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Confidential Treatment Requested by Acutus Medical, Inc.
Pursuant to 17 C.F.R. Section 200.83

As confidentially submitted to the Securities and Exchange Commission on May 27, 2021
This draft registration statement has not been filed publicly with the Securities and Exchange Commission and all information contained herein remains strictly confidential.

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

ACUTUS MEDICAL, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**3841**	**45-1306615**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

2210 Faraday Ave., Suite 100
Carlsbad, CA 92008
(442) 232-6080
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Vince Burgess
Chief Executive Officer
Acutus Medical, Inc.
2210 Faraday Ave., Suite 100
Carlsbad, CA 92008
(442) 232-6080
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

Alan F. Denenberg **Davis Polk & Wardwell LLP** **1600 El Camino Real** **Menlo Park, CA 94025** **(650) 752-2000**	*Copies to:* **Tom Sohn** **Senior Vice President, General Counsel & Secretary** **Acutus Medical, Inc.** **2210 Faraday Ave., Suite 100** **Carlsbad, CA 92008** **(442) 232-6080**	**Kristin VanderPas** **Charles S. Kim** **Dave Peinsipp** **Denny Won** **Cooley LLP** **4401 Eastgate Mall** **San Diego, CA 92121** **(858) 550-6000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☑

Emerging growth company ☑

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Amount to be Registered(1)**	**Proposed Maximum Offering Price Per Share(2)**	**Proposed Maximum Aggregate Offering Price(1)(2)**	**Amount of Registration Fee**
Common stock, $0.001 par value per share		$	$	$

(1) Includes the aggregate amount of additional shares that the underwriters have the option to purchase.
(2) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(a) under the Securities Act of 1933, as amended.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission acting pursuant to said Section 8(a) may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED , 2021

Shares

Common Stock

We are offering shares of our common stock. Our common stock is listed on The Nasdaq Global Select Market under the symbol "AFIB." On , 2021, the last reported sale price of our common stock on The Nasdaq Global Select Market was $ per share.

We are an emerging growth company under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 13.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses, to us	$	$

(1) See "Underwriting" for additional disclosure regarding the underwriting discounts and commissions and estimated offering expenses.

We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of our common stock.

The underwriters expect to deliver the shares against payment in New York, New York on , 2021.

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

Goldman Sachs & Co. LLC

, 2021

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We and the underwriters have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may provide you. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock.

This prospectus includes industry and market data that we obtained from periodic industry publications, third-party studies and surveys, filings of public companies in our industry and internal company surveys. These sources may include government and industry sources. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. Although we believe the industry and market data to be reliable as of the date of this prospectus, this information could prove to be inaccurate. Industry and market data could be wrong because of the method by which sources obtained their data and because information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties. In addition, we do not know all of the assumptions regarding general economic conditions or growth that were used in preparing the forecasts from the sources relied upon or cited herein.

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PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus or in the documents incorporated by reference in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read the entire prospectus, including the section titled "Risk Factors" herein and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and related notes incorporated by reference in this prospectus from our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, or our 2020 Annual Report, and our Quarterly Report on Form 10-Q for the three months ended March 31, 2021, or our March 2021 Quarterly Report. As used in this prospectus, references to "we," "our," "us," the "Company" and "Acutus" refer to Acutus Medical, Inc. and, where appropriate, its wholly-owned subsidiary unless the context requires otherwise.

Overview

We are an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated. Despite several decades of efforts by 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 efficiently and effectively. 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 the geographic markets that we serve.

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.

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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 for determining 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 as needed. We believe these features will drive more efficient and predictable procedures and better outcomes for a broader range of arrhythmias.

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 the CE Mark 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 are also planning two investigational device exemption, or IDE, trials for U.S. Food and Drug Administration, or FDA, Premarket Approval, or PMA, in the United States. In the first half of 2021, the first IDE trial seeking a right atrial typical flutter indication received an IDE approval from the FDA and commenced enrollment. The second IDE trial seeking a paroxysmal and persistent atrial fibrillation indication received IDE approval in May 2021 and we expect to commence enrollment in the second half of 2021. We currently anticipate FDA PMA and the U.S. commercial launch of our AcQBlate Force Sensing Ablation System in the second half 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.

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. We estimate there were approximately 415,000 ablation procedures worldwide for SVTs in 2020.

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 87,000 global ablation procedures for ventricular arrhythmias in 2020.

Because currently marketed mapping systems rely on tissue contact and a fixed timing reference to collect and align data in the proper sequence, they are designed to map simple, stable and repetitive arrhythmias, including certain SVTs and VTs. Collecting a critical mass of data points to see even a stable rhythm is time consuming with contact mapping technologies, often taking 15 to 20 minutes per map. 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.

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 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. 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.

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.

Excellent 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 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 Sensing Ablation System, which we commercialized following the December 2020 receipt of the CE Mark in Europe. In the first quarter of 2021, we commenced enrollment in one of two IDE trials for FDA PMA in the United States with the second IDE trial planned to commence enrollment in the second half of 2021. We currently anticipate FDA PMA, and the U.S. commercial launch, of our AcQBlate Force Sensing Ablation System in the second half 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.

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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 with a broad base of customer accounts and physicians;
- strategically expanding our commercial organization across key global markets to increase physician awareness and drive adoption;
- driving market penetration and portfolio utilization;
- continuing to 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.

Risks Associated with Our Business

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

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- 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 in the United States and the rest of the world.

Company Information

We were incorporated in Delaware on March 25, 2011 as Acutus Medical, Inc. Our principal executive offices and manufacturing facilities are located at 2210 Faraday Ave., Suite 100, Carlsbad, CA 92008, and our telephone number is (442) 232-6080. Our website address is www.acutusmedical.com. The information on, or that may be accessed through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus 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 prospectus are our property. Solely for convenience, our trademarks and trade names referred to in this prospectus 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 prospectus are the property of their respective owners.

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, presenting only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of

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Operations" disclosure in this prospectus, 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.

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THE OFFERING

Common stock offered by us	shares.
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of our common stock.
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds from the sale of our common stock in this offering will be approximately $ million (or approximately $ million if the underwriters exercise their option to purchase additional shares in full) and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to support our commercial expansion, including hiring additional commercial personnel, for the completion of all of our ongoing clinical trials, for our research and development activities, and the remainder, if any, for working capital and other general corporate purposes. We may also use a portion of the net proceeds of this offering for acquisitions or strategic transactions, though we have not entered into any agreements or commitments with respect to any specific transactions and have no understandings or agreements with respect to any such transactions at this time. See the section titled "Use of Proceeds" for more information.
Risk factors	See the section titled "Risk Factors" and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.
Nasdaq trading symbol	"AFIB"

The number of shares of common stock that will be outstanding after this offering is based on 28,113,165 shares of our common stock outstanding as of March 31, 2021, and excludes:

- 824,608 shares of our common stock issuable upon the exercise of warrants to purchase shares of our common stock outstanding as of March 31, 2021, with a weighted-average exercise price of $9.10 per share;
- 3,379,575 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of March 31, 2021, with a weighted-average exercise price of $13.45 per share;
- 865,629 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted after March 31, 2021, with a weighted-average exercise price of $13.65 per share;
- 466,785 shares of our common stock issuable upon the vesting and settlement of outstanding performance-based restricted stock units, or PSUs, and restricted stock units, or RSUs, as of March 31, 2021;
- 2,132,646 shares of our common stock reserved for future issuance under our 2020 Equity Incentive Plan, or our 2020 Plan, as of March 31, 2021, plus shares of our common stock subject to the 2,636,188

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awards outstanding under our 2011 Equity Incentive Plan, or our 2011 Plan, as of March 31, 2021, which expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us, which shares will be added to the shares to be reserved under our 2020 Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to the 2020 Plan; and

- 387,063 shares of our common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, or our 2020 ESPP, as of March 31, 2021, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to the 2020 ESPP.

In addition, unless otherwise indicated, all information in this prospectus assumes or gives effect to:

- no exercise of outstanding options or warrants or settlement of outstanding RSUs described above; and
- no exercise by the underwriters of their option to purchase up to an additional shares of our common stock in this offering.

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SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth a summary of our historical consolidated financial data as of and for the periods indicated. We have derived the summary consolidated statements of operations and comprehensive loss data for the years ended December 31, 2020 and 2019 from our audited consolidated financial statements incorporated by reference herein from our 2020 Annual Report. We have derived the summary consolidated statements of operations and comprehensive loss data for the three months ended March 31, 2021 and 2020 and the consolidated balance sheet data as of March 31, 2021 from our unaudited interim consolidated financial statements incorporated by reference herein from our March 2021 Quarterly Report. You should read this data together with our consolidated financial statements and related notes incorporated by reference in this prospectus and the information in the sections titled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing in our 2020 Annual Report and in our March 2021 Quarterly Report, which are incorporated by reference herein. The summary consolidated financial data included in this section are not intended to replace the consolidated financial statements and related notes and are qualified in their entirety by our consolidated financial statements and related notes incorporated by reference in this prospectus. Our historical results are not necessarily indicative of the results to be expected for any other period and our interim results are not necessarily indicative of the results to be expected for the full year ending December 31, 2021 or for any other period.

(in thousands, except share and per share data)	Year Ended December 31,		Three Months Ended March 31,	
	2020	2019	2021	2020
			(unaudited)	
Consolidated Statements of Operations and Comprehensive Loss Data:				
Revenue(1)	$ 8,464	$ 2,836	$ 3,591	$ 1,583
Costs and operating expenses:				
Cost of products sold(2)	15,889	9,243	6,955	3,194
Research and development(2)	33,454	23,029	9,370	7,973
Research and development—license acquired	—	15,000	—	—
Selling, general and administrative(2)	50,357	26,847	16,252	10,235
Impairment of property and equipment	—	786	—	—
Change in fair value of contingent consideration	97	500	(1,153)	(2,219)
Total costs and operating expenses	99,797	75,405	31,424	19,183
Loss from operations	(91,333)	(72,569)	(27,833)	(17,600)
Other income (expense):				
Change in fair value of warrant liability	(5,555)	(1,919)	—	581
Loss on debt extinguishment	—	(1,447)	—	—
Interest income	436	1,164	40	275
Interest expense	(5,506)	(22,268)	(1,388)	(1,354)
Total other expense, net	(10,625)	(24,470)	(1,348)	(498)
Loss before income taxes	(101,958)	(97,039)	(29,181)	(18,098)
Income tax benefit	23	—	—	—
Net loss	$ (101,981)	$ (97,039)	$ (29,181)	$ (18,098)
Net loss per common share, basic and diluted(3)	$ (8.94)	$ (144.41)	$ (1.04)	$ (25.84)
Weighted-average shares outstanding, basic and diluted(3)	11,407,542	671,953	28,031,686	700,505

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(1) The following tables set forth our revenue for disposables, systems and service/other for the years ended December 31, 2020 and 2019 and the three months ended March 31, 2021 and 2020:

(in thousands)	Year Ended December 31, 2020	2019	Three Months Ended March 31, 2021	2020
			(unaudited)	
Acutus Direct				
Disposables	$ 5,221	$ 2,764	$ 1,783	$ 1,017
Systems	1,660	—	613	520
Service/Other	91	19	35	10
Total Acutus direct revenue	6,972	2,783	2,431	1,547
Distribution agreements	1,492	53	1,160	36
Total revenue	$ 8,464	$ 2,836	$ 3,591	$ 1,583

(in thousands)	Year Ended December 31, 2020	2019	Three Months Ended March 31, 2021	2020
			(unaudited)	
Acutus Direct				
United States	$ 4,625	$ 738	$ 1,468	$ 770
Europe	2,347	2,045	963	777
Total Acutus direct revenue	6,972	2,783	2,431	1,547
Distribution Agreements				
United States	229	—	113	—
Europe	1,263	53	1,047	36
Total revenue through distribution	1,492	53	1,160	36
Total revenue	$ 8,464	$ 2,836	$ 3,591	$ 1,583

(2) The following table sets forth the stock-based compensation expense included in our consolidated results of operations for the years ended December 31, 2020 and 2019 and the three months ended March 31, 2021 and 2020:

(in thousands)	Year Ended December 31, 2020	2019	Three Months Ended March 31, 2021	2020
			(unaudited)	
Cost of products sold	$ 440	$ 209	$ 157	$ 108
Research and development	1,002	656	442	211
Selling, general and administrative	10,661	2,129	2,311	1,422
Total stock-based compensation expense	$ 12,103	$ 2,994	$ 2,910	$ 1,741

(3) See Note 17 to our consolidated financial statements incorporated by reference in this prospectus for an explanation of the calculations of our basic and diluted net loss per common share and the weighted-average number of shares used in the computation of the per share amounts.

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(in thousands)	As of March 31, 2021	
	Actual	As Adjusted(1)
	(unaudited)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 95,519	$
Working capital(2)	97,636	
Total assets	161,946	
Contingent consideration, short- and long-term	5,600	
Long-term debt	39,339	
Accumulated deficit	(390,196)	
Total stockholders' equity	100,261	

(1) The as adjusted consolidated balance sheet data gives effect to the issuance and sale by us of shares of our common stock in this offering based on the assumed public offering price of $ per share, which was the last reported sale price of our common stock on The Nasdaq Global Select Market on , 2021, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase or decrease in the assumed public offering price of $ per share would increase or decrease, as applicable, the as adjusted cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity amounts by $, assuming the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares of common stock offered by us would increase or decrease the as adjusted cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity amounts by $, assuming the assumed public offering price of $ per share remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

(2) Working capital is defined as total current assets less total current liabilities. See our consolidated financial statements and related notes incorporated by reference in this prospectus for further details regarding our current assets and current liabilities.

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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 prospectus or incorporated by reference herein, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes incorporated by reference herein from our 2020 Annual Report and our March 2021 Quarterly Report, 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. In that event, the market price of our common stock could decline, and you could lose all or part of your investment. Please also see the sections titled "Special Notes Regarding Forward-Looking Statements" and "Market, Industry and Other Data."

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, and aim to educate referring physicians regarding the patient population that would benefit from our products. 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. 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. Future 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, 2020, 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, 2020 and 2019, 43% and 74%, 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 U.K.'s 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 United States Foreign Corrupt Practices Act of 1977, or 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;

- expand our sales force across key markets to increase physician awareness;
- 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.

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 2020, our headcount increased by 41%, and we released seven new disposable products, four hardware products and four 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 Medical Device Reporting, or 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.

