited to, revenue recognition, useful lives of intangible assets, assessment of impairment of goodwill, measurement of operating lease liabilities, and the fair value of common stock, stock options, warrants, intangible assets, contingent consideration and goodwill. 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 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, 2021 and 2020, exceeded federally insured limits.

Restricted cash serves as collateral for the Company’s corporate credit card program. 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).

	<b>December 31, 2021</b>	<b>December 31, 2020</b>
Cash and cash equivalents	\$ 24,071	\$ 25,234
Restricted cash	150	150
Total cash, cash equivalents and restricted cash	<u>\$ 24,221</u>	<u>\$ 25,384</u>

### **Marketable 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 (deficit) until their disposition or maturity. See “Fair Value Measurements” below. 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 did not record any 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, 2021 or 2020.

### ***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. The Company's marketable securities portfolio consists of investments in money market funds, commercial paper, U.S. treasury securities, Yankee debt securities, supranational, asset-backed securities and short-term high credit quality corporate debt securities.

### ***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 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.

For new customers, the Company places its medical diagnostic equipment, 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, 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. 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.

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 the 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 will be 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 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 SE & Co. KG ("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 includes, but is not limited to, transactions where the specific performance obligations are sold separately, list prices and 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, 2021 and 2020.

In May 2020, the Company entered into bi-lateral distribution agreements with Biotronik (the "Bi-Lateral Distribution Agreements"). 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 to the other party specified transfer prices 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.



The following table sets forth the Company's revenue for disposables, systems, and service/other for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
Disposables	\$ 11,938	\$ 6,713
Systems	4,058	1,660
Service/Other	1,267	91
Total revenue	\$ 17,263	\$ 8,464

The following table provides revenue by geographic location for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
United States	\$ 8,325	\$ 4,854
Outside the United States	8,938	3,610
Total revenue	\$ 17,263	\$ 8,464

### **Inventory**

Inventory is comprised of raw materials, direct labor and manufacturing overhead and 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 based on management's review of inventories on hand, compared to estimated future usage and sales, shelf-life and assumptions about the likelihood of obsolescence of \$1.3 million and \$0.1 million for the years ended December 31, 2021 and 2020, respectively.

### **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, 2021 or 2020.

### **Property and Equipment, Net**

Property and equipment are 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, acquired in-process technology, trademarks and trade names and a customer-related intangible which were acquired as part of the acquisition of Rhythm Xience, Inc. ("Rhythm Xience") in June 2019. 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 was classified as an indefinite-lived intangible asset, until the receipt of U.S. Food and Drug Administration ("FDA") approval for the technology in January 2020. Once the FDA approval was received, the in-process technology was classified as a finite-lived intangible and amortization for in-process technology began. 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.

### **Goodwill**

Goodwill represents the excess of the purchase price of an entity over the estimated fair value of the assets acquired and liabilities assumed, and it is presented as goodwill in the accompanying consolidated balance sheets. 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 could first assess 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. The Company has one reporting unit. For the years ended December 31, 2021 and 2020, the quantitative testing did not indicate any impairment for the carrying amount of goodwill.

#### ***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, 2021 and 2020, the Company determined that there was no impairment of property and equipment or intangible assets.

#### ***Foreign Currency Translation and Transactions***

The assets, liabilities and results of operations of Acutus NV are measured using their functional currency, the Euro, which is the currency of the primary foreign economic environment in which this subsidiary operates. Upon consolidating this entity 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.

#### ***Lessee Leases***

The Company accounts for its leases 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. 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 has elected to combine lease and non-lease components. The Company excludes short-term leases having initial terms of twelve months or less from the new guidance as an accounting policy election.

#### ***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.

In April 2021, the Company and Biotronik entered into a Feasibility and Development Agreement to pursue the development of hardware, software and IT infrastructure to implement the Qubic Connect System (“QBS”). The QBS will allow data transfer

from multiple diagnostic and therapeutic medical products during an electrophysiology procedure to be aggregated and analyzed for the purposes of designing improved treatment protocols.

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 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. The Company expenses all SG&A costs as incurred.

#### ***Fair Value Measurements***

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 has been used in determining the inputs used in 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 that are financial instruments whose values are determined 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, 2021 and 2020.

As of December 31, 2021 and 2020, 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 the instruments. 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, 2021 and 2020 (in thousands):

	Fair Value Measured 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)	Fair Value at December 31, 2021
<b>Assets included in:</b>				
Cash and cash equivalents				
Money market securities	\$ 21,893	\$ —	\$ —	\$ 21,893
<b>Marketable securities at fair value</b>				
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
<b>Total fair value</b>	<b>\$ 21,893</b>	<b>\$ 83,822</b>	<b>\$ —</b>	<b>\$ 105,715</b>
<b>Liabilities included in:</b>				
Contingent consideration	\$ —	\$ —	\$ 2,000	\$ 2,000
<b>Total fair value</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 2,000</b>	<b>\$ 2,000</b>

	Fair Value Measured as of December 31, 2020			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value at December 31, 2020
<b>Assets included in:</b>				
Cash and cash equivalents				
Money market securities	\$ 19,070	\$ —	\$ —	\$ 19,070
<b>Marketable securities at fair value</b>				
Corporate debt securities	—	31,353	—	31,353
Asset-backed securities	—	8,726	—	8,726
U.S. treasury securities	—	20,531	—	20,531
Commercial paper	—	53,955	—	53,955
<b>Total fair value</b>	<b>\$ 19,070</b>	<b>\$ 114,565</b>	<b>\$ —</b>	<b>\$ 133,635</b>
<b>Liabilities included in:</b>				
Contingent consideration	\$ —	\$ —	\$ 9,300	\$ 9,300
<b>Total fair value</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 9,300</b>	<b>\$ 9,300</b>

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

The Company's portfolio of marketable securities is comprised of commercial paper, asset-backed securities, U.S. treasury securities, Yankee debt securities, supranational and short-term highly liquid, high credit quality corporate debt securities. The fair value for the available-for-sale marketable securities is determined based on trade prices in active markets for identical

assets (Level 1 inputs) or 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.

The following table presents changes in Level 3 liabilities measured at fair value for the years ended December 31, 2021 and 2020 (in thousands):

	Common and Preferred Stock Warrant Liability	Contingent Consideration	Total
<b>Balance, December 31, 2019</b>	\$ 8,919	\$ 13,900	\$ 22,819
Payment of contingent consideration	—	(2,500)	(2,500)
Issuance of preferred stock for contingent consideration	—	(2,197)	(2,197)
Reclassification of warrant liability to additional paid-in capital	(14,474)	—	(14,474)
Change in fair value	5,555	97	5,652
<b>Balance, December 31, 2020</b>	\$ —	\$ 9,300	\$ 9,300
Payment of contingent consideration	—	(3,435)	(3,435)
Escrow release	—	(119)	(119)
Change in fair value	—	(3,746)	(3,746)
<b>Balance, December 31, 2021</b>	\$ —	\$ 2,000	\$ 2,000

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.

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. 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, 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. 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, 2021 and December 31, 2020 were as follows:

	December 31, 2021	December 31, 2020
Risk-free interest rate	0.60%	0.20%
Expected term in years	1.0 - 2.0	1.0 - 2.0
Expected volatility	28.8%	17.2%

### Stock-Based Compensation

The Company accounts for all stock-based payments to employees and non-employees, including grants of stock options, restricted stock awards ("RSAs"), restricted stock units ("RSUs") and restricted stock units with non-market performance and service conditions ("PSUs") 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 RSAs, RSUs and PSUs 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. As the PSUs have a performance condition, compensation expense was recognized for each vesting tranche over the respective requisite service period of each tranche upon the registration statement becoming effective on August 5, 2020, when the Company's management deemed it probable that the performance conditions were satisfied. The Company recognized a cumulative true-up adjustment related to PSUs once the conditions became probable of being satisfied as the related service period had been completed in a prior 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 also "Note 16—Stock-Based Compensation" below.

### **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 net operating loss ("NOL") carryforwards and research and development ("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.