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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. 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 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 have disrupted and are expected to continue to impact our business. On March 19, 2020, the Executive Department of the State of California issued Executive Order N-33-20, ordering all individuals in the State of California to stay home or at their place of residence except as needed to maintain continuity of operations of the federal critical infrastructure sectors. Our primary operations are located in Carlsbad, California. As a result of such order, the majority of our employees have telecommuted, which impacted certain of our operations. Moreover, beginning in March 2020, access to hospitals and other customer sites was restricted to essential personnel, which negatively impacted our ability to install our AcQMap consoles and workstations in new customer accounts and for our sales representatives and mappers to promote the use of our products with physicians, and thus negatively impacted our revenues. Moreover, hospitals and other therapeutic centers suspended many elective procedures, resulting in a significantly reduced volume of procedures using our products. In addition, all clinical trials in Europe were suspended with follow-ups for clinical trials done via telecom, and we believe enrollment timing in our planned clinical trials has been slowed due to COVID-19 driven delayed access to enrollment sites. As the COVID-19

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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 further 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. As a result of the interruptions to our business due to COVID-19, we enacted a cash conservation program, which included delaying certain non-critical capital expenditures and other projects and implementing a hiring freeze, headcount reductions and temporary compensation reductions throughout our organization (which ended in August 2020). Although the initial effects of the pandemic began to decrease in late April 2020 as electrophysiology labs began reopening and procedure volumes began increasing as compared to COVID-19 related low points in March 2020, a resurgence of the COVID-19 pandemic adversely impacted electrophysiology procedural activity, and thus our revenue, during the fourth quarter of 2020 and the first quarter of 2021. COVID-19 continues to create significant uncertainty in several markets that we serve, most notably in Western Europe and the United Kingdom, as we are continuing to see hospitals focusing on COVID-19 patients and slowing elective procedures. 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 the COVID-19 pandemic continues to evolve. 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 continue to prioritize those patients, additional restrictions may be implemented which would further 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. 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. Quarantines, shelter-in-place 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 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. 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; and (vi) 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 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 2020 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 30% and 43% of our revenue in 2020, 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 Quality System Regulation, or 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 institutional review board, or 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.

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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."

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Pursuant to 17 C.F.R. Section 200.83

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 was outstanding as of March 31, 2021. Of the remaining $30.0 million, none is available for borrowing, as the lenders' commitments to fund such additional amount had terminated as of December 31, 2020. 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 arrangements. 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, 2020 and 2019, approximately 43% and 74%, respectively, of our sales were denominated in currencies other than U.S. dollars. For the three months ended March 31, 2021 and 2020, approximately 56% and 51%, 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, 2020, we had U.S. federal and state net operating loss, or NOL, carryforwards of approximately $303.5 million and $74.9 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 (the “Code”), 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, this offering or 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, including in connection with this offering, 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.

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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 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 as early as July 1, 2020. The CCPA has been amended from time to time, and 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 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 the Health Insurance Portability and Accountability Act, or 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 General Data Protection Regulation, or 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 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 United Kingdom, or the UK, approved an exit from the EU, the UK 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 UK. Following December 31, 2020, and the expiry of transitional arrangements between the UK and EU, the data protection obligations of the GDPR continue to apply to UK-related processing of personal information in substantially unvaried form under the so-called 'UK GDPR' (i.e., the GDPR as it continues to form part of UK law by virtue of section 3 of the EU (Withdrawal) Act 2018, as amended). However, going forward, there is increasing risk for divergence in application, interpretation, and enforcement of the data protection laws as between the UK and European Economic Area, or the EEA. Furthermore, the relationship between the UK and the EEA in relation to certain aspects of data protection law remains uncertain. For example, pursuant to a postBrexit trade deal between the UK and the EU, transfers of personal information from the EEA to the UK are not considered restricted transfers under the GDPR for a period of up to six months from January 1, 2021. However, unless the EU Commission makes an adequacy finding with respect to the UK before the end of that period, the UK will be considered a "third country" under the GDPR and transfers of European personal information to the UK will require an adequacy mechanism or an additional safeguard. We may incur liabilities, expenses, costs and other operational losses under the GDPR and privacy laws of the applicable EU Member States and the UK 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.

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, 2020 and 2019, we had a net loss of $102.0 million and $97.0 million (which included $15.0 million in payments attributable to the product line we acquired from Biotronik pursuant to the Biotronik License Agreement), respectively, and for the three months ended March 31, 2021 and 2020, we had a net loss of $29.2 million and $18.1 million, respectively. 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, 2020 and 2019, we had an accumulated deficit of $361.0 million and $259.0 million, respectively, and as of March 31, 2021, we had an accumulated deficit of $390.2 million. Prior to our initial public offering, or our IPO, our operations have 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. 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 March 31, 2021 and December 31, 2020, we had $95.5 million and $131.1 million, respectively, in cash, cash equivalents and marketable securities. While we believe the net proceeds from this offering, together with 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 prospectus, 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 European Economic Area, or EEA, our products must comply with the essential requirements of the European Union Medical Devices Directive (Council Directive 93/42/EEC), or 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.

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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 PMAs 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.

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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 the Centers for Medicare & Medicaid Services, or CMS, payments and other transfers of value to all U.S. physicians and U.S. teaching hospitals, with the reported information made publicly available on a searchable website. 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. Once applicable, the new regulations will, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve 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 European Union; and
- strengthen 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 Law, 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 (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.

- 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 Law. 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 Civil Monetary Penalties Law 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.

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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, judicial and Congressional 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 will remain 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.

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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.

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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

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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.

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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 and This Offering

The market price for our common stock has been volatile, it may decline regardless of our operating performance, an active trading market may not be sustained in our common stock, and you may not be able to resell our common stock at or above the offering price.

The market price of our common stock has been volatile, and it may fluctuate or decline substantially. You may not be able to resell your shares at or above the offering price 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 or capital commitments;
- industry or financial analyst or investor reaction to our press releases, other public announcements and filings with the Securities and Exchange Commission, or 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;
- the expiration of market stand-off or contractual lock-up agreements and 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 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.

You will incur immediate dilution in the net tangible book value of the shares you purchase in this offering.

The public offering price of our common stock will be higher than the net tangible book value per share of outstanding common stock prior to completion of this offering. Based on our net tangible book value as of March 31, 2021 and upon the issuance and sale of shares of common stock by us at the public offering price of $ per share, if you purchase our common stock in this offering, you will suffer immediate dilution of $ per share in net tangible book value. Dilution is the amount by which the offering price paid by purchasers of our common stock in this offering will exceed the pro forma net tangible book value per share of our common stock upon completion of this offering. If the underwriters exercise their option to purchase additional shares, you will experience further dilution. A total of 2,580,423 shares of common stock were initially reserved for future issuance under our 2020 Plan and our 2020 ESPP, and 2,636,188 and 1,210,172 shares of our common stock were subject to outstanding equity awards as of March 31, 2021 under our 2011 Plan and 2020 Plan, respectively. You may experience additional dilution upon future equity issuances or the exercise of stock options to purchase common stock granted to our directors, officers and employees under our current and future stock-based compensation plans, including our 2020 Plan and our 2020 ESPP. See the section titled "Dilution."

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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 date 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.

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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.

We have broad discretion to determine how to use the funds raised in this offering, and we may use them in ways that may not enhance our operating results or the price of our common stock.

Though we currently intend to use the net proceeds from this offering for the purposes described in the section titled "Use of Proceeds," our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled "Use of Proceeds." We could spend the proceeds from this offering in ways that our stockholders may not agree with or that do not yield a favorable return. You will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Investors in this offering will need to rely upon the judgment of our management and board of directors with respect to the use of proceeds. If we do not use the net proceeds that we receive in this offering effectively, our business, financial condition, results of operations and prospects could be harmed, and the market price of our common stock could decline.

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, 2020, our directors, executive officers and holders of more than 5% of our common stock beneficially owned, as a group, 47.0% of our common stock. After this offering, our directors, executive officers and holders of more than 5% of our common stock, together with their affiliates, will beneficially own, in the aggregate, % of our outstanding common stock, assuming no exercise of the underwriters' option to purchase additional shares of our common stock in this offering. In addition, as of December 31, 2020, 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.

Future sales, or the perception of future sales, by us or our existing stockholders in the public market following this offering could cause the market price for our common stock to decline.

After this offering, the sale of shares of our common stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of shares of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Upon completion of this offering, we will have a total of shares of common stock outstanding. All shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, unless purchased by our affiliates.

In connection with this offering, we and our directors and executive officers and certain of our stockholders have each agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of our or their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 90 days after the date of this prospectus, except with the prior written consent of Goldman Sachs & Co. LLC. See the section titled “Underwriting” for a description of these lock-up agreements.

Upon the expiration of such contractual lock-up agreements or if such lock-up agreements are waived, approximately 12.6 million additional outstanding shares will be eligible for sale in the public market, though such shares held by directors, executive officers and other affiliates will be subject to volume, manner of sale and other limitations under Rule 144. Following completion of this offering, shares covered by registration rights would represent % of our outstanding common stock (or %, if the underwriters exercise in full their option to purchase additional shares). Registration of any of these outstanding shares of common stock would result in such shares becoming freely tradable without compliance with Rule 144 upon effectiveness of the registration statement. See the section titled “Shares Eligible for Future Sale.”

As restrictions on resale end or if these stockholders exercise their registration rights, the market price of our shares of common stock could drop significantly if the holders of these shares sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of our shares of common stock or other securities.

In addition, the shares of our common stock reserved for future issuance under our stock-based compensation plans will become eligible for sale in the public market once those shares are issued, subject to provisions relating to various vesting agreements, lock-up agreements and Rule 144, as applicable. A total of 2,193,360 shares of our common stock and 387,063 shares of our common stock were initially reserved for future issuance under our 2020 Plan and our 2020 ESPP, respectively, and 2,636,188 and 1,210,172 shares of our common stock were subject to outstanding equity awards as of March 31, 2021 under our 2011 Plan and 2020 Plan, respectively.

In the future, we may also issue our securities in connection with investments or acquisitions. The amount of shares of our common stock issued in connection with an investment or acquisition could constitute a material portion of our then-outstanding shares of our common stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution to you.

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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. See the section titled "Description of Capital Stock."

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. For a more complete summary of these agreements, see the section titled "Business—Biotronik Agreements."

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In connection with the preparation of our consolidated financial statements as of and for the years ended December 31, 2019 and 2018, the Company and our independent registered public accounting firm identified a material weakness in the Company's internal control over financial reporting. While the material weakness has been remediated, if we are not able to maintain an effective system of internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock could be materially and adversely affected.

As a privately-held company, we were not required to evaluate our internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404(a) of the Sarbanes-Oxley Act and to date, we have not conducted an evaluation and testing of our internal control required by Section 404 of the Sarbanes-Oxley Act. As a public company, we have significant requirements for enhanced financial reporting and internal controls. We may also experience situations in the future where our evaluation and testing processes required by Section 404 of the Sarbanes-Oxley Act, or work performed by independent registered public accountants, may identify one or more material weaknesses in our internal control over financial reporting that will result in our inability to assert that our internal control over financial reporting is effective. During our evaluation and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports.

The process of designing and implementing effective internal controls is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. If we are unable to establish or maintain appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations on a timely basis, result in material misstatements in our consolidated financial statements and harm our results of operations. For example, in 2020 we detected an irregularity in the reported timing of the receipt of two purchase orders. While this did not result in a misstatement in our financial statements as we promptly detected the improper reporting and took appropriate action, there can be no assurance that our system of internal control will operate as effectively to detect any improper purchase orders or other irregularities in the future. In addition, we will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting in our annual report for the year ending December 31, 2021. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. Testing and maintaining internal controls may divert our management's attention from other matters that are important to our business. Our independent registered public accounting firm will be required to issue an attestation report on the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company and after we meet the definition of an accelerated filer. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by the SEC and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

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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.

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General Risk Factors

Economic conditions may adversely affect our business.

Adverse worldwide economic conditions, including 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.

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.

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.

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

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

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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.

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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.

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SPECIAL NOTES REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained or incorporated by reference herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

These forward-looking statements include, but are not limited to, statements about:

- our plans and expected timeline related to our products, or developing new products, to address additional indications or otherwise;
- the expected use of our products by physicians;
- the size and growth potential of the markets for our products, and our ability to serve those markets;
- our ability to identify and develop new planned products and/or acquire new products;
- our plans to conduct further clinical trials;
- our ability to obtain, maintain and expand regulatory clearances for our products and any new products;
- our ability to maintain or expand our relationships with strategic partners, or to identify and develop new strategic partnerships;
- our ability to expand our business into new geographic markets;
- the expected growth of our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to retain and recruit key personnel, including the continued development of a sales and marketing infrastructure;
- our expectations regarding the impact of the COVID-19 pandemic and the end of the COVID-19 pandemic on our business;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers, some of whom are single-source suppliers;
- our ability to manufacture sufficient quantities of our products with sufficient quality;
- our ability to obtain, maintain, enforce and defend intellectual property protection for our products;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing;
- our expected uses of the net proceeds from this offering;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act; and
- developments and projections relating to our competitors or our industry.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results

to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this prospectus or in the documents incorporated by reference herein may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed in the section titled "Risk Factors" and elsewhere in this prospectus and in the documents incorporated by reference herein. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements.

These forward-looking statements speak only as of the date of this prospectus. We assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future, except as required by applicable law. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations, except as required by applicable law.

You should read this prospectus and the documents incorporated by reference herein and the documents that we reference in this prospectus or in the documents incorporated by reference herein that have been filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

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MARKET, INDUSTRY AND OTHER DATA

This prospectus and the documents incorporated by reference herein contain estimates and information concerning our industry, including the incidence of certain medical conditions and procedures, healthcare costs, market size and growth rates of the markets in which we participate, that are based on industry publications and reports. We relied on industry, market data, peer-reviewed journals, formal presentations at medical society meetings and independent third-party sources for procedure data in the United States, as well as publicly available data and other sources. We also rely on our own research and estimates in this prospectus and the documents incorporated by reference herein. In some cases, we do not expressly refer to the sources from which this data is derived. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to these estimates. We have not independently verified the data contained in any third-party information and cannot assure you of its accuracy or completeness.

Although we believe the market position, market opportunity, market size and medical information included in this prospectus and the documents incorporated by reference herein is reliable, such information is inherently imprecise. In addition, projections, assumptions, and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in these publications and reports.

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DIVIDEND POLICY

We have never declared or paid, and do not anticipate declaring or paying, any cash dividends on any of our capital stock. We do not anticipate paying any dividends in the foreseeable future, and we currently intend to retain all available funds and any future earnings, if any, for use in the operation of our business, to finance the growth and development of our business and for future repayment of debt. Future determinations as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then-existing conditions, including our operating results, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. In addition, our 2019 Credit Agreement restricts our ability to pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions.

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of our common stock in this offering will be $ million (or $ million if the underwriters exercise their option to purchase additional shares in full) based on the assumed public offering price of $ per share of common stock, which was the last reported sale price of our common stock on The Nasdaq Global Select Market on , 2021, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or decrease in the assumed public offering price of $ per share would increase or decrease, as applicable, the net proceeds to us from this offering by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares offered by us would increase or decrease, as applicable, the net proceeds to us from this offering by $ million, assuming that the assumed public offering price remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the public offering price or the number of shares by these amounts would have a material effect on our use of proceeds from this offering.

We currently intend to use the net proceeds from this offering as follows: approximately $ million to support our commercial expansion, including hiring additional commercial personnel, approximately $ million for research and development activities, and the remainder, if any, for working capital and other general corporate purposes.

Based on our current business plans, we believe that the net proceeds of this offering, together with our existing cash, cash equivalents and marketable securities and expected revenue from sales of our products, will be adequate to support our commercialization, clinical trials and research and development activities for at least the next 12 months.

We believe opportunities may exist from time to time to expand our current business through license or acquisitions of, or investments in, complementary businesses, products or technologies. While we have no current agreements, commitments or understandings for any specific licenses, acquisitions or investments at this time, we may use a portion of the net proceeds for these purposes.

Our management will have broad discretion over the use of the net proceeds from this offering. The amounts and timing of our expenditures will depend upon numerous factors, including cash flows from operations, the extent and success of our commercial expansion, the extent and results of our research and development efforts, the timing and success of our studies and clinical trials, the timing and results of regulatory submissions, reimbursement and the anticipated growth of our business. Pending their uses, we plan to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

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CAPITALIZATION

The following table sets forth our cash, cash equivalents and marketable securities and capitalization as of March 31, 2021 on:

- an actual basis; and
- an as adjusted basis to give further effect to our issuance and sale of shares of common stock in this offering based on the assumed public offering price of $ per share, which was the last reported sale price of our common stock on The Nasdaq Global Select Market on , 2021, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with our consolidated financial statements and related notes incorporated by reference in this prospectus, as well as the sections titled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" incorporated by reference in this prospectus.

(in thousands, except share and per share data)	As of March 31, 2021	
	Actual	As Adjusted
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 106,894	$
Long-term debt	$ 39,339	$
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized, no shares issued or outstanding, actual and as adjusted	—	
Common stock, $0.001 par value per share; 260,000,000 shares authorized, 28,113,165 shares issued and outstanding, actual; 260,000,000 shares authorized, shares issued and outstanding, as adjusted	28	
Additional paid-in capital	490,369	
Accumulated deficit	(390,196)	
Accumulated other comprehensive income	60	
Total stockholders' equity	100,261	
Total capitalization	$ 139,600	$

The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease in the assumed public offering price of $ per share, which was the last reported sale price of our common stock on The Nasdaq Global Select Market on , 2021, would increase or decrease, as applicable, the as adjusted cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders' equity and total capitalization amounts by $ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares of common stock offered by us would increase or decrease, as applicable, the as adjusted cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders' equity and total capitalization amounts by $ million, assuming the assumed public offering price of $ per share remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters' option to purchase additional shares is exercised in full, the as adjusted cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders' equity, total capitalization and shares outstanding as of March 31, 2021 would be $ million, $ million, $ million, $ million and shares, respectively.

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The number of shares of common stock that will be outstanding after this offering is based on 28,113,165 shares of our common stock outstanding as of March 31, 2021, and excludes:

- 824,608 shares of our common stock issuable upon the exercise of warrants to purchase shares of our common stock outstanding as of March 31, 2021, with a weighted-average exercise price of $9.10 per share;
- 3,379,575 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of March 31, 2021, with a weighted-average exercise price of $13.45 per share;
- 865,629 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted after March 31, 2021, with a weighted-average exercise price of $13.65 per share;
- 466,785 shares of our common stock issuable upon the vesting and settlement of outstanding PSUs and RSUs as of March 31, 2021;
- 2,132,646 shares of our common stock reserved for future issuance under our 2020 Plan, as of March 31, 2021, plus shares of our common stock subject to the 2,636,188 awards outstanding under our 2011 Plan, as of March 31, 2021, which expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us, which shares will be added to the shares to be reserved under our 2020 Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to the 2020 Plan; and
- 387,063 shares of our common stock reserved for future issuance under our 2020 ESPP, as of March 31, 2021, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to the 2020 ESPP.

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DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock immediately after this offering.

Our net tangible book value as of March 31, 2021 was $82.7 million, or $2.94 per share of our common stock. Our net tangible book value is the amount of our total tangible assets less our total liabilities. Net tangible book value per share represents net tangible book value divided by the number of shares of our common stock outstanding as of March 31, 2021.

After giving further effect to our sale of shares of common stock in this offering at the assumed public offering price of $ per share, which was the last reported sale price of our common stock on The Nasdaq Global Select Market on , 2021, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2021 would have been approximately $ million, or approximately $ per share. This represents an immediate increase in as adjusted net tangible book value per share of $ to our existing stockholders and an immediate dilution in as adjusted net tangible book value per share of approximately $ to new investors purchasing common stock in this offering. Dilution per share to new investors purchasing common stock in this offering is determined by subtracting as adjusted net tangible book value per share after this offering from the public offering price per share paid by new investors.

The following table illustrates this dilution on a per share basis:

Assumed public offering price per share		$
Net tangible book value per share as of March 31, 2021	$2.94	
Increase in as adjusted net tangible book value per share attributable to new investors purchasing shares in this offering		
As adjusted net tangible book value per share after this offering		
Dilution per share to new investors purchasing shares in this offering		$

The dilution information discussed above is illustrative only and will change based on the actual public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease in the assumed public offering price of $ per share, which was the last reported sale price of our common stock on The Nasdaq Global Select Market on , 2021, would increase or decrease, as applicable, the as adjusted net tangible book value per share after this offering by $ per share and dilution per share to new investors participating in this offering by $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, would increase or decrease, as applicable, the as adjusted net tangible book value per common share after this offering by $ per share and increase or decrease, as applicable, the dilution per common share to new investors participating in this offering by $ per share, assuming the assumed public offering price remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, at the assumed public offering price of $ per share, which was the last reported sale price of our common stock on The Nasdaq Global Select Market on , 2021, our adjusted net tangible book value per share after the offering would be $, and the dilution per share to new investors would be $, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

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The foregoing table and calculations (other than the historical net tangible book value calculation) are based on the 28,113,165 shares of our common stock outstanding as of March 31, 2021, and excludes:

- 824,608 shares of our common stock issuable upon the exercise of warrants to purchase shares of our common stock outstanding as of March 31, 2021, with a weighted-average exercise price of $9.10 per share;
- 3,379,575 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of March 31, 2021, with a weighted-average exercise price of $13.45 per share;
- 865,629 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted after March 31, 2021, with a weighted-average exercise price of $13.65 per share;
- 466,785 shares of our common stock issuable upon the vesting and settlement of outstanding PSUs and RSUs as of March 31, 2021;
- 2,132,646 shares of our common stock reserved for future issuance under our 2020 Plan, as of March 31, 2021, plus shares of our common stock subject to the 2,636,188 awards outstanding under our 2011 Plan, as of March 31, 2021, which expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us, which shares will be added to the shares to be reserved under our 2020 Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to the 2020 Plan; and
- 387,063 shares of our common stock reserved for future issuance under our 2020 ESPP, as of March 31, 2021, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to the 2020 ESPP.

To the extent that any outstanding options to purchase shares of our common stock are exercised or new awards are granted under our equity compensation plans, or we issue additional shares of common stock or other securities convertible into or exercisable or exchangeable for shares of our capital stock in the future, there will be further dilution to investors participating in this offering.

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BUSINESS

Overview

We are an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated. Despite several decades of efforts by 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 efficiently and effectively. 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.

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. As a result, cardiac ablation is a well-established therapy for the large and rapidly growing patient population, with clear and substantial reimbursement in developed markets. We estimate that in 2020 there were over 50 million individuals worldwide with arrhythmias and approximately 1.0 million ablation procedures performed globally, reflecting a $6.1 billion global market that has grown approximately 12% annually since 2016 but is still less than 5% penetrated.

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 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 for determining 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 as needed. We believe these features will drive more efficient and predictable procedures and better outcomes for a broader range of arrhythmias.

These key clinical and workflow benefits are supported by the results of our clinical trials, including our UNCOVER AF post-market approval trial, which demonstrated that use of our AcQMap System in challenging persistent AF patients resulted in 73% and 93% freedom from atrial fibrillation at 12-months following their initial procedure after one or two procedures, respectively. These outcomes compare favorably to those of other clinical trials in the field that utilized currently marketed contact-based mapping catheters and systems, including the landmark STAR AF II trial, which demonstrated 61% and 79% freedom from atrial fibrillation after one or two procedures, respectively, in a similar cohort of persistent atrial fibrillation patients.

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 Sensing Ablation System, which we commercialized following the December 2020 receipt of the CE Mark in Europe. We are also planning two IDE trials for FDA PMA in the United States. In the first half of 2021, the first IDE trial seeking a right atrial typical flutter indication received an IDE approval from the FDA and commenced enrollment. The second IDE trial seeking a paroxysmal and persistent atrial fibrillation indication received IDE approval from the FDA in May 2021 and we expect to commence enrollment in the second half of 2021. We currently anticipate FDA PMA, and the U.S. commercial launch, of our AcQBlate Force Sensing Ablation System in the second half 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.

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 SE & Co. KG, or 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.

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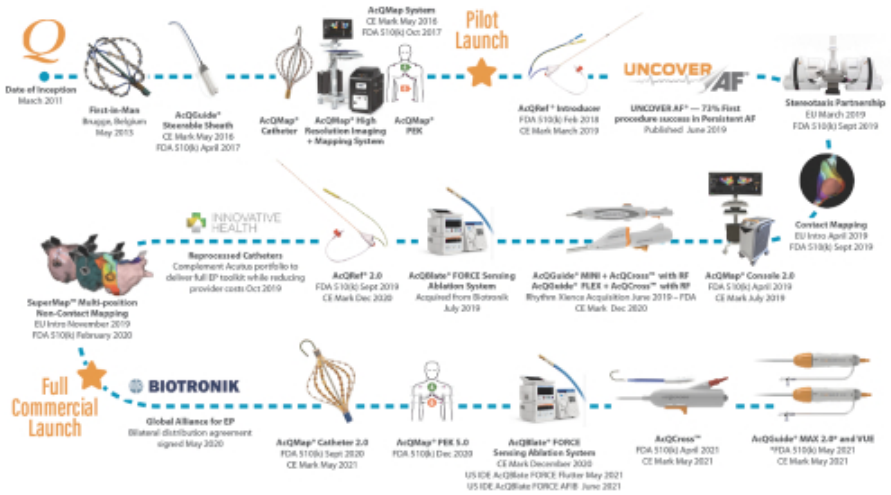
Early versions of our AcQMap System and certain related accessory products have been used in the United States since May 2018 and Western Europe since July 2016 in a limited, pilot launch capacity, where our focus was on optimizing workflow and validating our value proposition. We fully commenced the launch of our commercial-grade console and software products in the first quarter of 2020. Critical to our launch were a series of 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, Inc., or Rhythm Xience; and the acquisition of our AcQBlate Force Sensing Ablation System 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. The diagram below depicts a chronology of these and other key events since our inception:



Our revenue has historically consisted predominantly of sales of our disposable products (principally our mapping catheter and related access sheaths, and to a lesser extent our transseptal crossing tools, ablation catheters and other accessories), as we generally loaned our first-generation AcQMap console and workstation to our customers without charge to facilitate the use of our disposable products. 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 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 or financed purchase. In addition, beginning in the second quarter of 2020, pursuant to our bi-lateral distribution agreements, we began marketing Biotronik's full suite of diagnostic and ablation catheters in Europe, and Biotronik began marketing our AcQMap System in Europe and certain other international markets. Each party pays to the other party specified transfer prices on the sale of the other party's products under the bi-lateral distribution agreements and, accordingly, earns a distribution margin on the sale of the other party's products.

In advance of our commercial launch, we made significant investments in our infrastructure, including our manufacturing capabilities and sales force, to support our commercial launch and to enable our production volumes to scale as our business grows. Accordingly, our cost structure has not changed materially since the launch. The COVID-19 pandemic and the measures imposed to contain this pandemic disrupted our business beginning in early March 2020, following the full commencement of the launch of our commercial-grade console

and software products. Although the initial effects of the pandemic began to decrease in late April 2020 as electrophysiology labs began reopening and procedure volumes began increasing as compared to COVID-19 related low points in March 2020, a resurgence of the COVID-19 pandemic adversely impacted electrophysiology procedural activity during the fourth quarter of 2020 and the first quarter of 2021. COVID-19 continues to create significant uncertainty in several markets that we serve, most notably in Western Europe and the United Kingdom, as we are continuing to see hospitals focusing on COVID-19 patients and slowing elective procedures. See the sections titled "Risk Factors" herein and "Management's Discussion and Analysis of Financial Condition and Results of Operations" incorporated by reference herein for more information.

Our Competitive Strengths

Paradigm-Shifting Intracardiac Mapping System Offering Significant Advantages Relative to the Current Standard of Care. Our foundational and most highly differentiated product is our AcQMap imaging and mapping system. Our AcQMap System combines two innovative arrhythmia mapping concepts, the use of ultrasound to create a more anatomically accurate image of the heart chamber, and charge density electrical mapping to display the heart's true activation patterns and pathways. These features allow physicians to create a map of an entire heart chamber and any arrhythmia in under three minutes, without contacting the chamber wall. The speed and ease of creating a map makes it practical for physicians to iteratively map, treat, re-map and adjust additional therapy as needed. We believe that by offering electrophysiologists a faster and more comprehensive decision-making tool, our AcQMap System allows them to improve ablation procedure outcomes, reduce procedure time and increase certainty around resource utilization. We are seeking to establish our AcQMap System as the standard of care for intracardiac mapping in electrophysiology procedures and to leverage its paradigm-shifting nature to drive adoption and utilization across a broad portfolio of tools for catheter-based ablation procedures.

Broad and Expanding Product Portfolio. 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 product portfolio includes novel access sheaths, transseptal crossing tools, diagnostic and mapping catheters, ablation catheters (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. 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 commercialized following the December 2020 receipt of the CE Mark in Europe. We are also planning two IDE trials for FDA PMA in the United States. In the first half of 2021, the first IDE trial seeking right atrial typical flutter indication received IDE approval from the FDA and commenced enrollment. The second IDE trial seeking a paroxysmal and persistent atrial fibrillation indication received IDE approval in May 2021 and we expect to commence enrollment in the second half of 2021. We currently anticipate FDA PMA, and the U.S. commercial launch, of our AcQBlate Force Sensing Ablation System in the second half of 2022 or early 2023. We believe that our ability to offer a broad portfolio will support adoption of our products and drive an increasingly efficient revenue model with a growing component of recurring revenue per procedure.

Attractive Value Proposition for Hospitals, Physicians, Patients and Payors. We believe that by creating high definition, clinically accurate activation maps, our AcQMap System offers physicians better decision-making tools for determining where to ablate. Similarly, by materially simplifying the process and reducing the time required to create an intracardiac map from 15 to 20 minutes to under three minutes, our AcQMap System makes it practical for physicians to iteratively map, treat, re-map and adjust additional therapy as needed. We believe these features will drive more efficient and predictable procedures and better outcomes for a broader range of arrhythmias. For hospitals, we believe our AcQMap System will materially reduce procedure times and allow our customers to improve lab throughput. Lastly, by driving better outcomes, including freedom from

arrhythmia and reduced need for repeat procedures, our AcQMap System will reduce the financial burden for payors. We believe these benefits will continue to support the adoption of our AcQMap System by hospitals and physicians.

Large, Rapidly Growing and Underpenetrated Market with Established Reimbursement. Arrhythmias are a common and often progressive condition which, if left untreated, can result in debilitating symptoms, heart failure, stroke and sudden cardiac death. As a result, ablation of arrhythmias is a well-established therapy for a large and rapidly growing global population, with clear and substantial reimbursement in developed markets. We estimate that in 2020, there were over 50 million individuals worldwide with arrhythmias and approximately 1.0 million ablation procedures globally, reflecting a global market of $6.1 billion that is less than 5% penetrated. While the global market has grown at approximately 12% annually since 2016 due to demographic trends and improving therapies, we believe that the size of this market has historically been constrained by the capabilities of existing technologies, which have demonstrated limited effectiveness in treating more complex and unstable arrhythmias. We believe our differentiated technology has the potential to drive adoption of our products within the existing market as well as to expand the market by facilitating wider treatment of complex or unstable arrhythmias that are not as frequently treated with cardiac ablation.