### **Warrant Liability**

The Company accounted for certain common stock warrants and convertible preferred stock warrants outstanding as a liability, in accordance with ASC 815, *Derivatives and Hedging* ("ASC 815"), at fair value. This liability was subject to re-measurement at each reporting period and upon conversion to equity-classified warrants, and any change in fair value was recognized in the consolidated statements of operations and comprehensive loss. In connection with the IPO on August 10, 2020, the common stock warrants and convertible preferred stock warrants that had been liability-classified were automatically converted into an equal number of warrants to purchase common stock and became equity-classified. The fair value of the outstanding liability on the conversion date was reclassified to additional paid-in capital in the Company's consolidated balance sheet.

### **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 represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired.

### **Recently Adopted Accounting Pronouncements**

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects related to accounting for income taxes. ASU No. 2019-12 removes certain exceptions to the general principles in ASC 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company adopted this guidance in the first quarter of 2021, which did not have a material impact on its consolidated financial statements.

### **Accounting Pronouncements to Be Adopted**

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)*. The ASU 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. This ASU is effective for smaller reporting companies in 2023. The Company is currently assessing the impact of the adoption of this ASU on its consolidated financial statements.

In March 2020, the FASB issued ASU No. 2020-4, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, which provides temporary optional guidance to ease the potential burden in accounting for reference rate reform. The new guidance provides optional expedients and exceptions for applying U.S. GAAP to transactions affected by reference rate reform if certain criteria are met. These transactions include: contract modifications, hedging relationships and sale or transfer of debt securities classified as held-to-maturity. Entities may apply the provisions of the new standard as of the beginning of the reporting period when the election is made (i.e., as early as the first quarter 2020). Unlike other topics, the provisions of this update are only available until December 31, 2022, when the reference rate replacement activity is expected to have been completed. The Company is currently evaluating the impact of this standard on its consolidated financial statements and has yet to elect an adoption date.

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)*, 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. This ASU is effective for smaller reporting companies in 2022. The Company does not expect the impact of the adoption of this ASU to have a material effect on its consolidated financial statements.

In May 2021, the FASB issued ASU No. 2021-05, *Leases (Topic 842), Lessors – Certain Leases with Variable Lease Payments*, 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 does not expect the impact of the adoption of this ASU to have a material effect on its consolidated financial statements.

### **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”) to obtain certain licenses to the Biotronik Parties’ patents, whereby the Company acquired certain manufacturing equipment and obtained from the Biotronik Parties a license under certain patents and technology to develop, commercialize, distribute and manufacture the AcQBlate FORCE ablation catheters and Qubic Force Device. In exchange for the rights granted to the Company, the Company made cash payments totaling \$10.0 million during the year ended December 31, 2019, and issued 273,070 shares of Series D convertible preferred stock with an implied value of \$5.0 million during the three months ended March 31, 2020. The implied value of \$5.0 million was recorded as an accrued liability as of December 31, 2019. 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. On the acquisition date, the products licensed had not yet received regulatory approval and the intellectual property did not have an alternative use. Accordingly, the \$15.0 million paid to Biotronik was immediately charged to research and development expense - licensed acquired in the consolidated statement of operations and comprehensive loss in July 2019.

Additional contingent milestone payments of up to \$10.0 million, of which \$2.0 million has been paid as of December 31, 2021, are to be made to the Biotronik Parties contingent upon certain regulatory approvals and first commercial sale. 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 Company also makes per unit royalty payments. As of December 31, 2021, less than \$0.1 million has been included within accrued liabilities for these royalties. The Company determined that the remaining \$8.0 million of contingent milestones are not probable and estimable and therefore have not been recorded as a liability as of December 31, 2021 and December 31, 2020. Upon regulatory approval in December 2020 of the Company’s force sensing ablation catheter in Europe, the \$2.0 million milestone was capitalized and is being amortized, and the royalty payments are recorded as cost of products sold as sales of catheters are recognized.

### **Rhythm Xience Business Combination**

On June 18, 2019 (the “Acquisition Date”), the Company acquired an integrated family of transeptal 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 cash payment did not include the potential \$17.0 million in earn out consideration, of which \$2.2 million was paid with the issuance of Series D convertible preferred stock in February 2020 and the remainder is to be paid based on the achievement of certain regulatory milestones and revenue milestones. In accordance with ASC 805, the Rhythm Xience Acquisition was accounted for as a business combination.

As part of the Rhythm Xience Acquisition, the Company recorded a contingent consideration liability for potential additional payments due to the sellers of Rhythm Xience if certain regulatory approval milestones and revenue milestones are achieved. The initial contingent consideration liability of \$13.4 million was based on the fair value of the contingent consideration liability at the Acquisition Date. During the year ended December 31, 2020, the Company issued 119,993 shares of Series D convertible preferred stock and paid \$2.5 million of the contingent consideration for the achievement of certain regulatory and revenue milestones. During the year ended December 31, 2021, the Company paid an additional \$3.4 million of the contingent consideration for the achievement of certain regulatory and revenue milestones. Additionally, the Company recorded a \$3.7 million decrease and \$0.1 million increase for the years ended December 31, 2021 and 2020, respectively, which is included in change in fair value of contingent consideration in the consolidated statements of operations and comprehensive loss. As of December 31, 2021, the contingent consideration liability of \$2.0 million is the fair value of the remaining payments due to the sellers of Rhythm Xience if certain revenue milestones are achieved.

For the years ended December 31, 2021 and 2020, no acquisition costs were incurred or recorded.

### **Note 4—Marketable Securities**

Marketable securities consisted of the following as of December 31, 2021 and 2020 (in thousands):

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>Available-for-sale securities - short-term:</b>				
Corporate debt securities, short-term	\$ 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, short-term	12,128	—	(12)	12,116
<b>Total available-for-sale securities - short-term</b>	<b>76,741</b>	<b>—</b>	<b>(39)</b>	<b>76,702</b>
Corporate debt securities, long-term	3,082	—	(2)	3,080
Asset-backed securities, long-term	4,044	—	(4)	4,040
<b>Total available-for-sale securities - long-term</b>	<b>7,126</b>	<b>—</b>	<b>(6)</b>	<b>7,120</b>
<b>Total available-for-sale securities</b>	<b>\$ 83,867</b>	<b>\$ —</b>	<b>\$ (45)</b>	<b>\$ 83,822</b>



	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>Available-for-sale securities - short-term:</b>				
Corporate debt securities	\$ 31,359	\$ —	\$ (6)	\$ 31,353
U.S. treasury securities	20,533	—	(2)	20,531
Commercial paper	53,955	—	—	53,955
<b>Total available-for-sale securities - short-term</b>	<b>105,847</b>	<b>—</b>	<b>(8)</b>	<b>105,839</b>
Asset-backed securities, long-term	8,726	—	—	8,726
<b>Total available-for-sale securities</b>	<b>\$ 114,573</b>	<b>\$ —</b>	<b>\$ (8)</b>	<b>\$ 114,565</b>

As of December 31, 2021, the Company's available-for-sale securities classified as short-term of \$76.7 million mature in one year or less and the available-for-sale securities classified as long-term of \$7.1 million mature within two years. As of December 31, 2020, the Company's available-for-sale securities classified as short-term of \$105.8 million mature in one year or less and the available-for-sale securities classified as long-term of \$8.7 million mature within two to four years.

### Note 5—Inventory

Inventory as of December 31, 2021 and 2020 consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Raw materials	\$ 6,779	\$ 7,960
Work in process	1,772	1,267
Finished goods	7,857	3,731
Total inventory	<b>\$ 16,408</b>	<b>\$ 12,958</b>

### Note 6—Lessor Sales-Type Leases

The Company recognizes revenue and costs, as well as a lease receivable, at the time embedded sales-type leases within its deferred equipment agreements commence. Lease revenue related to sales-type leases was \$1.1 million and \$0.8 million for the years ended December 31, 2021 and 2020, 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.

The Company has a short-term lease receivable of \$0.9 million and \$0.4 million included in prepaid expenses and other current assets, and a long-term lease receivable of \$0.7 million and \$0.4 million included in other assets as of December 31, 2021 and 2020, respectively.