Efficient Commercial Model. 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 order to efficiently address international markets, we have entered into bi-lateral distribution agreements with Biotronik that allow us to leverage their experienced sales force to distribute our products in international markets where Biotronik has a significant presence and existing infrastructure. The target market for our product portfolio is highly concentrated with an existing physician user base that is already well trained and experienced in diagnosing and ablating arrhythmias. In the United States, we believe there are approximately 1,000 physicians and 750 hospitals that perform cardiac ablation procedures and that over 60% of the 163,000 cardiac ablation procedures performed in the United States in 2020 took place in approximately 200 high volume hospitals. We plan to leverage the concentrated nature of procedure volumes to focus our initial commercial efforts on the high and medium volume centers in our markets in the United States and Western Europe. 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 recurring revenue model allows for more efficient commercial sales and increased pull-through of additional products. We believe that hospitals worldwide spend between $3,000 to $10,000 on disposable products in each ablation procedure, depending on the type of procedure and geography. As we continue to expand our product portfolio, we aim to capture an increasing portion of the overall procedure spend.

Pure-Play Electrophysiology Focus. Our deep commitment to understanding the needs of our customers has allowed us to develop and commercialize a platform with a differentiated value proposition. Our exclusive focus on electrophysiology has supported our rapid cadence of innovation, including our ability to establish a complete portfolio of devices for diagnosing and treating any arrhythmia. We intend to continue to leverage our engineering and algorithmic expertise to increase the AcQMap System's utility and continue seeking approval for additional labeled indications as well as to expand our portfolio to further improve and simplify the entire procedural experience. Additionally, our commitment to disrupting the industry and evolving a decades-old standard of care has also allowed us to attract a highly experienced commercial organization that has medical device sales and clinical expertise, specifically in the electrophysiology, interventional cardiology and cardiac rhythm segments.

Deep Technology-Driven Competitive Advantage Supported by a Robust Patent Portfolio, Trade Secrets and Know-how, and In-Licensed and Acquired Technology. We believe our AcQMap System represents a meaningful improvement over contact-based mapping, the existing standard of care. Our technology lead is supported by a combination of our strong patent portfolio, trade secrets, in-licensed technology and know-how. As of December 31, 2020, we solely owned or exclusively licensed more than 74 issued patents globally and

more than 70 pending patent applications that include device, apparatus and method claims surrounding mapping, anatomy reconstruction, energy modalities for ablation therapy as well as endovascular access to all chambers of the heart. In addition, we believe that our deep competitive advantage is further supported by the fact that other companies' platforms do not currently perform non-contact mapping, and we believe for them to add that capability, it would require not only developing non-contact based mapping catheters and supporting software algorithms, but also replacing their fleet of installed mapping consoles.

Highly Experienced Senior Management Team with Broad Cardiovascular Industry Expertise. Our senior management team consists of seasoned medical device professionals with deep industry experience. Our team has successfully led and managed dynamic growth phases in organizations and commercialized products in markets with established incumbents by addressing the unmet needs of the clinicians and patients they serve. Members of our team have worked with well-regarded medical technology companies such as Volcano Corporation, Boston Scientific Corporation, Guidant Corporation, Medtronic plc, Abbott Laboratories, St. Jude Medical, Inc., Philips and Biotronik.

Our Growth Strategies

Utilizing our Superior Mapping Technology and Open Platform to Establish our Presence with a Broad Base of Customer Accounts and Physicians. We are seeking to establish our AcQMap System as the standard of care for intracardiac mapping in electrophysiology procedures and to leverage its paradigm-shifting nature to drive adoption of our full product portfolio in new customer accounts. We believe that by offering electrophysiologists a faster and more comprehensive decision-making tool, our AcQMap System will allow for improved ablation procedure outcomes, reduced procedure time and increased certainty around resource utilization. We believe these benefits offer an attractive value proposition for key stakeholders including physicians, hospitals and payors and will continue to drive adoption. We expect the value proposition of our AcQMap System to continue to drive demand for opening new customer accounts.

Strategically Expanding our Commercial Organization Across Key Global Markets to Increase Physician Awareness and Drive Adoption. We have taken and continue to take a measured approach to account targeting and physician training. We have assembled a team with in-depth knowledge of the target markets in which we compete and seek to compete. As of March 31, 2021, our commercial organization consisted of 75 individuals with substantial applicable medical device, sales and clinical experience, including sales management, sales representatives and mappers, who act as technical and clinical support personnel on site in the electrophysiology lab during procedures. Over time, we plan to selectively add highly qualified personnel to our commercial organization with a strategic mix of sales representatives and mappers to cover the concentrated group of hospitals that we believe perform the majority of the cardiac ablation procedures in our direct markets. In order to efficiently address international markets and complement our direct presence in Western Europe, we have entered into bi-lateral distribution agreements with Biotronik that allow us to leverage their large and established sales force in international markets where they have significant infrastructure and presence. As we grow the size of our direct and indirect sales organizations, we will continue to take a proactive approach to training our sales force across the organization, allowing us to maximize cross-selling opportunities and drive adoption across our portfolio.

Driving Market Penetration and Portfolio Utilization. As we expand our presence with an increasing network of hospital customers, we aim to drive increasing utilization of our products. We plan to leverage the value proposition of our AcQMap System to drive its adoption across arrhythmia cases that are being treated with competitive systems as well as to enable more electrophysiologists to address more complex, unstable arrhythmias that may not have otherwise been treated with ablation therapy. We devote significant resources to training and educating physicians to increase awareness and utilization of our AcQMap System and broader portfolio. Additionally, we have developed an on-site curriculum at our Carlsbad, California facility where physicians receive in-depth presentations and hands-on training in our simulation lab. We also offer a variety of live and virtual opportunities for ongoing professional education, including for electrophysiologists to observe

cases with leading practitioners and frequent hands-on, preclinical training sessions in our AcQLab. In addition to professional education, we also plan to leverage our mappers, who are present in cases, to drive utilization of our full portfolio of devices for cardiac ablation procedures.

Continuing to Expand our Portfolio of Products and Broaden Indications for Existing Products. We have established a broad portfolio of products that complements our AcQMap System. We believe that our ability to offer a broad and differentiated portfolio will support the willingness of hospitals and physicians to champion the adoption of our AcQMap System in their institutions. A broad portfolio also drives an increasingly efficient revenue model with a growing component of recurring revenue per procedure. 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.

Leveraging our Strategic Partnerships to Efficiently Scale Globally and Broaden our Product Portfolio. We have entered into alliances with a number of strategic partners, including Biotronik, Stereotaxis, and Innovative Health. These partnerships have rapidly broadened our product portfolio, significantly expanded our geographic reach and provided co-marketing opportunities. With these partnerships in place, we expect to be able to rapidly develop high volume markets through broadening and deepening our relationships with electrophysiologists both in the United States and internationally. Further, by broadening our portfolio through partnerships, we have equipped our team with a full suite of products to offer to customer accounts which, we believe, will lead to greater utilization of our AcQMap System.

Continuing to Build our Clinical Evidence Base. The safety and effectiveness of our AcQMap System are supported by data from our three completed clinical trials that collectively evaluated 223 subjects across 16 centers in multiple countries. We are currently conducting two additional post-market trials that we expect will provide valuable evidence to support the clinical utility of our AcQMap System and will continue to drive its adoption and utilization. Our RECOVER AF trial is designed to demonstrate the value of our AcQMap System in patients being re-treated after one or two failed AF ablations. We are also sponsoring and enrolling patients in the DISCOVER patient registry and designing the PLASZMA trial to produce valuable data that we believe will further demonstrate how our AcQMap System can be used to standardize best practices, speed procedures and improve electrophysiology lab productivity. As part of our portfolio expansion strategy, we are also planning two IDE trials to support regulatory approval of our AcQBlate Force Sensing Ablation System, one of which began enrollment in the first quarter of 2021 and the other of which we expect to commence enrollment in the second half of 2021.

Our Market and Industry

Cardiac Arrhythmias

Cardiac arrhythmias, or heart rhythm disorders, are common and can occur when the heart beats too rapidly, too slowly or irregularly. Symptoms associated with arrhythmias include fatigue, reduced exercise tolerance, palpitations, lightheadedness, shortness of breath and significant quality of life impairment. If left untreated, arrhythmias can result in debilitating symptoms, heart failure, stroke and sudden cardiac death.

Arrhythmias can affect a broad range of patient populations across all ages and lifestyles. Multiple factors can impact the development of cardiac arrhythmias, including genetics, structural heart damage, heart dysfunction, obesity, high blood pressure, obstructive sleep apnea and aging, among other factors. We estimate that in 2020, there were over 50 million people worldwide who suffered from chronic or newly diagnosed arrhythmias. This population has steadily grown as a result of multiple demographic trends, including an aging population and the increasing proliferation of the "western lifestyle." The increasing utilization of wirelessly-connected implantable devices, as well as the accessibility of both medical-grade and consumer-oriented wearable cardiac monitoring devices, is also driving broader awareness and diagnosis of cardiac arrhythmias.

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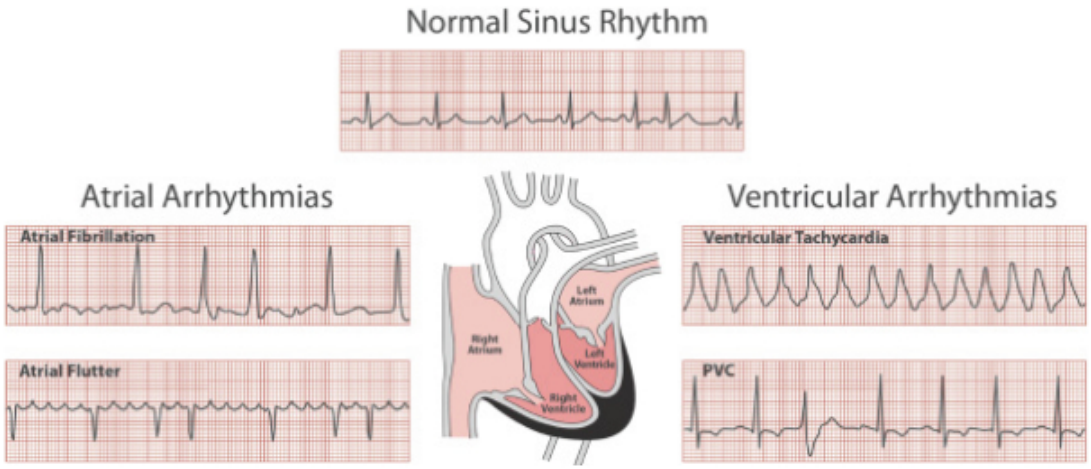
Between the costs associated with treatment and the downstream complications associated with arrhythmias, it is estimated that they cost global healthcare systems between $21 and $61 billion annually. These costs and the associated societal burden have led medical societies to recommend, and government and private payors to reimburse, treatment. While some types of arrhythmias can be effectively managed with medications and/or implantable devices, there is still a significant unmet need for effective diagnostic and treatment alternatives for three major categories of arrhythmias: atrial fibrillation; supraventricular tachycardias (other than atrial fibrillation); and ventricular arrhythmias.

Atrial fibrillation and other supraventricular tachycardias such as atrial flutter are arrhythmias that occur in the upper chambers of the heart, above the ventricles, and ventricular arrhythmias occur in the ventricles, or the lower chambers of the heart, as depicted in the graphic below.



Illustrative electrical activity of the major categories of arrhythmias traced on an electrocardiogram, as compared to normal sinus rhythm.

Atrial Fibrillation

Atrial fibrillation, or AF, is the most common arrhythmia with a global prevalence of over 30 million people in 2020. Atrial fibrillation is characterized by rapid and irregular activation of the heart. During atrial fibrillation, the heart's two upper chambers, or the atria, beat chaotically and irregularly, out of coordination with the two lower chambers, or the ventricles. 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. Individuals with atrial fibrillation are five times more likely to have an embolic stroke than those without atrial fibrillation, and strokes caused by atrial fibrillation are known to be more severe than those due to other causes. Atrial fibrillation is also a costly condition, leading to over 450,000 hospitalizations annually at a cost of approximately $16 to $26 billion to the U.S. healthcare system each year.

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Once diagnosed, atrial fibrillation is classified into three primary categories based on the duration of continuous arrhythmia. The table below summarizes the types of atrial fibrillation and our estimates of the relative prevalence of each within the affected and treated populations, respectively.

Type of Atrial Fibrillation	Description	Prevalence of Arrhythmia Type	AF Type Treated with Ablation in 2019
Paroxysmal AF	Atrial fibrillation that terminates spontaneously or with intervention within 7 days of onset	34%	53%
Persistent AF	Continuous atrial fibrillation that is sustained beyond 7 days but less than 12 months	33%	33%
Long-standing Persistent AF	A type of persistent AF defined as continuous atrial fibrillation for longer than 12 months	33%	14%

We estimate that there were approximately 470,000 cardiac ablation procedures globally for atrial fibrillation in 2020, representing a current market size of approximately $3.5 billion in disposable product revenue. We believe this market is significantly underpenetrated. For example, while 470,000 cardiac ablation procedures were performed globally in 2020, we estimate that there are 30 million individuals worldwide with atrial fibrillation. While a variety of factors contribute to this disparity, including a lack of ready access to healthcare, we believe a significant portion of this disparity is attributable to the limitations of the current standard of care. Because atrial fibrillation is difficult to map and treat using currently marketed contact-based mapping systems, we believe that a significant number of individuals with atrial fibrillation who may benefit from ablation therapy are not being referred for or treated with ablation therapy today. With faster and more detailed arrhythmia visualization tools that allow for an iterative mapping and adaptive ablation approach, we believe there is a significant opportunity to address a greater portion of the up to 30 million individuals worldwide with AF.

Supraventricular Tachycardias (Atrial Arrhythmias other than AF)

Supraventricular tachycardias (other than AF), or SVTs, which are characterized by a rapid heartbeat in the upper chambers of the heart, had an estimated global prevalence of 17.1 million people in 2020. SVTs include right and left-sided arrhythmias such as atrial flutter or atrial tachycardia, among others. These arrhythmias can arise organically or as a result of an incomplete ablation for atrial fibrillation.

We estimate that there were approximately 410,000 ablation procedures worldwide for SVTs in 2020, reflecting a market size of approximately $2.0 billion in disposable product revenue. We estimate, however, that there are 17.1 million individuals worldwide with SVTs. While a variety of other factors contribute to this disparity, including a lack of ready access to healthcare, we believe a significant portion of this disparity is attributable to the limitations of the current standard of care. Atrial flutters and tachycardias, which often result from incomplete ablations for atrial fibrillation, are often extremely complex, featuring varying cycle lengths and multiple morphologies that make them difficult and time-consuming to map using contact-based mapping systems. As a result, many electrophysiologists are reluctant to treat patients with these arrhythmias who may otherwise benefit from ablation therapy, and they can go undetected when they arise during or after an AF procedure. We believe that there is a significant opportunity to leverage advanced mapping and ablation tools to address a greater portion of the estimated 17.1 million individuals worldwide with SVTs.

Ventricular Arrhythmias

Ventricular arrhythmias affect the lower chambers of the heart and consist primarily of ventricular tachycardias, or VTs, and premature ventricular contractions, or PVCs. VTs are characterized by an abnormal, rapid ventricular heart rate that does not allow the heart to fill with blood before contracting, limiting the amount of oxygenated blood delivered to the body. PVCs are a condition in which the ventricles contract too soon, out of

sequence with the normal heartbeat. Frequent PVCs can lead to palpitations, shortness of breath, dizziness and cardiomyopathy. If left untreated, VTs and PVCs can lead to heart failure, ventricular fibrillation, and sudden cardiac death.