As of December 31, 2021, estimated future maturities of customer sales-type lease receivables for each of the following years were as follows (in thousands):

Year ending December 31, 2022	\$ 859
Year ending December 31, 2023	408
Year ending December 31, 2024	244
Year ending December 31, 2025	71
Year ending December 31, 2026	—
Lease receivable	<b>\$ 1,582</b>

### Note 7—Property and Equipment, Net

The Company's property and equipment, net, consisted of the following as of December 31, 2021 and 2020 (in thousands):

	December 31, 2021	December 31, 2020
Medical diagnostic equipment	\$ 16,759	\$ 13,242
Furniture and fixtures	433	388
Office equipment	1,538	1,392
Laboratory equipment and software	5,302	3,491
Leasehold improvements	582	608
Construction in process	958	468
Total property and equipment	25,572	19,589
Less: accumulated depreciation	(11,902)	(7,233)
Property and equipment, net	<u>\$ 13,670</u>	<u>\$ 12,356</u>

Property and equipment includes certain medical diagnostic equipment, 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 expenses the cost of the equipment when it is subsequently sold or enters into a sales-type lease agreement. See also "Note 6—Lessor Sales-Type Leases" above.

Depreciation expense was \$5.8 million and \$2.8 million for the years ended December 31, 2021 and 2020, respectively. For the years ended December 31, 2021 and 2020, the Company determined that there was no impairment of property and equipment.

### Note 8—Goodwill and Intangible Assets

The tables below summarize goodwill and intangible assets activities as of December 31, 2021 and 2020 (in thousands):

	Goodwill	Intangible Assets
Balance, December 31, 2019	\$ 12,026	\$ 4,110
Biotronik license agreement	—	2,000
Amortization expense	—	(457)
Balance, December 31, 2020	12,026	5,653
Amortization expense	—	(640)
Balance, December 31, 2021	<u>\$ 12,026</u>	<u>\$ 5,013</u>

	Estimated Useful Life (in years)	Weighted Average Remaining Life (in years)	Intangible Assets	Accumulated Amortization	December 31, 2021
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			<u>\$ 6,300</u>	<u>\$ (1,287)</u>	<u>\$ 5,013</u>

	Estimated Useful Life (in years)	Weighted Average Remaining Life (in years)	Intangible Assets	Accumulated Amortization	December 31, 2020
Developed technology	10	8.6	\$ 4,200	\$ (600)	\$ 3,600
Customer-related intangible	5	3.5	100	(30)	70
Licensed intangibles	10	9.9	2,000	(17)	1,983
Total			<u>\$ 6,300</u>	<u>\$ (647)</u>	<u>\$ 5,653</u>

Acquired in-process technology was classified as an indefinite-lived intangible asset until the receipt of FDA approval for the technology in January 2020. Once FDA approval was received, the in-process technology was reclassified as developed technology and amortization began. The Company recorded amortization expense related to the above intangible assets of \$0.6 million and \$0.5 million for the years ended December 31, 2021 and 2020, respectively.

The following table shows the remaining amortization expense associated with amortizable intangible assets as of December 31, 2021 (in thousands):

	Developed Technology	Customer- Related Intangible	Licensed Intangibles	Total Amortization
Year ending December 31, 2022	\$ 420	\$ 20	\$ 200	\$ 640
Year ending December 31, 2023	420	20	200	640
Year ending December 31, 2024	420	10	200	630
Year ending December 31, 2025	420	—	200	620
Year ending December 31, 2026	420	—	200	620
Thereafter	1,080	—	783	1,863
<b>Total</b>	<b>\$ 3,180</b>	<b>\$ 50</b>	<b>\$ 1,783</b>	<b>\$ 5,013</b>

### Note 9—Accrued Liabilities

Accrued liabilities consisted of the following as of December 31, 2021 and 2020 (in thousands):

	December 31, 2021	December 31, 2020
Compensation and related expenses	\$ 7,088	\$ 6,250
Professional fees	158	120
Deferred revenue	401	301
Sales and use tax	71	169
Clinical studies	541	187
Clinician accounts	358	149
Accrued royalties	129	86
Other	350	46
<b>Total accrued liabilities</b>	<b>\$ 9,096</b>	<b>\$ 7,308</b>

### Note 10—Debt

Outstanding debt as of December 31, 2021 and 2020 consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
2019 Credit Agreement (1)	\$ 44,550	\$ 44,550
Total debt, gross	44,550	44,550
Less: Unamortized debt discount and fees	(4,135)	(5,539)
<b>Total long-term debt</b>	<b>\$ 40,415</b>	<b>\$ 39,011</b>

(1) The 2019 Credit Agreement includes final payment fees of \$4.6 million.

### 2019 Credit Agreement

On May 20, 2019, the Company entered into a credit agreement (the “2019 Credit Agreement”). The 2019 Credit Agreement 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. Of the remaining \$30.0 million, none is available for borrowing. The 2019 Credit Agreement bears interest per annum at 7.75% plus LIBOR for such interest period and the principal amount of term loans outstanding under the 2019 Credit Agreement is due on May 20, 2024. The 2019 Credit Agreement provides for final payment fees of an additional \$4.6 million that are due upon prepayment or on the maturity date or upon acceleration.

Upon the occurrence and during an event of default, which includes but is not limited to payment default, covenant default or the occurrence of a material adverse change, the lenders may declare all outstanding principal and accrued and unpaid interest immediately due and payable, there would be an increase in the applicable interest rate by 10% per annum, and the lenders would be entitled to exercise their other rights and remedies provided for under the 2019 Credit Agreement. Additionally, the lenders may request repayment of a portion of obligations outstanding under the 2019 Credit Agreement to the extent of the Company's receipt of any (i) net casualty proceeds or (ii) net asset sales proceeds, as defined. These acceleration and early payment features are an embedded derivative that is separately measured from the loan host instrument and classified with the loan host instrument.

In connection with the issuance of the 2019 Credit Agreement, the Company issued liability-classified 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 then were automatically converted into warrants to purchase an equal number of shares of common stock at \$16.67 per share. The initial recognition of the warrant liability and direct fees of \$1.2 million and final payment fees of \$4.6 million for the 2019 Credit Agreement resulted in a discount of \$6.7 million, which is being amortized to interest expense over the term of the 2019 Credit Agreement using the effective interest method.

The Company's obligations under the 2019 Credit Agreement are secured by substantially all of its assets, including its intellectual property, and is guaranteed by Acutus NV. The 2019 Credit Agreement contains customary affirmative and negative covenants, including with respect to the Company's ability to enter into fundamental transactions, incur additional indebtedness, grant liens, pay any dividend or make any distributions to its holders, make investments and merge or consolidate with any other person or engage in transactions with its affiliates, but does not include any financial covenants, other than a minimum liquidity requirement. As of and for the years ended December 31, 2021 and 2020, the Company was in compliance with all such covenants.

### Note 11—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.

The Company also 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 Company has a renewal option for an additional three-year term upon the expiration date of the lease, which has been included in the calculation of the right-of-use asset as it is reasonably certain to be exercised.

The following table summarizes quantitative information about the Company's operating leases for the years ended December 31, 2021 and 2020 (dollars in thousands):

	Year Ended December 31,	
	2021	2020
Operating cash flows from operating leases	\$ 853	\$ 1,013
Weighted average remaining lease term – operating leases (in years)	3.6	1.6
Weighted average discount rate – operating leases	7.0 %	7.0 %

The following table provides the components of the Company's lease cost for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
Operating leases		
Operating lease cost	\$ 950	\$ 864
Variable lease cost	325	311
Total rent expense	<u>\$ 1,275</u>	<u>\$ 1,175</u>

As of December 31, 2021, future minimum payments under the non-cancelable operating leases were as follows (in thousands):

Year ending December 31, 2022	\$ 903
Year ending December 31, 2023	1,135
Year ending December 31, 2024	1,167
Year ending December 31, 2025	1,151
Year ending December 31, 2026	1,185
Thereafter	1,221
Total	<u>6,762</u>
Less: present value discount	(1,776)
Operating lease liabilities	<u>\$ 4,986</u>

### Note 12—Commitments and Contingencies

As of December 31, 2021, the Company was not a party to any material legal proceedings and is not aware of any pending or threatened claims. From time to time however, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. For example, the Company and certain of its current 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 (case numbers 22CV206 and 22CV0388). 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 13—Warrants

As of December 31, 2021 and 2020, the outstanding warrants to purchase the Company's common stock were comprised of the following:

	Equity Upon Exercise (After Conversion)	Exercise Price	Expiration Date	December 31, 2021	December 31, 2020
Warrants issued in 2015	Common stock	\$ 5.25	1/30/25	3,808	3,808
Warrants issued with 2018 Convertible Notes	Common stock	\$ 0.10	6/7/28	346,689	373,810
Warrants issued with 2018 Term Loan	Common stock	\$ 16.67	7/31/28	26,998	26,998
Warrants issued with 2019 Credit Agreement	Common stock	\$ 16.67	5/20/29	419,992	419,992
Total Warrants				<u>797,487</u>	<u>824,608</u>

The Company's warrant activity for the years ended December 31, 2021 and 2020 is as follows:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Balance - December 31, 2019	956,552	\$ 7.88	8.8
Exercised	(131,944)	0.25	7.5
Balance - December 31, 2020	824,608	\$ 9.10	7.9
Exercised	(26,958)	\$ 0.10	6.4
Shares withheld for exercise price	(163)	0.10	6.4
Balance - December 31, 2021	<u>797,487</u>	<u>\$ 9.41</u>	<u>6.9</u>

The Company's warrants provide the holder the option to purchase a specified number of shares for a specified price. The holder may exercise the warrant in cash or 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.

Prior to the IPO, in accordance with ASC 815, the warrants, other than the ones issued in 2015, were recorded as liabilities at fair value at the issuance date (the 2015 warrants have been equity classified since their issuance). Changes in the fair value were recognized in change in fair value of warrant liability in the consolidated statements of operations and comprehensive loss at the end of each reporting period. On August 10, 2020, in connection with the closing of the IPO, the warrants recorded as liabilities no longer met the definition of a derivative. Accordingly, the fair value of the common and preferred stock warrant liability of \$14.5 million was reclassified to additional paid-in capital in the consolidated balance sheet.

In connection with the Exchange Agreements (see Note 15), 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.

#### Note 14—Convertible Preferred Stock

On August 10, 2020, in connection with the closing of the IPO, all of the 391,210 shares of Series A, 3,088,444 shares of Series B, 4,499,921 shares of Series C and 8,593,360 shares of Series D convertible preferred stock automatically converted into an equal number of shares of common stock.

In February 2020, the Company issued 119,993 shares of its Series D convertible preferred stock with an implied value of \$2.2 million in connection with a contingent consideration payment related to the Rhythm Xience Acquisition.

In February 2020, the Company issued 273,070 shares of its Series D convertible preferred stock with an implied value of \$5.0 million for the final purchase consideration of the Biotronik Asset Acquisition.

#### Redemption

The convertible preferred stock was not unconditionally redeemable at the option of the holder thereof. However, the convertible preferred stock was contingently redeemable upon certain liquidation events. As redemption by the holders was not solely within the control of the Company, all of the outstanding convertible preferred stock was classified as temporary equity in the consolidated balance sheets, prior to the conversion to common stock on August 10, 2020.

#### Dividends

The holders of shares of convertible preferred stock were entitled to receive dividends, out of any assets legally available therefore, prior and in preference to any declaration or payment of any dividend on the common stock of the Company, at the

applicable dividend rate, payable on a *pro rata, pari passu* basis when, as and if declared by the Company’s board of directors. The dividend rate was \$0.68 per annum for each share of Series A convertible preferred stock, \$1.07 per annum for each share of Series B convertible preferred stock and \$1.36 per annum for each share of Series C convertible preferred stock and Series D convertible preferred stock, as adjusted. The dividend rights were not cumulative.

### **Liquidation**

The holders of the Series D convertible preferred stock were entitled to receive a liquidation preference prior to any distribution to the holders of Series A convertible preferred stock, Series B convertible preferred stock and Series C convertible preferred stock (collectively the “Junior Preferred Stock”) and the holders of common stock, in the amount of the original issue price plus declared but unpaid dividends on such shares (the “Series D Liquidation Preference”). The holders of the Junior Preferred Stock were entitled to receive a liquidation preference prior to any distribution to the holders of common stock, after payment of the Series D Liquidation Preference, in the amount of the applicable original issue price plus declared but unpaid dividends on such shares.

### **Voting Rights**

Holders of convertible preferred stock had the right to one vote for each share of common stock into which such preferred stock could then be converted, and with respect to such vote, such holder had full voting rights and powers equal to the voting rights and powers of the holders of common stock.

As long as any shares of Series D convertible preferred stock were outstanding, the holders of such shares of Series D convertible preferred stock (voting exclusively as a separate series) were entitled to elect one director. As long as any shares of Series C convertible preferred stock were outstanding, the holders of such shares of Series C convertible preferred stock (voting exclusively as a separate series) were entitled to elect three directors. As long as any shares of Series A convertible preferred stock or Series B convertible preferred stock were outstanding, the holders of such shares (voting together as a single class and not as separate series, and on an as converted basis) were entitled to elect four directors. The holders of outstanding common stock were entitled to elect one director. The holders of convertible preferred stock and common stock (voting together as a single class and not as separate series, and on an as-converted basis) were entitled to elect any remaining directors.

### **Conversion**

Each share of preferred stock was convertible, at the option of the holder thereof, at any time after the date of issuance of such share, into such number of fully paid and nonassessable shares of the Company’s common stock as was determined by dividing the original issue price, as adjusted, for such series by the applicable conversion price for such series in effect on the date the certificate is surrendered for conversion. The initial conversion price per share for each series of convertible preferred stock was the original issue price applicable to such series as follows:

Series	Conversion Price
Series A convertible preferred stock	\$ 8.295
Series B convertible preferred stock	\$ 13.370
Series C convertible preferred stock	\$ 16.667
Series D convertible preferred stock	\$ 16.667

Each share of convertible preferred stock was automatically converted into fully-paid, non-assessable shares of common stock at the conversion rate at the time in effect for such series of preferred stock immediately upon: (i) the date, or the occurrence of an event, specified by vote or written consent or agreement of the requisite investors; or (ii) the closing of the sale of shares of common stock to the public, at a price of at least \$50.00 per share, as adjusted, in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$50.0 million of net proceeds to the Company. As noted above, on August 10, 2020, all shares of Series A, Series B, Series C and Series D convertible preferred stock were converted into common stock.

### **Note 15—Stockholders’ Equity**

#### *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. In connection with the issuance of Series A Common Equivalent 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, par value \$0.001 per share, of the Company (the “Series A Certificate of Designation”) with the Secretary of State of the State of Delaware. The Series A Common Equivalent 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 Series A Common Equivalent 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 Series A Common Equivalent Preferred Stock is non-voting.

The holder thereof may convert each share of Series A Common Equivalent Preferred Stock into 1,000 shares of common stock at its election, 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 Securities Exchange Act of 1934, as amended (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, to 9.9%) of the total number of shares of common stock then issued and outstanding.

#### *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. 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 from the offering

On August 10, 2020, the Company issued 10,147,058 shares of common stock in its IPO, which included 1,323,529 shares of common stock issued upon the underwriters’ exercise in full of an option to purchase, at the public offering price less underwriting discounts and commissions, up to an additional 1,323,529 shares. The price to the public for each share was \$18.00. The Company received gross proceeds of \$182.6 million from the IPO. Net of underwriting discounts and commission and other offering costs, the Company received net proceeds of \$166.3 million from the IPO.

On August 10, 2020, in connection with the closing of the IPO, the Company filed an amended and restated certificate of incorporation (the “A&R Certificate”) with the Secretary of State of the State of Delaware. The A&R Certificate amended and restated the Company’s authorized shares of common stock to 260,000,000 and authorized shares of undesignated preferred stock to 5,000,000.