We estimate that in 2020 there were 5.5 million individuals worldwide with ventricular arrhythmias who may have benefitted from ablation therapy. However, we estimate that approximately 92,000 global ablation procedures for ventricular arrhythmias were performed in 2020, reflecting a market size of approximately $626 million in disposable product revenue. In order to map these arrhythmias with currently marketed contact-based mapping systems, the catheter must contact the tissue, which can itself cause these arrhythmias to occur during the procedure. When VTs and PVCs are induced during the procedure, patients can become hemodynamically unstable and rapidly deteriorate, presenting significant risks for the patient. Accordingly, with the right diagnostic and therapeutic tools, we believe there is significant opportunity to address a greater portion of the estimated 5.5 million individuals worldwide with ventricular arrhythmias who may benefit from ablation therapy.

The table below summarizes our estimates of the existing market for cardiac arrhythmias.

Type of Arrhythmia	2020 Global Prevalence	2020 Global Procedures	2020 Market Size (Disposables)
Atrial fibrillation (AF)	30.0 million	470,000	$ 3.5 billion
Supraventricular tachycardias (SVTs)	17.1 million	410,000	$ 2.0 billion
Ventricular arrhythmias (VTs and PVCs)	5.5 million	92,000	$ 0.6 billion
Total	52.6 million	972,000	$ 6.1 billion

Current Treatment Alternatives and Their Limitations

Arrhythmia treatments focus on relieving symptoms, improving quality of life and reducing the risk of stroke, heart failure or lethal arrhythmias. There are two primary treatment approaches for AF, SVTs, VTs and PVCs: medical management and catheter-based ablation of the tissue causing the heart's irregular rhythm. A minority of patients may also be treated with open heart surgery, minimally invasive epicardial ablation and/or implantable devices.

Medical Management

Medical management involves anticoagulation drugs to reduce stroke risk, anti-arrhythmic drugs, or AADs, to maintain the heart's regular rhythm, or rate controlling drugs to regulate the heart's rate. Medical management is often accompanied by cardioversion, which involves the application of an electric shock to the heart in order to restore the regular rhythm. Medical management has historically been considered first line therapy because of its noninvasive nature. However, current AADs have been associated with low success rates and an increased risk of adverse side effects that have been shown to result in a larger burden to the healthcare system than arrhythmias alone. Landmark trials comparing medical management to cardiac ablation, including the CABANA and CAPTAF trials, have shown medical management to be associated with poor quality of life outcomes, and the CASTLE-AF trial demonstrated that medical management is inferior to cardiac ablation in patients with heart failure with respect to reducing mortality, cardiovascular-related hospitalizations and the proportion of time that patients spend in atrial fibrillation.

While medical management is a common initial treatment modality for most patients, medical society guidelines have been changing to support cardiac ablation as a first line therapy. In addition, the Centers for Medicare & Medicaid Services, or CMS, reimbursement policies generally support treatment with cardiac ablation if a patient has failed or refuses medical management.

Cardiac Ablation

Cardiac ablation involves identifying and destroying tissue in the heart that is either determined or presumed to be responsible for initiating and/or maintaining an arrhythmia. Ablation therapy was pioneered based on the success of the Cox-Maze procedure, which utilized an open surgical approach to create incisional scars in the heart tissue to block abnormal electrical circuits. Catheter-based cardiac ablation was developed in 1994 as a less invasive alternative using catheters that enter the venous system through the groin and radiofrequency energy to emulate the lines created by the surgeons' scalpel. More recently, trials have demonstrated that electrical signals arising in the pulmonary veins are one source of arrhythmias and that electrically isolating the pulmonary veins from the left atrial body using ablation, referred to as pulmonary vein isolation, or PVI, can improve procedure success rates.

In order to perform a cardiac ablation procedure, an electrophysiologist gains access to the heart through an incision in the groin and then inserts one or more diagnostic mapping catheters. The mapping catheter is designed to recreate the chamber's anatomy and visualize the heart's electrical activation pathways on a console screen. Currently marketed mapping systems simultaneously collect data point-by-point through contact with the chamber wall to recreate the chamber anatomy and map the heart's electrical activation pathways. The contact-based electrical data points are sequenced to a stable timing reference in order to create a map of the electrical activation pathways. This combined anatomical and electrical map is used to determine the tissue area that is suspected of causing the arrhythmia. Once the area of interest is identified, an ablation catheter is inserted that then delivers the desired tissue-destructive therapy. 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 ablation therapy, including STOP Persistent AF and STAR AF II, have demonstrated that approximately 30 to 50% of ablations for atrial fibrillation result in recurrence within the first 12 months of the initial ablation procedure. We believe a primary reason for this is the inability of currently marketed mapping systems to quickly and reliably identify where to ablate and when ablation is complete.

Limitations of Current Mapping Systems

Because currently marketed mapping systems all rely on tissue contact and a fixed timing reference to collect and align data in the proper sequence, they are designed to map simple, stable and repetitive arrhythmias, including certain SVTs and certain VTs. Collecting a critical mass of data points to see even a stable rhythm is time consuming with contact mapping technologies, often taking 15 to 20 minutes per map. 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 and many types of SVTs.

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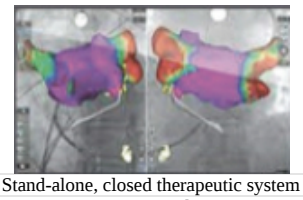
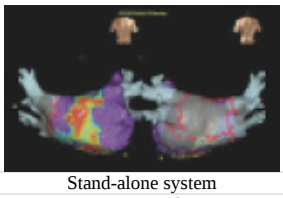
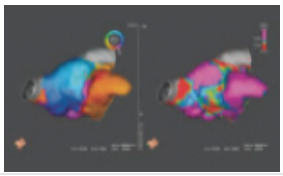
Below is a snapshot of the currently marketed mapping systems and their respective capabilities:

	Biosense Webster Inc. (a Johnson & Johnson Company)	Abbott Laboratories	Boston Scientific Corporation
Map image			
Platform type	Stand-alone, closed therapeutic system	Stand-alone system	Stand-alone system
Mapping capability	Contact only	Contact only	Contact only
Technology	Voltage only	Voltage only	Voltage only
Mappable rhythms	Stable rhythms (Atrial Tachycardia, Typical Atrial Flutter, Ventricular Tachycardia)	Stable rhythms (Atrial Tachycardia, Typical Atrial Flutter, Ventricular Tachycardia)	Stable rhythms (Atrial Tachycardia, Typical Atrial Flutter, Ventricular Tachycardia)
Time to map	15-20 mins / map	15-20 mins / map	15-20 mins / map

Limitations of Contact Mapping Systems for AF

PVI has become a first line ablation strategy for patients with AF. It has been shown to be an acceptable anatomic ablation strategy for most paroxysmal AF cases (which are typically less complex and easier to treat than persistent AF). Currently marketed mapping systems are well suited to reconstruct anatomical structures, such as the pulmonary veins, however, they are less suited to quickly and reliably map electrical activation in the atrial body. It is widely accepted that AF drivers and maintainers exist beyond the pulmonary veins in patients with more complex AF, such as persistent AF and long-standing persistent AF. These patients tend to have larger atriums and one or more areas of fibrosis that create electrical rhythm abnormalities that arise within the atrial body. Persistent and long-standing persistent AF patients have historically proven challenging to treat with cardiac ablation due to the inability of currently marketed mapping systems to quickly and reliably map unstable arrhythmias. This limitation makes it difficult to identify the AF drivers and maintainers of the arrhythmia and impractical from a time perspective for electrophysiologists to ablate tissue and then re-map to confirm treatment efficacy. The STAR AF II trial, which specifically evaluated three strategies for treating persistent and long-standing persistent AF patients, demonstrated that utilizing currently marketed mapping systems to identify additional areas for ablation was unable to improve outcomes relative to pulmonary vein isolation alone, and yielded 12-month freedom from AF below 60%. Arrhythmia recurrence following ablation often requires retreatment, which can be costly for the healthcare system and potentially harmful for the patient.

Despite incremental improvements in currently marketed mapping systems, patient outcomes remain unpredictable and procedures are still very lengthy and generally resource-intensive for the hospital. On average, procedures last approximately 2 hours and can take up to 6 hours in certain complex cases or in situations where the ablation procedure actually elicits additional arrhythmias, such as flutter and tachycardia. Given the time required to create a map with contact-based systems, it is often impractical for electrophysiologists to follow an iterative whole-chamber mapping and ablation approach to ensure they have addressed all arrhythmias. Iterative mapping (map-ablate-remap) allows for rapid decision-making through clinically actionable data. We believe that the inability to iteratively map throughout a procedure means patients undergoing therapy for AF are more likely to require a repeat procedure and experience increased incidence of other SVTs after a procedure.

We believe that with better tools to diagnose areas in the heart that require ablation and rapidly assess therapy effect in real-time, there is significant opportunity to improve cardiac ablation success, reduce procedure times and increase the adoption of ablation therapy.

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Limitations of Contact Mapping Systems for SVTs and Ventricular Arrhythmias

Currently marketed mapping technologies also face significant limitations in addressing SVTs and ventricular arrhythmias which, in turn, has limited the penetration of cardiac ablation therapy to a small portion of these affected populations.

While currently marketed mapping systems are effective at treating SVTs, approximately 40% to 60% of patients with SVTs also have atrial fibrillation. Current systems, which can only map one rhythm at a time, require a new map to diagnose each arrhythmia. Similarly, for atypical atrial flutter and atrial tachycardia, which comprise the majority of patients in this market segment, current technologies lack the ability to quickly and reliably locate the source of the arrhythmia, as these arrhythmias are generally transient in nature and have varying cycle lengths. As a result, physicians often default to medical management for treatment of these SVTs.

Ventricular arrhythmias are often hemodynamically unstable arrhythmias and are aggravated by contact with the ventricular wall. Similarly, PVCs can be difficult to map due to their lack of stability and repetitiveness, as they often occur as a single beat. These factors make current contact-based, point-by-point mapping systems impractical and in many cases unable to address them. As a result, we believe that physicians often prefer to rely on medical management or device therapy for treatment of these ventricular arrhythmias.

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 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 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 with a growing component of recurring revenue.

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 is designed to help electrophysiologists map stable and unstable arrhythmias, as well as to efficiently assess and adapt therapy during the procedure. The AcQMap System is the only commercially available non-contact mapping system that introduces two novel concepts to 3D-mapping: ultrasound to reconstruct the endocardial surface anatomy and charge density for mapping arrhythmias. Our mapping catheter can collect the data required to create a comprehensive map of the cardiac anatomy and electrical propagation patterns and pathways in under three minutes. In comparison to contact mapping, which is the current standard of care, non-contact mapping reduces signal artifact and distortion that can affect the quality, accuracy and reproducibility of the map. Additionally, our AcQMap System can accurately map all arrhythmias, whereas contact mapping systems are not able to reliably map unstable arrhythmias such as AF, PVCs and many types of SVTs.

Our AcQMap System consists of our AcQMap catheter, console and workstation. The AcQMap catheter is a single-use, 10F catheter that is introduced into the chamber of interest over a guidewire. The distal end of the catheter is deployed into a 25 millimeter diameter spheroid, formed by six splines. Each spline has eight ultrasound transducers interspersed between eight biopotential electrodes, resulting in a total of 48 sensors of each type. The ultrasound transducers reconstruct the cardiac anatomy while the high fidelity, low impedance electrodes sample the voltage potential field to create maps of cardiac activation using charge density.

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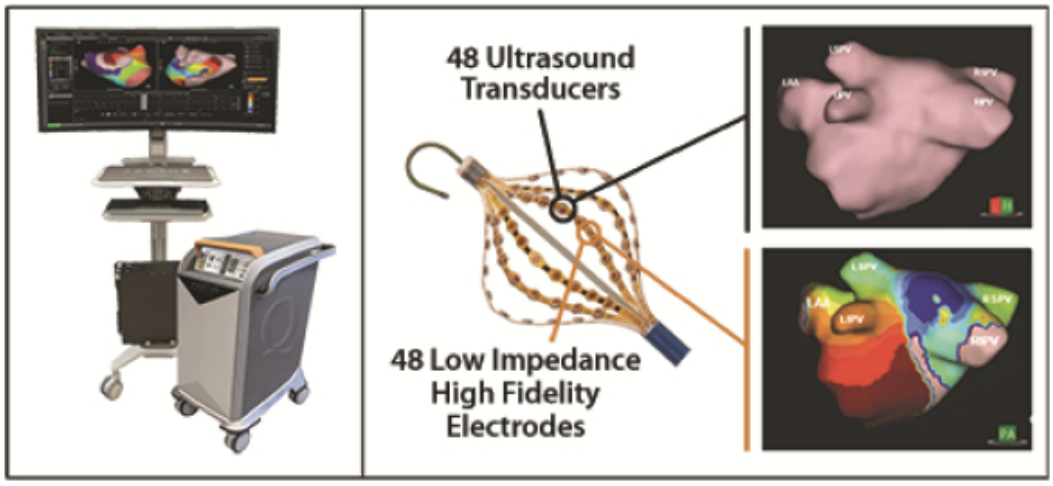
Our AcQMap catheter maps the full heart chamber and is able to capture both stable and unstable rhythms in a single data acquisition. Our AcQMap System acquires up to 115,000 ultrasound data points per minute to accurately reconstruct the cardiac anatomy and simultaneously collects 9 million biopotential samples per minute to visualize cardiac activation. This allows us to create comprehensive diagnostic maps of the chamber anatomy and electrical propagation patterns and pathways 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, as depicted in the graphic below.



(Left): Our AcQMap console and workstation. (Middle): Our AcQMap 2.0 mapping catheter. (Upper Right): Ultrasound reconstruction of the heart chamber anatomy using our AcQMap System. (Lower Right): Display of the electrical propagation patterns of the heart chamber using our AcQMap System. In the map, dark red is the front edge of the rhythm wavefront, with the trailing colors showing where the wavefront has been within the heart chamber. (Anatomy Terms): LSPV—Left superior pulmonary vein, LAA—Left atrial appendage, LIPV—Left inferior pulmonary vein, RSPV—Right superior pulmonary vein, RIPV—Right inferior pulmonary vein. PA— Posteroanterior.

Our AcQMap catheter is attached to the AcQMap console, which contains electronic instrumentation that drives transmission and acquisition of the ultrasound, localization, and cardiac electrical data. The data is passed from the AcQMap console to the AcQMap workstation on which the AcQMap software analyzes and maps the arrhythmia using one of our three mapping algorithms, depending on the type of arrhythmia. Our current suite of mapping algorithms includes our proprietary Single Position and SuperMap modes, along with a basic contact mode. Electrophysiologists can seamlessly toggle between these modes during procedures.

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Our flagship Single Position algorithm was developed to map unstable, complex tachyarrhythmias, which are known to include AF, as well as simple and complex stable tachycardias. Based on learnings from our UNCOVER AF trial, we developed the SuperMap algorithm to allow electrophysiologists to identify and address atrial flutters and other tachycardias that commonly arise during cardiac ablation procedures targeting AF. SuperMap allows us to collect data from multiple positions (also non-contact) within the chamber of interest and map multiple simple and complex, stable tachycardias within the same data acquisition. Lastly, our contact mode allows electrophysiologists to use traditional point-by-point or multi-point data collection to map simple, stable tachycardias in less complex cases. The table below lays out the key features of our proprietary Single Position and SuperMap algorithms.

Mapping Algorithm	Single Position	SuperMap
Algorithm description	• Ultrasound is used to create the anatomy • Non-contact data is collected from a single, central position within the chamber of interest • Selected segments of the data are processed through the charge density algorithm • Charge density maps display activation patterns and pathways	• Ultrasound is used to create the anatomy • Non-contact data is collected from multiple positions throughout the chamber of interest • Data is automatically binned based on signal morphology • The data in each unique bin is sequenced to a stable, timing reference • Charge density maps display the activation pathway
Mappable rhythms	• Simple, stable tachycardias (Atrial Tachycardia, Typical Atrial Flutter, Ventricular Tachycardia) • Complex, stable tachycardias (Atypical Atrial Flutter, Atrial and ventricular tachycardias with small cycle length variations) • Complex, unstable tachyarrhythmias (Atrial fibrillation)	• Simple, stable tachycardias (Atrial Tachycardia, Typical Atrial Flutter, Ventricular Tachycardia) • Complex, stable tachycardias (Atypical Atrial Flutter, Atrial and ventricular tachycardias with small cycle length variations)
Number of rhythms that can be mapped from a single data collection	Multiple	Multiple
Time to create map	<3 minutes	<3 minutes

Key Benefits of AcQMap System

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. The design of our non-contact AcQMap catheter allows it to map both the anatomy and the electrical propagation patterns and pathways of an entire heart chamber in less than three minutes. 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. We believe our technology creates the most accurate and robust map available to electrophysiologists. Ultrasound technology allows us to create an anatomically accurate image of the heart chamber, which is critical for properly defining the locations of charge sources, and non-contact charge

density mapping is our novel approach that allows the AcQMap System to display the heart's true activation patterns and pathways. In contrast to the broad and smooth view contact-based voltage mapping offers, charge density 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 in our proprietary AcQMap System 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. With our AcQMap System, electrophysiologists can map both stable and unstable rhythms that incumbent 3D mapping systems are not capable of mapping. In addition, electrophysiologists can toggle between our sophisticated SuperMap and Single Position modalities to capture any occurring arrhythmia, or multiple concurrent arrhythmias, without interrupting case flow or extending procedure times. These features allow electrophysiologists to see changes in conduction during the procedure and arm them with an optimal solution to better customize therapy.

Excellent Clinical Outcomes

Our AcQMap System has been clinically demonstrated to drive excellent outcomes across a broad range of the most common simple and complex arrhythmias, including atrial fibrillation. Our UNCOVER AF post-market approval trial, which assessed the effectiveness of the AcQMap System in identifying and ablating patient-specific targets outside of the pulmonary veins in addition to PVI, demonstrated favorable freedom from AF outcomes. In the UNCOVER AF trial, utilization of our AcQMap System in persistent AF patients demonstrated 73% and 93% freedom from AF at 12 months following their initial procedure after one or two procedures, respectively. Even for patients that did not achieve freedom from AF at 12 months, the UNCOVER AF data demonstrated reduced AF burden and a significant quality of life improvement. Additionally, the UNCOVER AF data demonstrated that patients were 9.4 times more likely to maintain normal sinus rhythm when three or more arrhythmia targets were ablated in addition to PVI, as guided by the AcQMap System.

In comparison, in the landmark STAR AF II trial, Abbott Laboratories evaluated cardiac ablation methodologies in a similar set of persistent AF patients and demonstrated only 61% freedom from AF at 12 months after one procedure and 79% freedom from AF after multiple procedures with PVI. The STAR AF II trial demonstrated lower effectiveness outcomes when electrophysiologists used competitive 3D mapping tools to identify and ablate other targets outside the pulmonary veins. There were two meaningful differences in the subject inclusion/exclusion criteria between the STAR AF II and UNCOVER AF studies. In the STAR AF II study, subjects were included if they had Persistent AF with sustained episodes lasting more than seven days and less than three years, UNCOVER AF included patients with sustained episodes lasting more than seven days and less than one year. In addition, STAR AF II excluded subjects with left atrial size ³ 60 mm and UNCOVER AF excluded subjects with left atrial size ³ 50mm. A comparison of demographics between the two studies indicated that enrolled subjects were similar across several key demographic characteristics including left atrial size. In addition, in STAR AF II, multivariate analysis did not indicate that the duration of persistent AF episodes was a predictor of the study outcome between persistent and longstanding persistent AF subjects.

We believe the key differentiator in outcomes was the use of our AcQMap System to map and identify these key ablation patterns and targets and map and treat them in an iterative (map-ablate-remap) fashion. The table below shows the effectiveness endpoints of our UNCOVER AF trial as well as the same endpoints from the STAR AF II trial for each of the three treatment arms in that trial.

Variable	UNCOVER AF PVI + Targets 12M (%)	STAR AF II PVI 12M (%)	STAR AF II PVI + CFAE 12M (%)	STAR AF II PVI + Lines 12M (%)
Freedom from AF > 30 seconds after one procedure, with or without AAD	73	61	54	50
Freedom from AF > 30 seconds after multiple procedures, with or without AAD	93	79	70	70

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CFAE and Lines are ablation strategies targeting potential sources of arrhythmia outside of the pulmonary veins. Complex Fractionated Atrial Electrograms, or CFAE, are electrograms that show either rapid or continuous electrical activity during atrial fibrillation identified by validated, automated software in the mapping system (EnSite). Lines were ablated along the atrial roof and mitral valve isthmus.

Three additional clinical trials recently reported results in similar patient populations:

- The CONVERGE trial, sponsored by AtriCure Inc., was a 2:1 randomized study with Hybrid- Epicardial (on the surface of the outside of the heart) and Endocardial (on the surface of the inside of the heart) ablation (each procedure separated by 30 days) compared to Endocardial ablation only which enrolled 203 subjects. The CONVERGE Hybrid therapy group demonstrated 71% freedom from AF and a 65.7% freedom from AF/Atrial Flutter/Atrial Tachycardia, or AF/AFL/AT, at 12 months. Although the CONVERGE Hybrid outcomes were similar, albeit slightly lower, than UNCOVER AF, they required a more clinically invasive two-part procedure. The CONVERGE Endocardial ablation only group reported 51% freedom from AF and 49% freedom from AF/AFL/AT at 12 months. The effectiveness outcomes were comparable to STAR AF II as similar versions of competitive 3D mapping tools and strategies were used during ablation. Like STAR AF II, the CONVERGE study included both persistent and long-standing persistent AF; UNCOVER AF only included persistent AF subjects.
- The PRECEPT IDE Study sponsored by Biosense Webster Inc. (a Johnson & Johnson Company) was a non-randomized study of persistent AF subjects that enrolled 381 subjects. Inclusion/exclusion criteria for PRECEPT and UNCOVER AF were very similar, however there were two key differences in the study designs; the length of the blanking period and allowance of ablation therapy during the blanking period. The PRECEPT study utilized a six-month blanking period during which subjects who had an AF recurrence could receive up to two additional ablation treatments and would not be considered a failure of the primary endpoint. In contrast, the UNCOVER AF study utilized a three-month blanking period and considered any ablation retreatment a failure of the primary endpoint. The PRECEPT study demonstrated 61.7% freedom from AF/AFL/AT at 15 months (including patients that were ablated during the blanking period) compared to UNCOVER AF which demonstrated a true single procedure freedom from AF/AFL/AT of 69.2%.
- The STOP Persistent AF Study sponsored by Medtronic, Inc. was a non-randomized study of persistent AF subjects that enrolled 186 subjects. There were two meaningful differences in the study designs between the STOP Persistent AF and UNCOVER AF studies; (1) inclusion/exclusion criteria and (2) allowance of ablation during the blanking period. In the STOP Persistent AF study, subjects were included if they had Persistent AF with sustained episodes lasting more than seven days and less than six months, UNCOVER AF included patients with sustained episodes lasting more than seven days and less than one year. While both studies utilized a 30-day blanking period, the STOP Persistent AF study allowed for one repeat PVI-only or CTI ablation during the blanking period, whereas the UNCOVER AF study considered any ablation retreatment a failure of the primary endpoint. The STOP Persistent AF study demonstrated 54.8% freedom from AF/AFL/AT at 12 months (including patients that were ablated during the blanking period) compared to UNCOVER AF which demonstrated a true single procedure freedom from AF/AFL/AT of 69.2%.

New peer reviewed clinical evidence supporting the use of the AcQMap System has been recently published.

- A single center in Brussels, Belgium recently published results of their study to evaluate the safety and feasibility of our SuperMap algorithm in identifying and guiding ablation in the setting of atrial tachycardia following index atrial fibrillation ablation procedures. The study noted that atrial tachycardias can be observed following ablation of atrial fibrillation in 5 to 25% of cases. Seven consecutive patients underwent ablation for atrial tachycardia utilizing the SuperMap algorithm. The study noted that all areas of clinical significance were appropriately identified and successfully treated, and that no major or minor complications occurred. In addition, the study noted that the mean

procedure time was 56 minutes, which is short by current standards. This study highlighted that mapping with the AcQMap System greatly contributed to short procedure times.

- A single center in the United Kingdom published their results characterizing activation patterns visualized with the AcQMap System during AF. Twenty-five patients with persistent AF were mapped using the AcQMap System. A total of 144 AF segments were mapped and identified activation patterns were analyzed and plotted across the left atrial chamber. Patterns were classified as focal, rotational, and irregular activations. Consistent with the UNCOVER AF study, irregular activation was the most frequent pattern comprising 63% of all patterns, followed by rotational activations at 20% and focal activations at 17%. Almost all patients demonstrated changing activation patterns arising from the same location. Conduction patterns were preferentially located in the mid-anterior and low-posterior wall locations. The study concluded that more data is needed to determine the clinical importance of these activation patterns in initiating and maintaining AF.
- A multi-center study in the United Kingdom published their results using an AcQMap guided core-to-boundary ablation strategy. The study enrolled 40 *de novo* persistent AF patients who were treated with the AcQMap guided core-to-boundary ablation strategy and then compared to a propensity matched cohort of 80 patients treated with an empiric PVI + posterior wall isolation lesion set guided by conventional contact mapping. Patients were mapped with the AcQMap System before and after pulmonary vein isolation. Non-pulmonary vein targets (focal, LRA and LIA targets) that were within 1 cm of the pulmonary veins were incorporated as part of the PVI. Following isolation of the veins, the article noted that 77% of the pre-PVI targets were still present. The remaining targets were predominantly located on the anterior wall, the posterior wall and the septum. Using a core-to-boundary ablation strategy, the physician would ablate the central location of the ablation target and then create an anchor line to the nearest anatomic or non-conducting boundary. Targets were ablated until termination occurred or remapping demonstrated no further targets remained. If termination did not occur on the left side, the right atrium was mapped and identified targets ablated. In the study, 20% of patients terminated following PVI, another 53% terminated after ablation of left and right sided targets. The remaining patients were cardioverted to sinus rhythm. At 24-months after a single procedure, 68% of the AcQMap Guided core-to-boundary patients were arrhythmia free compared to 46% of the patients that received an empiric PVI + posterior wall isolation (p=.043). The authors noted that given the frequency of targets on the anterior wall and septum, the empiric strategy of isolating the veins and the posterior wall would have missed these sites likely contributing to the lower success rate seen in the comparison group.

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 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 Sensing Ablation System, which we commercialized following the December 2020 receipt of the CE Mark in Europe. We are also planning two IDE trials for FDA PMA in the United States. In the first half of 2021, the first IDE trial seeking right atrial typical flutter indication received IDE from the FDA and commenced enrollment. The second IDE trial seeking a paroxysmal and persistent atrial fibrillation indication received IDE approval in May 2021 and we expect to commence enrollment in the second half of 2021. We currently anticipate FDA PMA, and the U.S. commercial launch, of our AcQBlate Force Sensing Ablation System in the second half 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

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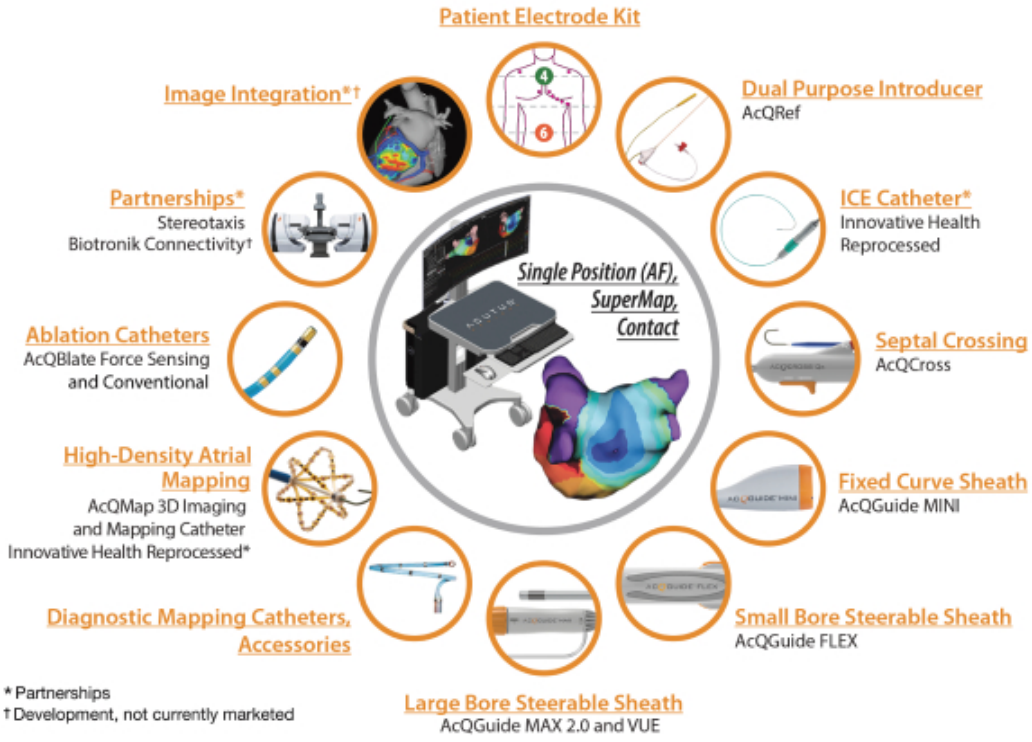
workstation is established in a customer account, our revenue from that account becomes predominantly recurring in nature and derived from the sale of our portfolio of disposable products used with our system. In addition, our AcQMap System is an open platform, allowing physicians to use third-party access, diagnostic and therapeutic disposable products, which we believe further encourages adoption. Our suite of products either currently marketed or in late stages of development are depicted in the graphic below:



Benefits for Key Stakeholders

We believe the key clinical benefits of our portfolio offer an attractive value proposition for all stakeholders that will drive its continued adoption by hospitals and physicians.

Patients. Our AcQMap System demonstrated excellent clinical outcomes in treating AF and other atrial arrhythmias in the UNCOVER AF trial and in ongoing real-world experience. We believe our ability to improve ablation effectiveness will improve patients' quality of life by reducing symptoms, hospitalizations for repeat procedures and the need for medical management.