During the year ended December 31, 2021 and 2020, stock options to acquire 111,804 shares and 124,938 shares were exercised for shares of common stock. The Company received \$0.7 million and \$0.6 million for the exercise price of the stock options for the year ended December 31, 2021 and 2020, respectively. Additionally, during the year ended December 31, 2021, in conjunction with the 2020 Employee Stock Purchase Plan (the “2020 ESPP”), 33,641 shares of common stock were issued for consideration of \$0.4 million (see Note 16). No shares were issued related to the 2020 ESPP plan for the year ended December 31, 2020. During the year ended December 31, 2021, the Company issued 134,050 shares of common stock upon vesting of RSUs and 186 shares of common stock for RSAs. During the year ended December 31, 2020, the Company issued 285,369 shares of common stock upon vesting of RSUs and 34,051 shares of common stock for RSAs.

#### **Note 16—Stock-Based Compensation**

##### *2020 Equity Incentive Plan*

The 2020 Equity Incentive Plan (the “2020 Plan”), which permits 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, 2021, 3,313,017 shares of common stock were authorized for issuance under the 2020 Plan and 1,077,978 shares remain available for issuance under the 2020 Plan, including 300,092 shares forfeited under the Company’s 2011 Equity Incentive Plan (the “2011 Plan”).



### 2011 Equity Incentive Plan

The 2011 Plan permits the granting of incentive stock options, non-statutory stock options, restricted stock, restricted stock units and other stock-based awards to employees, directors, officers and consultants. As of December 31, 2021, 2,258,659 shares of common stock were authorized for issuance under the 2011 Plan and no shares remain available for issuance under the 2011 Plan. 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. The Company's common stock became publicly traded in August 2020 and lacks company-specific historical and implied volatility information. Therefore, 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 has been 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 of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following assumptions were used to estimate the fair value of stock option for the years ended December 31, 2021 and 2020:

	Year Ended December 31,	
	2021	2020
Risk-free interest rate	0.76% - 1.39%	0.35% - 0.90%
Expected dividend yield	—	—
Expected term in years	5.5 - 7	7
Expected volatility	60% - 75%	60% - 80%

The following table summarizes stock option activity during the years ended December 31, 2021 and 2020:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2019	2,041,205	\$ 9.52	7.7	\$ 10,782
Options granted	1,794,895	16.91		
Options exercised	(172,312)	7.52		\$ 1,660
Options forfeited	(260,181)	12.10		
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	3,781,636	\$ 13.12	7.6	\$ 93
Options vested and exercisable as of December 31, 2021	1,799,522	\$ 11.74	6.1	\$ 64

The aggregate intrinsic value for options outstanding in the above table represents the product of the number of options outstanding multiplied by the difference between the per share fair value of the Company's stock on the last day of the fiscal period, which was \$3.41 and \$28.81 as of December 31, 2021 and 2020, respectively, 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, 2021 and 2020 was \$8.46 and \$11.58, respectively. As of December 31, 2021, the total unrecognized compensation related to unvested

stock option awards granted was \$26.6 million, which the Company expects to recognize over a weighted-average period of approximately 2.6 years.

#### **Performance-Based Restricted Stock Units and Restricted Stock Units**

In June 2019, the Company granted 567,509 PSUs, with a grant date fair value of \$13.37. Vesting of the PSUs was dependent upon the satisfaction of both a service condition and a performance condition, which is an IPO or a change of control. The Company began recording compensation expense related to the PSUs upon the declaration of the Company's registration statement becoming effective on August 5, 2020, as the performance conditions were satisfied. The compensation expense was determined using the original grant date fair value and is being recognized over the remaining service period.

The Company's PSU and RSU activity for the years ended December 31, 2021 and 2020 was as follows:

	Number of Shares	Weighted Average Grant Price
Unvested as of December 31, 2019	567,509	\$ 13.37
Granted	270,718	19.87
Forfeited	(7,386)	18.00
Vested	(285,375)	13.37
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

#### **Restricted Stock Awards**

The Company's RSA activity for the years ended December 31, 2021 and 2020 was as follows:

	Number of Shares	Weighted Average Grant Price
Unvested as of December 31, 2019	—	\$ —
Granted	34,051	16.85
Vested	(34,051)	16.85
Unvested as of December 31, 2020	—	\$ —
Granted	186	14.75
Vested	(186)	14.75
Unvested as of December 31, 2021	—	\$ —

#### **Employee Stock Purchase Plan**

The 2020 ESPP, which permits employees to purchase shares of the Company's common stock, became effective on August 5, 2020 and 387,063 shares of common stock were authorized for sale under the 2020 ESPP.

The 2020 ESPP will be implemented by 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. The first offering period began on February 1, 2021. In November 2021, the Company amended its 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, 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 determinations of the Compensation Committee of the Company's Board of Directors, in its sole discretion.

The fair value of the 2020 ESPP shares is estimated using the Black-Scholes option pricing model.

The following table summarizes the total stock-based compensation expense for the stock options, PSUs, RSUs, RSAs and ESPP expense recorded in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
Cost of products sold	\$ 864	\$ 440
Research and development	2,181	1,002
Selling, general and administrative	10,709	10,661
Total stock-based compensation	\$ 13,754	\$ 12,103

#### 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, PSUs, RSUs and warrants because their effect would be anti-dilutive due to the Company's net loss. Since the Company had a net 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:

Shares issuable upon:	Year Ended December 31,	
	2021	2020
Conversion of Series A Common Equivalent Preferred Stock	6,665,841	—
Exercise of stock options	3,781,636	3,403,607
Exercise of common stock warrants	797,487	824,608
Vesting of PSUs and RSUs	995,091	545,466
Total	12,240,055	4,773,681

#### 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 did not provide any contributions to the 401(k) retirement savings plan for the years ended December 31, 2021 and 2020.

#### Note 19—Income Taxes

The components of pretax loss from operations for the years ended December 31, 2021 and 2020 are as follows:

	December 31,	
	2021	2020
U.S. domestic	\$ (117,868)	\$ (102,048)
Foreign	185	90
Pretax loss from operations	\$ (117,683)	\$ (101,958)

The components of income tax expense for continuing operations are as follows:

	December 31,	
	2021	2020
Current tax provision:		
Federal	\$ —	\$ —
State	—	23
Foreign	—	—
Total provision for income taxes	<u>\$ —</u>	<u>\$ 23</u>

There was no provision for state incomes taxes for the year ended December 31, 2021. The provision for state income taxes was less than \$0.1 million for the year ended December 31, 2020. Current income taxes are based upon the year's income taxable for federal, state and foreign tax reporting purposes. Deferred income taxes (benefits) 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.

A reconciliation of the expected tax computed at the U.S. statutory federal income tax rate to the total expense for income taxes for the years ended December 31, 2021 and 2020 is as follows (dollars in thousands):

	Year Ended December 31,			
	2021		2020	
Income tax benefit at federal statutory rate	\$ (24,714)	21.00 %	\$ (21,411)	21.00 %
Adjustments for tax effects of:				
State taxes, net	(2,343)	2.00 %	(2,237)	2.19 %
Permanent adjustments	352	(0.30)%	968	(0.95)%
Warrants	—	— %	1,167	(1.14)%
Research and development credit	(2,255)	1.90 %	(5,870)	5.76 %
Unrecognized tax benefit	676	(0.60)%	1,761	(1.73)%
Valuation allowance	26,935	(22.90)%	26,619	(26.11)%
Rate change	532	(0.50)%	(737)	0.72 %
Other	817	(0.60)%	(237)	0.23 %
Income tax expense	<u>\$ —</u>	<u>— %</u>	<u>\$ 23</u>	<u>(0.03)%</u>

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2021 and 2020 were as follows (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating losses	\$ 93,668	\$ 68,727
Stock-based compensation	2,468	1,225
Research and development credit	8,803	7,225
Accrued vacation	432	390
Accrued expenses	446	745
Inventory	202	—
Intangible assets	3,564	3,863
Lease liability	1,114	439
Other	11	196
<b>Total gross deferred tax assets</b>	<b>110,708</b>	<b>82,810</b>
Valuation allowance	(106,717)	(79,782)
<b>Net deferred tax asset</b>	<b>3,991</b>	<b>3,028</b>
Deferred tax liabilities:		
Property and equipment	(1,986)	(1,979)
Prepaid expenses	(593)	(642)
Right of use assets	(1,009)	(349)
IRC 263A	—	(58)
Other deferred tax liabilities	(313)	—
Debt	(90)	—
<b>Total deferred tax liabilities</b>	<b>(3,991)</b>	<b>(3,028)</b>
<b>Net deferred tax assets (liabilities)</b>	<b>\$ —</b>	<b>\$ —</b>

In assessing the realizability of deferred tax assets as of December 31, 2021 and 2020, 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 has determined it is more likely than not that its net deferred tax assets will not be realized. Accordingly, a valuation allowance has been recorded as of December 31, 2021 and 2020, to fully offset the net deferred tax assets of \$106.7 million and \$79.8 million, respectively.

As of December 31, 2021, the Company had approximately \$415.3 million of NOL carryforwards available for federal tax purposes. As a result of the Tax Cuts and Jobs Act, for U.S. income tax purposes, NOLs generated prior to December 31, 2017 can still be carried forward for up to 20 years, but NOLs generated after December 31, 2017 carryforward indefinitely, but are limited to 80% utilization against taxable income. Of the total federal NOL of \$415.3 million, \$108.2 million will begin to expire in 2031 and \$307.1 million will not expire but will only offset 80% of future taxable income.

On December 27, 2020, the United States enacted the Consolidated Appropriations Act of 2021 ("CAA"). The CAA includes provisions extending certain CARES Act provisions and adds coronavirus relief and tax and health extenders.

As of December 31, 2021, the Company also had approximately \$105.7 million of state NOL carryforwards. The state NOLs begin to expire in 2029.

As of December 31, 2021, the Company had no NOL carryforwards available for foreign tax purposes.

As of December 31, 2021, the Company had approximately \$8.1 million of R&D credit carryforwards available for federal tax purposes, which begin to expire in 2031. As of December 31, 2021, the Company also had approximately \$5.6 million of R&D credit carryforwards for California. The state R&D credits do not expire.

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.

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, 2021 and 2020 (in thousands):

	December 31,	
	2021	2020
Balance at beginning of year	\$ 3,397	\$ 1,539
Increases related to prior year tax positions	—	1,210
Increases related to current year tax positions	731	648
Balance at end of year	<u>\$ 4,128</u>	<u>\$ 3,397</u>

As of December 31, 2021, the Company has unrecognized tax benefits of \$4.1 million of which \$3.8 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, 2021 and 2020.

#### Note 20—Related Party Transactions

In August 2021, the Company entered into the Exchange Agreements with 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).

The Company licenses certain patent rights from a former director and shareholder. The license agreement provides for royalty payments to the shareholder of 3% of net product sales, as defined in the agreement. Royalties earned prior to the director’s resignation were less than \$0.1 million for the year ended December 31, 2020. Additionally, the former director and shareholder also works for one of the Company’s customers and can significantly influence the customer to purchase the Company’s product. Prior to the director’s resignation, the Company recorded sales to this customer of \$0.5 million for the year ended December 31, 2020.

The Company has a consulting agreement with the chairman of the Company’s board of directors. The Company recorded \$0.1 million and \$0.2 million for the years ended December 31, 2021 and 2020, respectively, in SG&A expense in the consolidated statements of operations and comprehensive loss, for the consulting services.

With the completion of the IPO, the performance condition was satisfied 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 for these awards for the year ended December 31, 2020 in SG&A expense in the consolidated statement of operations and comprehensive loss.

Multiple preferred stock shareholders entered into the 2018 Convertible Notes and 2019 Convertible Notes that also contained detached warrants. Additionally, OrbiMed Royalty Opportunities II, LP and Deerfield Private Design Fund II, L.P. entered into the 2019 Credit Agreement with the Company in 2019 for a total of \$70.0 million with \$40.0 million being drawn as of December 31, 2021 and 2020. The Company recorded \$5.7 million and \$5.5 million for the years ended December 31, 2021 and 2020, respectively, in interest expense related to this debt agreement.

**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, 2021, 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, 2021 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, 2021.

***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, 2021 and 2020
  - Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2021 and 2020
  - Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) for the Years Ended December 31, 2021 and 2020
  - Consolidated Statements of Cash Flows for the Years Ended December 31, 2021 and 2020
  - Notes to the Consolidated Financial Statements for the Years Ended December 31, 2021 and 2020
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	<a href="#">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</a>	S-1	333-239873	2.1	July 15, 2020
3.1	<a href="#">Amended and Restated Certificate of Incorporation</a>	8-K	001-39430	3.1	August 10, 2020
3.2	<a href="#">Amended and Restated Bylaws</a>	8-K	001-39430	3.2	August 10, 2020
3.3	<a href="#">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.</a>	8-K	001-39430	3.1	August 23, 2021
4.1	<a href="#">Specimen Common Stock Certificate</a>	S-1/A	333-239873	4.2	July 30, 2020
4.2	<a href="#">Amended and Restated Investors' Rights Agreement</a>	S-1	333-239873	4.1	July 15, 2020
4.3*	<a href="#">Description of the Registrant's Securities</a>				
4.4	<a href="#">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</a>	S-1	333-239873	4.3	July 15, 2020

4.5	<a href="#">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</a>	S-1	333-239873	4.4	July 15, 2020
4.6	<a href="#">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</a>	S-1	333-239873	4.5	July 15, 2020
4.7	<a href="#">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</a>	S-1	333-239873	4.6	July 15, 2020
10.1	<a href="#">Credit Agreement, dated May 20, 2019, among the Registrant, the lenders from time to time party thereto, Wilmington Trust, National Association as Administrative Agent and OrbiMed Royalty Opportunities II, LP, as Origination Agent (“Credit Agreement”)</a>	S-1	333-239873	10.1	July 15, 2020
10.2	<a href="#">Pledge and Security Agreement, dated May 20, 2019, between the Registrant and Wilmington Trust, National Association</a>	S-1	333-239873	10.2	July 15, 2020
10.3	<a href="#">License and Distribution Agreement, dated July 2, 2019, among the Registrant, Biotronik SE &amp; Co. KG and VascoMed GmbH</a>	S-1	333-239873	10.3	July 15, 2020
10.4	<a href="#">Bi-Lateral Distribution Agreement, dated May 11, 2020, between the Registrant and Biotronik SE &amp; Co. KG (Acutus as distributor)</a>	S-1	333-239873	10.4	July 15, 2020
10.5	<a href="#">Bi-Lateral Distribution Agreement, dated May 11, 2020, between the Registrant and Biotronik SE &amp; Co. KG (Biotronik as distributor)</a>	S-1	333-239873	10.5	July 15, 2020
10.6	<a href="#">License Agreement, dated May 10, 2011, between the Registrant and Dr. Christoph Scharf</a>	S-1	333-239873	10.6	July 15, 2020
10.7	<a href="#">First Amendment to License Agreement, dated September 30, 2011, between the Registrant and Dr. Christoph Scharf</a>	S-1	333-239873	10.7	July 15, 2020
10.8	<a href="#">Master License Agreement, dated March 11, 2014, between the Registrant and Biotectix, LLC</a>	S-1	333-239873	10.8	July 15, 2020
10.9	<a href="#">Exclusive Patent License Agreement, dated April 21, 2014, between the Registrant and Regents of the University of Minnesota</a>	S-1	333-239873	10.9	July 15, 2020
10.10	<a href="#">First Amendment to Exclusive Patent License Agreement, dated October 20, 2014, between the Registrant and Regents of the University of Minnesota</a>	S-1	333-239873	10.10	July 15, 2020
10.11	<a href="#">Lease Agreement, dated January 22, 2015, as amended, between the Registrant and Carlsbad 2210, LLC</a>	S-1	333-239873	10.11	July 15, 2020
10.12†	<a href="#">Form of Indemnification Agreement between the Registrant and each of its directors and executive officers</a>	S-1	333-239873	10.12	July 15, 2020
10.13†	<a href="#">2011 Equity Incentive Plan, as amended, and forms of agreement thereunder</a>	S-1	333-239873	10.13	July 15, 2020