Physicians. We believe the ability to accurately and iteratively map during the procedure improves the effectiveness of procedures and allows electrophysiologists to treat difficult cases that may have otherwise been referred for medical management or sent to an academic center of excellence. As such, physicians benefit from the ability to grow their practices by increasing the volume and types of procedures they can perform. Similarly, we believe that the speed of our iterative mapping approach will ultimately result in shorter and more predictable procedure duration. In addition, our mapping system is open in architecture, allowing optimal flexibility in the tools physicians use for diagnosing and treating arrhythmias.

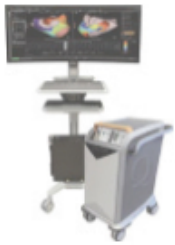
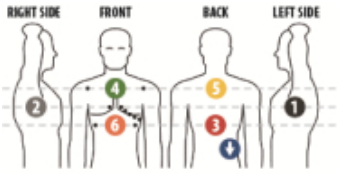
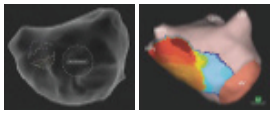
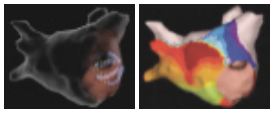
Hospitals. By increasing patient throughput, reducing procedure times and improving the predictability of procedure duration, we believe our products will improve hospital workflow efficiency. This will allow hospitals to better utilize their operating room capacity and fixed overhead as well as increase their return on capital. Our

portfolio of products also increases the opportunity set of addressable procedures, allowing hospitals to treat patients that would otherwise have relied on medical management or have been referred to other academic centers for treatment.

Payors. We believe increased adoption of our products will reduce the financial burden of cardiac arrhythmias for payors by reducing repeat procedures for arrhythmia recurrence and extensive hospitalizations arising from complications of arrhythmias.

Our Product Portfolio

Through internal product development, acquisitions and global partnerships, we have established a broad portfolio of electrophysiology products. Our 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. An overview of our key products is presented in the table below.

Product Portfolio	
Diagnostic System & Accessories	
AcQMap Console and Workstation 	An advanced imaging, navigation and mapping system that offers physicians better decision-making tools for determining where to ablate and makes it practical for physicians to iteratively map, treat, re-map and adjust additional therapy as needed.
Patient Electrode Kit 	Single-use AcQMap patient electrode kit, consisting of localization patches, an analog ground patch and ECG electrodes, which is required in every procedure to provide cardiac signals, catheter localization and AcQMap System grounding.
Software Mapping Modes	
Single Position 	State-of-the-art, non-contact mapping solution that enables the AcQMap System to map unstable, complex arrhythmias, which are known to include AF, as well as simple and complex stable tachycardias.
SuperMap 	Revolutionary non-contact mapping solution allows the AcQMap System to collect data from numerous locations within the chamber of interest and map multiple simple and complex, stable tachycardias within the same data acquisition. Developed to allow electrophysiologists to identify and address atrial flutters and other tachycardias that occur organically or commonly arise during and after AF ablations.

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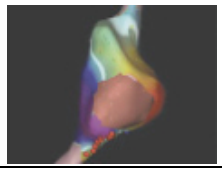
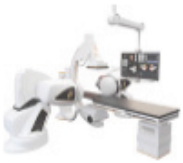
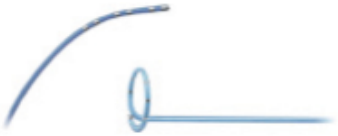
Product Portfolio	
Contact Mapping 	Conventional contact mapping solution that uses traditional point-by-point or multi-point data collection to map simple, stable tachycardias in less complex, routine cases.
Stereotaxis Integration 	Through our partnership with Stereotaxis, we offer a version of our Single Position and SuperMap software mapping modes that allows our AcQMap System to be used with Stereotaxis' unique-in-the-industry robotic platform for cardiac ablation.
Diagnostic & Monitoring Devices	
AcQMap 3D Imaging and Mapping Catheter 	An advanced, non-contact, over-the-wire, intracardiac device used for mapping during standard and complex electrophysiology procedures. The single-use catheter enables acquisition of ultrasound and biopotential data to reconstruct the cardiac anatomy and map electrical propagation patterns and pathways, resulting in images with a four times higher resolution than voltage-based maps. Our AcQMap catheter is currently indicated for use in the atria. Our research and development initiatives include expanding the indication for use to the ventricles.
Conventional Diagnostic Catheters* 	Through our partnership with Biotronik, we offer a family of conventional diagnostic catheters including multi-polar, steerable and loop catheters which are commonly used during mapping and ablation procedures. CE Mark is currently in place for these catheters in Europe and we currently anticipate receiving FDA clearance in the first half of 2021. These catheters can be used for contact mapping or in conjunction with our AcQMap catheter. These catheters will be sold under the Acutus brand.
Reprocessed Diagnostic Catheters 	Through our partnership with Innovative Health, we offer reprocessed versions of a wide variety of commercial catheters, including diagnostic, multipole, fixed, steerable and advanced mapping and imaging (e.g., intracardiac echocardiography) catheters. These reprocessed catheters allow us to provide customers with a full suite of physician preferred devices and confer cost savings to providers.

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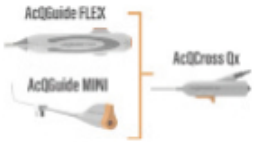
Product Portfolio	
Access Devices	
AcQRef Introducer 	Dual-purpose introducer sheath with integrated electrode that provides stable electrical reference and vascular access, eliminating the need for an additional introducer and quadripolar reference catheter.
AcQGuide MAX Steerable Introducer 	Large diameter specialty sheath to facilitate the intracardiac placement and maneuverability of diagnostic and ablation catheters, including our AcQMap catheter. Enables optimal maneuverability and increased control, providing a stable platform to ensure smooth catheter passage and precision placement.
Transseptal Access Product Family 	Our integrated transseptal and sheath line of products is fast, safe and easy to use in any septal anatomy. The AcQCross Qx transseptal needle facilitates either a mechanical or RF-facilitated septal puncture. The fixed curve AcQGuide MINI and steerable AcQGuide FLEX introducers interlock with the AcQCross Qx transseptal needle for smooth delivery across the septum without the need for a guidewire exchange.
Therapeutic Devices	
AcQBlate FORCE Ablation Catheters 	Innovative catheter platform that combines optical fiber technology for contact force sensing and a unique-in-the-industry irrigated gold ablation tip that offers excellent electrical and thermal properties compared to the platinum-iridium tip commonly used in marketed devices. The force sensor information can be visualized on both the AcQMap System and/or an external monitor integrated with our Qubic Force control unit. We received the CE Mark of our AcQBlate Force Sensing Ablation System in Europe in December 2020 and we commenced an IDE trial for FDA PMA in the first quarter of 2021 and plan on commencing a second IDE trial during the second half of 2021.
AlCath Ablation Catheters* 	Through our partnership with Biotronik, we will offer an Acutus private-labeled version of the AlCath ablation catheter platform that utilizes a gold ablation tip. The AlCath ablation catheter family encompasses a range of irrigated and non-irrigated catheters. We will sell this line of catheters under the Acutus brand in the United States subject to regulatory approval, which we anticipate receiving by the first half of 2023 and in certain markets in Western Europe and the United Kingdom (where CE Mark is currently in place).

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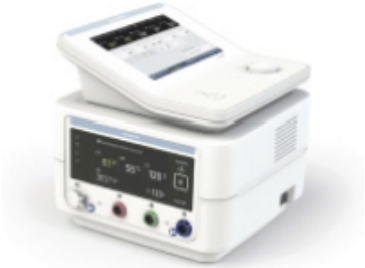
Product Portfolio	
MedFact Robotic Navigation Enabled Ablation Catheters* 	Through our supply agreement with MedFact, we distribute specialty magnetic catheters in CE Mark countries for use with Stereotaxis' robotic platform for cardiac ablation.
Qubic Force 	Our Qubic Force control unit is used in conjunction with our AcQBlate Force sensing ablation catheters to allow the electrophysiologist to monitor and adjust the contact force of the ablation catheter tip on the cardiac wall during ablation. We received CE Mark in December 2020 for the Qubic Force control unit and anticipate FDA PMA in the second half of 2022 or early 2023.
Qubic RF Generator and Pulse Stimulator* 	Through our partnership with Biotronik, we will distribute the Qubic RF Generator and Pulse Stimulator in the United States and certain countries in Asia and Western Europe. Both devices are currently CE Marked. Regulatory approval for these devices in the United States is expected by the second half of 2022. The Qubic RF generator has the smallest footprint of any RF ablation generator in the electrophysiology industry and allows an easy integration into virtually any electrophysiology lab. The Qubic RF generator operates seamlessly with the Qiona pump and Qubic Force control units.
Qiona Pump* 	Through our partnership with Biotronik, we will distribute the Qiona Pump in the United States and certain countries in Asia and Western Europe. The Qiona Pump is currently CE Marked. Regulatory approval for this device in the United States is expected by the second half of 2022. The Qiona Pump is a peristaltic irrigation pump that delivers cooling fluid to reduce the risk of thrombus forming on the ablation tip and to maintain the correct temperature at the ablation catheter tip and the treatment site and helps to protect the surrounding healthy tissues. The Qiona Pump operates seamlessly with the Qubic RF and Qubic Force control units.

* *Strategic partnership—private label and/or distribution rights*

Our Commercial Strategy

We market our portfolio of 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, including products licensed through various partnerships, to those accounts for

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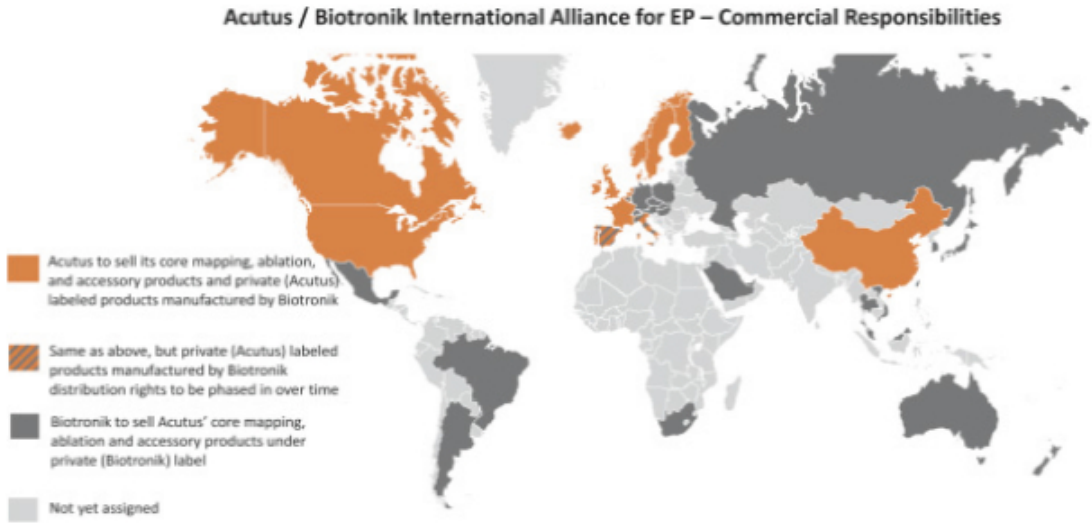
use with our system. In other international markets, we leverage our partnership with Biotronik to install our AcQMap console and workstation with customer accounts and then to sell our disposable products to those accounts.

Through our bi-lateral distribution agreements with Biotronik, we will leverage Biotronik's highly tenured sales force to distribute our AcQMap System and associated products in certain markets in Germany, Japan, Mexico, Switzerland and multiple countries in Asia-Pacific, Eastern Europe, the Middle East and South America where they have an established, long-standing presence and existing infrastructure. Additionally, the bi-lateral distribution agreements allow us to sell a range of Biotronik's electrophysiology products under our private label (Acutus branded) in our direct markets. These products complement our AcQMap System and provide us with a broad electrophysiology portfolio. The bi-lateral distribution agreements are also expected to enable us to cooperatively bundle electrophysiology and cardiac rhythm management product lines across the Acutus and Biotronik portfolios in certain markets. Further, through our bi-lateral distribution agreements with Biotronik, we also expect to be able to utilize Biotronik's proprietary digital infrastructure. This should eventually allow our commercial team to monitor and support cases remotely and should enable us to build a collaborative library of cases in order to develop workflow strategies, establish best practices and deliver training programs. See the section titled "—Biotronik Agreements—Bi-Lateral Distribution Agreements" for a further description of the bi-lateral distribution agreements. The territories in which we and Biotronik, respectively, have responsibility for commercializing and selling our products under the bi-lateral distribution agreements are depicted in the graphic below:



Acutus currently has direct sales operations in the United States, the United Kingdom, Germany, France, Belgium, the Netherlands, Italy and the Czech Republic.

In the United States and Western Europe, our target market is highly concentrated. In the United States, we believe there are approximately 1,000 physicians and 750 electrophysiology programs that perform cardiac ablation procedures and that over 60% of the procedures in the United States take place in approximately 200 high volume electrophysiology centers. In our direct markets in Western Europe, we believe there is similar concentration across electrophysiology centers and procedures. For example, in France, Italy, Germany, Spain and the United Kingdom, we believe there are approximately 750 electrophysiology programs and approximately 200 high volume centers that perform more than 150 ablation procedures per year. We plan to leverage the concentrated nature of procedure volumes to focus our direct commercial efforts on the high and medium volume centers in our markets in the United States and Western Europe.

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Our sales force consists of sales representatives and mappers that have substantial applicable medical device sales and clinical experience, specifically in the electrophysiology, interventional cardiology and cardiac rhythm spaces. Our sales representatives are responsible for developing territory business plans, targeting and opening new customer accounts, promoting the benefits of our product portfolio and driving adoption and utilization of the AcQMap System. Our mappers, who provide clinical procedure support, are also focused on driving penetration and utilization across our portfolio. We also support our sales organization with strategic marketing and practice development initiatives.

As of March 31, 2021, our commercial organization consisted of 75 individuals with substantial applicable medical device, sales and clinical experience, including sales managers, sales representatives and mappers. As we continue to grow the size of our sales organization, with an emphasis on increasing adoption by existing customers and expanding our current customer base, we expect to focus on adding a strategic mix of sales representatives and mappers.

Professional Education and Sales Training

We are focused on developing strong relationships with our customers and supporting the value proposition that our products deliver. We devote significant resources to training and educating physicians in the use of our AcQMap System and our associated products. We have developed a robust training course, which we host at our facility in Carlsbad, California. During our training courses, physicians receive in-depth presentations on our product portfolio and can experience hands-on training in our simulation lab. We also offer a variety of live and virtual opportunities for ongoing professional education, including for electrophysiologists to observe cases with leading practitioners and frequent hands-on preclinical training sessions in our AcQLab.

In order to provide support to our physician customers in the field, our highly specialized sales representatives and mappers receive in-depth training and develop a thorough understanding of complex cardiac arrhythmias, key aspects of our technology and procedure planning. Our extensive training and continuous education programs consist of both virtual and in-person foundational training, procedure observation, and sales skills development. Furthermore, as part of our partnership with Biotronik, we have developed a closely coordinated ongoing training program where we cross-train our respective sales forces and mappers on the key technical benefits and value drivers across both portfolios.

Clinical Data

The safety and effectiveness of our AcQMap System are supported by data from three clinical trials that collectively evaluated 223 subjects across 16 centers in multiple countries. The data from our First-in-Man trial established the safety and functionality of our AcQMap System, and our subsequent DDRAMATIC-SVT trial supported its FDA clearance and CE Mark approval. Our UNCOVER AF trial, which evaluated the effectiveness of our AcQMap System in the persistent AF population, provides additional high-quality evidence supporting its adoption in the field.