10.14†	<a href="#">2020 Equity Incentive Plan and forms of agreement thereunder</a>	S-1/A	333-239873	10.14	July 30, 2020
10.15†	<a href="#">2020 Employee Stock Purchase Plan</a>	S-1/A	333-239873	10.15	July 30, 2020
10.16†	<a href="#">Executive Incentive Compensation Plan</a>	S-1	333-239873	10.16	July 15, 2020
10.17†	<a href="#">Executive Chairman Agreement between the Registrant and Scott Huennekens</a>	S-1	333-239873	10.17	July 15, 2020
10.18†	<a href="#">Restricted Stock Unit Award Agreement between the Registrant and Scott Huennekens</a>	S-1	333-239873	10.18	July 15, 2020
10.19†	<a href="#">Employment Agreement between Registrant and Vince Burgess</a>	S-1	333-239873	10.19	July 15, 2020
10.20†	<a href="#">Employment Agreement between Registrant and Steven McQuillan</a>	S-1	333-239873	10.21	July 15, 2020
10.21†	<a href="#">Employment Agreement between Registrant and David Roman</a>	10-K	001-39430	10.22	March 19, 2021
10.22	<a href="#">Amendment No. 1 to Credit Agreement, dated June 7, 2019</a>	10-K	001-39430	10.24	March 19, 2021
10.23	<a href="#">Amendment No. 2 and Waiver to the Credit Agreement, dated October 21, 2020</a>	10-K	001-39430	10.25	March 19, 2021
10.24	<a href="#">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.</a>	8-K	001-39430	10.10	August 23, 2021
10.25	<a href="#">Exchange Agreement, dated as of August 23, 2021, by and among the Company, OrbiMed Private Investments IV, LP and OrbiMed Royalty Opportunities II, LP</a>	8-K	001-39430	10.20	August 23, 2021
10.26	<a href="#">Feasibility and Development Agreement, by and between Biotronik SE &amp; Co. KG and Acutus Medical, Inc.</a>	S-1	333-257844	10.24	July 12, 2021
21.1*	<a href="#">Subsidiaries of the Registrant</a>				
23.1*	<a href="#">Consent of KPMG LLP, Independent Registered Public Accounting Firm</a>				
24.1*	<a href="#">Power of Attorney (included on signature page)</a>				
31.1*	<a href="#">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.</a>				
31.2*	<a href="#">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.</a>				
32.1**	<a href="#">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.</a>				
32.2**	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				

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
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)

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\* 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.

**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 30, 2022.

Company Name

Date: March 30, 2022

By: /s/ Vince Burgess

**Vince Burgess**

**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 Vince Burgess and David Roman, 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.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Vince Burgess</u> Vince Burgess	President, Chief Executive Officer and Director (Principle Executive Officer)	March 30, 2022
<u>/s/ David H. Roman</u> David H. Roman	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2022
<u>/s/ R. Scott Huennekens</u> R. Scott Huennekens	Chairman of the Board	March 30, 2022
<u>/s/ David Bonita</u> David Bonita, M.D.	Director	March 30, 2022
<u>/s/ Daniella Cramp</u> Daniella Cramp	Director	March 30, 2022
<u>/s/ Andrew ElBardissi</u> Andrew ElBardissi, M.D.	Director	March 30, 2022
<u>/s/ Jim Hinrichs</u> Jim Hinrichs	Director	March 30, 2022
<u>/s/ Niamh Pellegrini</u> Niamh Pellegrini	Director	March 30, 2022
<u>/s/ Shaden Marzouk</u> Shaden Marzouk	Director	March 30, 2022
<u>/s/ John Sheridan</u> John Sheridan	Director	March 30, 2022

## DESCRIPTION OF CAPITAL STOCK

The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation, our Certificate of Designation of Preferences, Rights and Limitations of the Series A Common Equivalent Preferred Stock, par value \$0.001 per share, our amended and restated bylaws, the amended and restated investors rights agreement to which we and certain of our stockholders are parties, and of the Delaware General Corporation Law, or DGCL. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation, our Certificate of Designation of Preferences, Rights and Limitations of the Series A Common Equivalent Preferred Stock, par value \$0.001 per share, our amended and restated bylaws and amended and restated investors rights agreement, copies of which have been filed as exhibits to the Annual Report on Form 10-K of which this Exhibit is a part.

### **General**

Our authorized capital stock consists of 260,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share, of which 6,665,8410 have been designated as Series A Common Stock Equivalent Convertible Preferred Stock, and the remainder of which are undesignated.

### **Common Stock**

#### ***Voting Rights***

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors.

#### ***Dividends***

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. We do not have any plans to pay dividends to our stockholders.

#### ***Liquidation***

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

#### ***Rights and Preferences***

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

#### ***Fully Paid and Nonassessable***

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

### **Preferred Stock**

Our board of directors has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, rights and terms of



redemption, liquidation preferences, sinking fund provisions and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after completion of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

### ***Series A Common Stock Equivalent Convertible Preferred Stock***

On August 23, 2021, in connection with the issuance of 6,665,841 shares of our Series A Common Stock Equivalent Convertible Preferred Stock, par value \$0.001 per share, in exchange for 6,665,841 shares of our common stock, we filed a Certificate of Designation of Preferences, Rights and Limitations of the Series A Common Equivalent Preferred Stock, par value \$0.001 per share, with the Secretary of State of the State of Delaware.

The Series A Common Stock Equivalent Convertible Preferred Stock ranks senior to our common stock with respect to rights on the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of our affairs, having a liquidation preference equal to its par value of \$0.001 per share. The Series A Common Stock Equivalent Convertible Preferred Stock will participate equally and ratably on an as-converted basis with the holders of our common stock in all cash dividends paid on our common stock. The Series A Common Stock Equivalent Convertible Preferred Stock is non-voting.

A holder of Series A Common Stock Equivalent Convertible Preferred Stock may convert each share of Series A Common Stock Equivalent Convertible Preferred Stock into 1,000 shares of our common stock (subject to certain anti-dilution adjustments) at its election, except to the extent that, following such conversion, the number of shares of our common stock held by such holder, its affiliates and any other persons whose beneficial ownership of our common stock would be aggregated with such holder's for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, including shares held by any "group" (as defined in Section 13(d) of the Securities Exchange Act of 1934, as amended, 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 Certificate of Designation of Preferences, Rights and Limitations of the Series A Common Equivalent Preferred Stock, exceeds 4.9% (or, at the election of a holder that is not an affiliate of Deerfield Management, 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 our common stock then issued and outstanding.

### **Registration Rights**

Certain holders of shares of common stock or their transferees have the right to require us to register the offer and sale of their shares, or to include their shares in any registration statement we file, in each case as described below.

#### ***Demand Registration Rights***

The holders of at least 50% of the shares having registration rights then outstanding can request that we file a registration statement to register the offer and sale of their shares. We are only obligated to effect up to two such registrations. Each such request for registration must cover securities the anticipated aggregate gross proceeds of which, before deducting underwriting discounts and expenses, is at least \$20.0 million. These demand registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. If we determine that it would be materially detrimental to us and our stockholders to effect such a demand registration, we have the right to defer such registration, not more than twice in any twelve-month period, for a period of up to 90 days.

#### ***Form S-3 Registration Rights***

At any time when we are eligible to file a registration statement on Form S-3, the holders of the shares having these rights then outstanding can request that we register the offer and sale of their shares of our common stock on a

registration statement on Form S-3 so long as the request covers securities the anticipated aggregate public offering price of which is at least \$5.0 million. These stockholders may make an unlimited number of requests for registration on a registration statement on Form S-3. However, we will not be required to effect a registration on Form S-3 if we have effected two such registrations within the twelve-month period preceding the date of the request. These Form S-3 registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. Additionally, if we determine that it would be seriously detrimental to us and our stockholders to effect such a demand registration, we have the right to defer such registration, not more than twice in any twelve-month period, for a period of up to 90 days.

### ***Piggyback Registration Rights***

If we propose to register the offer and sale of shares of our common stock under the Securities Act, all holders of these shares then outstanding can request that we include their shares in such registration, subject to certain marketing and other limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to: (i) a registration related to any employee benefit plan or a corporate reorganization or other transaction covered by Rule 145 promulgated under the Securities Act; (ii) a registration relating to the offer and sale of debt securities; (iii) a registration on any registration form that does not permit secondary sales; or (iv) a registration pursuant to the demand or Form S-3 registration rights described in the preceding two paragraphs above, the holders of these shares are entitled to notice of the registration and have the right, subject to certain limitations, to include their shares in the registration.

### ***Expenses of Registration***

We will pay all expenses relating to any demand registrations, Form S-3 registrations and piggyback registrations, subject to specified exceptions.

### ***Termination***

The registration rights terminate upon the earliest of: (i) the date that is three years after the completion of our initial public offering; (ii) immediately prior to the closing of certain liquidation events; and (iii) as to a given holder of registration rights, the date after the completion of our initial public offering when such holder of registration rights can sell all of such holder's registrable securities during any ninety-day period pursuant to Rule 144 promulgated under the Securities Act.

### ***Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Our Amended and Restated Bylaws and Delaware Law***

Some provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of a non-friendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

***Preferred Stock***

Our amended and restated certificate of incorporation contains provisions that permit our board of directors to issue, without any further vote or action by the stockholders, shares of preferred stock in one or more series and, with respect to each such series, to fix the number of shares constituting the series and the designation of the series, the voting rights (if any) of the shares of the series and the powers, preferences or relative, participation, optional and other special rights, if any, and any qualifications, limitations or restrictions, of the shares of such series.

***Classified Board***

Our amended and restated certificate of incorporation provides that our board of directors is divided into three classes, designated Class I, Class II and Class III. Each class will be an equal number of directors, as nearly as possible, consisting of one third of the total number of directors constituting the entire board of directors. The term of initial Class I directors terminated on the date of our 2021 annual meeting, the term of the initial Class II directors shall terminate on the date of our 2022 annual meeting, and the term of the initial Class III directors shall terminate on the date of our 2023 annual meeting. At each annual meeting of stockholders, successors to the class of directors whose term expires at that annual meeting will be elected for a three-year term.

***Removal of Directors***

Our amended and restated certificate of incorporation provides that stockholders may only remove a director for cause by a vote of no less than a majority of the total voting power of all outstanding securities generally entitled to vote in the election of directors, voting together as a single class.

***Director Vacancies***

Our amended and restated certificate of incorporation authorizes only our board of directors to fill vacant directorships.

***No Cumulative Voting***

Our amended and restated certificate of incorporation provides that stockholders do not have the right to cumulate votes in the election of directors.

***Special Meetings of Stockholders***

Our amended and restated certificate of incorporation and amended and restated bylaws provides that, except as otherwise required by law, special meetings of the stockholders may be called only by our board of directors.

***Advance Notice Procedures for Director Nominations***

Our bylaws provide that stockholders seeking to nominate candidates for election as directors at an annual or special meeting of stockholders must provide timely notice thereof in writing. To be timely, a stockholder's notice generally will have to be delivered to and received at our principal executive offices before notice of the meeting is issued by the secretary of the company, with such notice being served not less than 90 nor more than 120 days before the meeting. Although the amended and restated bylaws will not give the board of directors the power to approve or disapprove stockholder nominations of candidates to be elected at an annual meeting, the amended and restated bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

***Action by Written Consent***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that any action to be taken by the stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by written consent.

### ***Amending our Certificate of Incorporation and Bylaws***

Our amended and restated certificate of incorporation may be amended or altered in any manner provided by the DGCL. Our amended and restated bylaws may be adopted, amended, altered or repealed by stockholders only upon approval of at least majority of the voting power of all the then outstanding shares of the common stock, except for any amendment of the above provisions, which would require the approval of a two-thirds majority of our then outstanding common stock. Additionally, our amended and restated certificate of incorporation provides that our bylaws may be amended, altered or repealed by the board of directors.

### ***Authorized but Unissued Shares***

Our authorized but unissued shares of common stock and preferred stock are available for future issuances without stockholder approval, except as required by the listing standards of Nasdaq, and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of the company by means of a proxy contest, tender offer, merger or otherwise.

### ***Exclusive Jurisdiction***

Our amended and restated bylaws provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim arising pursuant to the DGCL, any action regarding our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated bylaws provide further 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. Although our amended and restated bylaws contain the choice of forum provisions described above, it is possible that a court could rule that such provisions are inapplicable for a particular claim or action or that such provisions are unenforceable. For example, under the Securities Act of 1933, as amended, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act of 1933, as amended, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. In addition, this exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or any other claim for which the U.S. federal courts have exclusive jurisdiction.

### ***Business Combinations with Interested Stockholders***

We are governed by Section 203 of the DGCL. Subject to certain exceptions, Section 203 of the DGCL prohibits a public Delaware corporation from engaging in a business combination (as defined in such section) with an "interested stockholder" (defined generally as any person who beneficially owns 15% or more of the outstanding voting stock of such corporation or any person affiliated with such person) for a period of three years following the time that such stockholder became an interested stockholder, unless: (i) prior to such time the board of directors of such corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (ii) upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of such corporation at the time the transaction commenced (excluding for purposes of determining the voting stock of such corporation outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers of such corporation and (2) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer); or (iii) at or subsequent to such time the business combination is approved by the board of directors of such corporation and authorized at a meeting of stockholders (and not by written consent) by the affirmative vote of at least 66 2/3% of the outstanding voting stock of such corporation not owned by the interested stockholder.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we must indemnify our directors and officers to the fullest extent authorized by the DGCL. We are expressly authorized to, and do, carry directors' and officers' insurance providing coverage for our directors, officers and certain employees for some liabilities. We believe that these indemnification provisions and insurance are useful to attract and retain qualified directors and executive directors.

The limitation on liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. In addition, your investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

**Exchange Listing**

Our common stock is listed on The Nasdaq Global Market under the symbol "AFIB."

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021.

**Subsidiaries of Acutus Medical, Inc.**

The following is a list of subsidiaries of the Company as of December 31, 2021, omitting subsidiaries which, considered in the aggregate, would not constitute a significant subsidiary as defined by Rule 1-02(w) of Regulation S-X.

<b><u>Name of Subsidiary</u></b>	<b><u>Jurisdiction of Incorporation or Organization</u></b>
Acutus Medical, N.V.	Belgium
Acutus Medical UK Limited	UK

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the registration statements (Nos. 333-241143, 333-254799, and 333-262467) on Form S-8 of our report dated March 30, 2022, with respect to the consolidated financial statements of Acutus Medical, Inc.

/s/ KPMG LLP

San Diego, California  
March 30, 2022

**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**

I, Vince Burgess, certify that:

1. I have reviewed this annual report on Form 10-K of Acutus Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Vince Burgess

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Vince Burgess  
President and Chief Executive Officer  
(Principal Executive Officer)  
March 30, 2022



**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**

I, David Roman, certify that:

1. I have reviewed this annual report on Form 10-K of Acutus Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ David Roman

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David Roman  
Chief Financial Officer  
(Principal Financial Officer)  
March 30, 2022

**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**

The certification set forth below is being submitted in connection with Form 10-K (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

I, Vince Burgess, Chief Executive Officer of Acutus Medical, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Annual Report on Form 10-K for the period ended December 31, 2021 (the "Report") filed with the Securities and Exchange Commission:

- Fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Vince Burgess

Vince Burgess

President and Chief Executive Officer  
(Principal Executive Officer)

March 30, 2022

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The certification set forth below is being submitted in connection with Form 10-K (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

I, David Roman, Chief Financial Officer of Acutus Medical, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Annual Report on Form 10-K for the period ended December 31, 2021 (the "Report") filed with the Securities and Exchange Commission:

- Fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ David Roman

David Roman

Chief Financial Officer

(Principal Financial Officer)

March 30, 2022