We are currently conducting two post-market trials to provide physicians with additional safety and effectiveness data on the use of our AcQMap System, and we are planning two IDE trials to support regulatory approval of our AcQBlate Force Sensing Ablation System. Our ongoing and planned trials are anticipated to involve in aggregate of over 700 subjects in at least 35 centers in the United States and internationally. We expect to provide data readouts from these trials at various points in time through 2023.

Investment in clinical evidence is a core strategy of our company. We involve physician advisors who are recognized for excellence in electrophysiology to assist us with clinical trial designs. We also seek to ensure rigorous, high-quality data collection and reporting by using an independent assessment of safety and therapy effectiveness endpoints. Our clinical and regulatory organization, which manages trial design and execution, has

specialized expertise in trial management, data collection and biostatistics, in addition to U.S. and international medical device regulatory expertise.

First-in-Man Clinical Trial

Our First-in-Man trial was a single-arm trial conducted at two sites in Europe from March 2013 to October 2014. The First-in-Man trial was initiated as a feasibility trial to assess the safety and performance of the AcQMap System in subjects already scheduled for atrial ablation. The trial enrolled a total of 12 subjects and successfully demonstrated the ability of the AcQMap System to safely reconstruct an atrial anatomic chamber and create charge density maps in subjects with atrial arrhythmias.

DDRAMATIC-SVT (Dipole Density Right (and left) Atrial Mapping and Assessment of Therapy In Complex Supraventricular Tachycardia) Clinical Trial

Following completion of the First-in-Man trial, we conducted the DDRAMATIC-SVT trial, a multi-center, multi-national, single-arm, prospective trial, at eight sites in Europe and Canada. The DDRAMATIC-SVT trial was designed to demonstrate safety and effectiveness of the AcQMap System for creating charge density maps in subjects with SVTs and AF. The trial enrolled 85 subjects between March 2015 and June 2017. Data from the DDRAMATIC-SVT trial were used to support CE Mark approval of the AcQMap System in May 2016 and FDA 510(k) clearance in October 2017.

The DDRAMATIC-SVT trial enrolled subjects already scheduled for a cardiac ablation procedure, including *de novo* and retreatment subjects. The DDRAMATIC-SVT trial demonstrated that the AcQMap System was safe and could effectively collect data to construct pre- and post-ablation charge density activation maps of stable and unstable complex atrial arrhythmias.

The DDRAMATIC-SVT trial also assessed patients at 12-months follow-up for freedom from atrial arrhythmias and AF on or off antiarrhythmic drugs. Use of the AcQMap System in persistent AF patients resulted in 75.8% and 81.9% of patients becoming arrhythmia free and AF free, respectively, at 12-months on or off antiarrhythmic drugs. The excellent effectiveness outcomes in persistent AF patients supported our investment in the UNCOVER AF trial, which was designed to further establish the effectiveness of our AcQMap System in addressing complex, undertreated arrhythmias such as persistent AF.

UNCOVER AF (Utilizing Novel dipole density Capabilities to Objectively Visualize the Etiology of Rhythms in Atrial Fibrillation) Post-Market Approval Trial

We designed the UNCOVER AF trial based on learnings from DDRAMATIC-SVT and modeled it after the STAR AF II trial, a landmark trial sponsored by Abbott Laboratories and published in 2015. STAR AF II evaluated the effectiveness of ablation strategies in a similar persistent AF patient population.

The UNCOVER AF trial was a prospective, nonrandomized trial conducted in 13 centers across Europe and Canada between October 2016 and April 2017. Adults between the ages of 18 and 80 with persistent AF that were scheduled for their first cardiac ablation procedure were eligible to participate. Subjects were excluded from participation if they experienced AF lasting longer than 12 months, had a left ventricular ejection fraction <40% or left atrial size >50 mm, and if they had any prior history of stroke.

Per the trial protocol, our AcQMap System was used to collect ultrasound and biopotential data to reconstruct the atrial anatomy and create maps of atrial activation. After anatomic reconstruction, a charge density map was made during AF. If the subject presented in sinus rhythm, AF was induced using rapid atrial pacing. The atrial activation map was reviewed to identify areas of interest for ablation therapy. PVI was then

performed using radiofrequency energy or cryotherapy, based on physician preference. Physicians were encouraged whenever possible to incorporate target areas near the pulmonary veins within the area being isolated. After PVI, another charge density map was acquired to confirm the original areas of interest. Physicians were encouraged to ablate all areas of interest and map frequently to assess effectiveness of therapy and elimination of all identified areas. The efficiency of creating new maps with the AcQMap System encouraged iterative mapping following ablation therapy delivery. On average, electrophysiologists created four full-chamber maps per patient.

Follow-up data was collected prior to discharge and at seven days, and one, three, six, nine, and 12 months. At the three, six, nine, and 12-month follow-up, a 24-hour continuous ECG monitor was worn by the subject to assess for recurrence of atrial arrhythmias. Endpoint failures included any arrhythmia recurrence >30 seconds between three months and 12 months follow-up and ablation retreatment at any time through the duration of the trial.

The primary safety outcome of the trial was freedom from all device or procedural complications within 24 hours of the procedure. Pre-specified major adverse events, or MAEs, were identified and required to be reported by each site throughout the follow-up period. All adverse events were reviewed by an independent clinical events committee.

The primary effectiveness outcome was freedom from AF >30 seconds in duration at 12 months, with or without AADs. Because cardiac ablation for AF can cause other atrial arrhythmias, including atrial flutter and tachycardias, freedom from atrial arrhythmias >30 seconds off AADs was a key secondary effectiveness endpoint.

Other key secondary effectiveness endpoints included freedom from AF and atrial arrhythmias >30 seconds after two ablation procedures. AF burden, which measures the percent of the day that the patient is in AF and is considered by electrophysiologists to be an important metric for determining symptom improvement, was also measured by the combined continuous ECG recordings from each patient through 12 months. Patient quality of life was also assessed at each follow-up visit using the Atrial Fibrillation Effect on Quality of Life, or AFEQT, disease-specific questionnaire.

In the trial, 141 subjects were screened, 129 were enrolled and 127 were treated. The procedure was terminated for clinical reasons in two subjects. Follow-up was excellent with 12-month data recorded for 95% of patients. Patient demographics were similar to those in the landmark STAR AF II trial. Average patient age was 62 years and approximately three-fourths of enrolled patients were male. Enrolled patients were typical for the persistent AF population as indicated by the length of time in AF, AAD and cardioversion usage, left atrial diameter and associated co-morbidities. Mean left atrial diameter was 43 millimeters and mean left ventricular ejection fraction was 58%. Onset of first diagnosed AF was three years and onset of first diagnosed persistent AF was two years. Most patients had previously failed at least one AAD and had been cardioverted at least once within the previous two years. Comorbidities included hypertension, coronary artery disease, diabetes, valvular disease, cardiomyopathy and heart failure.

The key clinical outcomes of our UNCOVER AF trial are summarized below.

Safety Outcome

Ninety eight percent of subjects were MAE free. Three MAEs were adjudicated by the clinical events committee to be probably related to the procedure but not the AcQMap System. Two MAEs were related to cardiac tamponade and one was related to stroke, the symptoms of which resolved after five days.

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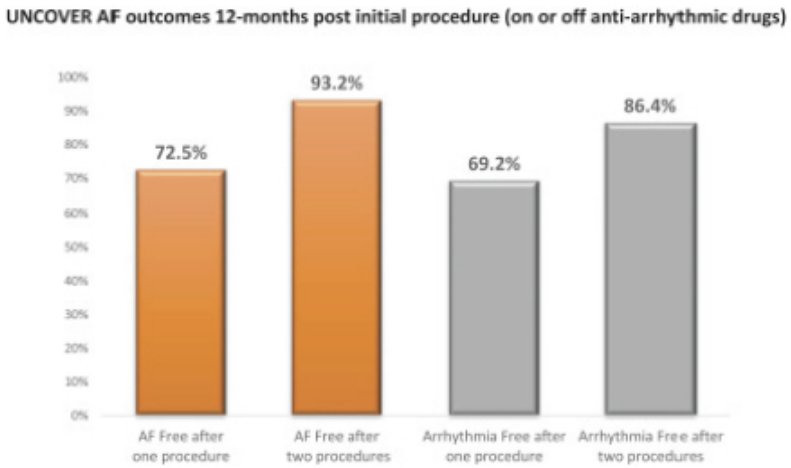
Key Primary and Secondary Effectiveness Outcomes

After a single procedure, 72.5% of patients were AF free, on or off AADs. After two procedures, 93.2% of patients were AF free, on or off AADs, at 12 months post-initial procedure.

Similarly, at 12 months follow-up, 69.2% of patients were free from other atrial arrhythmias, on or off AADs. After two procedures, 86.4% of patients were free from other atrial arrhythmias, on or off AADs.

The figure below summarizes these key effectiveness outcomes.



Single Procedure Freedom from AF and Atrial Arrhythmias On or Off Antiarrhythmic Drugs at 12-Month Follow-up

Following the cardiac ablation procedure, a 24-hour continuous ECG monitor was used to measure AF burden based on the total time spent in atrial fibrillation, atrial flutter and atrial tachycardia >30 seconds. Following a single ablation procedure, 81% of subjects had no episodes lasting >30 seconds, and 98% of patients spent <30% of the time in an atrial arrhythmia. Based on prior industry trials, including the DISCERN trial, we believe this reduction in AF burden reflects a significant quality of life improvement for patients. The DISCERN trial, which was published in 2018 in the Journal of the American Heart Association, indicated that when patients spent more than 35% of their day in AF, their quality of life, specifically their ability to perform daily activities, was greatly impaired.

Individually, each of the symptom severity, daily activity, treatment concern and treatment satisfaction domain scores on the quality of life questionnaire demonstrated a statistically significant improvement for subjects in sinus rhythm at 12 months. Similarly, the overall change from baseline to 12 months in the total quality of life score showed a statistically significant improvement for subjects in sinus rhythm compared with those who were in an atrial arrhythmia.

While the landmark STAR AF II trial implied that PVI alone for treating persistent AF may be a better approach than PVI plus additional ablation targets, we believe the results of our UNCOVER AF trial provide substantive evidence supporting the clinical utility of our AcQMap System in identifying areas of interest outside the pulmonary veins to be targeted for ablation therapy in subjects with persistent AF. To test this theory, we performed a multivariate analysis to assess the relationship between treatment and outcome variables across 54 potential predictors of outcomes in our UNCOVER trial. We found that patients were 9.4 times more likely to be in normal sinus rhythm when three or more AcQMap identified targets were ablated and 2.8 times more likely to be in normal sinus rhythm when at least two of three AcQMap-identified pattern types were ablated. We believe the key differentiator in outcomes was the use of our AcQMap System to map and identify these key ablation

patterns and targets. Importantly, the UNCOVER AF trial was the first time that many of the electrophysiologists participating in the trial had used the AcQMap System, indicating that the strong effectiveness outcomes were achievable without prior experience for the physicians.

Ongoing and Future Clinical Trials

We are currently conducting an additional multi-center, multi-national post-market approval trial, RECOVER AF, and have begun enrolling patients in the DISCOVER patient registry. We are also in the planning phase of our PLASZMA trial.

We designed our RECOVER AF trial to demonstrate the safety and effectiveness of the AcQMap System for recurrent atrial fibrillation following a first or second failed AF ablation in 106 treated patients in Europe and Canada. We completed follow-up for the RECOVER AF trial at the end of 2020 and anticipate results in the first half of 2021.

Our DISCOVER registry is a multi-national registry designed to collect data on real-world use patterns for our AcQMap System and accessories as well as to track procedural efficiency and patient outcomes. We began enrolling EU patients in October 2019 and U.S. patients in September 2020 and expect to enroll up to 500 patients in each geography. As of May 15, 2021, we had enrolled 259 patients.

Our PLASZMA (PVI + Left Atrial Slow Zone Mapping and Ablation) trial is a multi-center, non-randomized trial designed to examine the effectiveness of the AcQMap System in identifying consistent zones of slow conduction during sinus rhythm and pacing at various cycle-lengths within the chamber of interest and comparing those areas with conduction abnormalities in complex atrial arrhythmias such as atrial fibrillation, atrial flutter and atrial tachycardia. We anticipate beginning to enroll patients in the second half of 2021 and expect to enroll up to 100 patients.

We anticipate that these post-market approval trials will provide valuable evidence to support the clinical utility of our AcQMap System in treating arrhythmias and will continue to drive its adoption and utilization. As part of our portfolio expansion strategy, we are also planning two IDE trials to support regulatory approval of our AcQBlate Force Sensing Ablation System. In the first half of 2021, the first IDE trial seeking a right atrial typical flutter indication received full FDA IDE approval and commenced enrollment. The second IDE trial seeking a paroxysmal and persistent atrial fibrillation indication received IDE approval in May 2021 and we expect to commence enrollment in the second half of 2021. The FDA has approved the right atrial typical flutter IDE trial, which has a primary effectiveness endpoint of achieving bi-directional block of the cavo-tricuspid isthmus and is expected to take approximately two years to complete and obtain FDA PMA. The paroxysmal and persistent atrial fibrillation IDE trial has a primary effectiveness endpoint of freedom from atrial arrhythmias at 12-months and is expected to take three years to complete and obtain FDA PMA.

Research and Development

Our research and development efforts are focused on advancing the field of electrophysiology. We believe that our AcQMap System is a foundational platform that will drive a better standard of care for the treatment of cardiac arrhythmias. Our research and development activities are focused on increasing the AcQMap System's utility and seeking approval for additional labeled indications as well as expanding our portfolio of electrophysiology products 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. Other key programs in early stages of development include expanding our AcQMap Catheter indication to map ventricular arrhythmias as well as developing alternative ablation modalities such as pulse field ablation, also known as electroporation.

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Our research and development team has significant experience bringing innovative products to market across numerous medical device organizations. Our team has mechanical, electrical, software, systems and algorithms engineering experience in addition to specialized capabilities in physics, mathematics and ultrasound technology. In 2020, our research and development efforts continued to provide both new products as well as generational improvements to the current product lines through the release of five major versions of software, six disposables products including our first therapy device, and a significant improvement to our mapping system hardware. Additionally, research efforts evolved into development projects for advanced therapies, improved navigational accuracy, and enhanced mapping capabilities. Our research and development efforts are both directed from and executed at our facility in Carlsbad, California.

Reimbursement

We receive payment for our products directly from hospitals or other treatment facilities and do not directly bill any third-party payors. In the United States, physicians, hospitals and other treatment facilities receive payment for patient care from third-party payors, including private insurers and government insurance programs such as Medicare and Medicaid, for the total healthcare services required to diagnose and treat the patient's cardiac arrhythmias.

Diagnosis and treatment of cardiac arrhythmias can be performed in either an inpatient or outpatient setting. Each setting has its own coding and payment schedule. The choice to treat a patient as an inpatient or outpatient is a medical decision, but in general, sicker patients and those expected to need a longer hospital stay are admitted as inpatients.

Hospital Outpatient

Reimbursement for the facility in the outpatient setting is determined by CMS' comprehensive Ambulatory Payment Classification, or APC, system which assigns codes specifically related to a single procedure. Hospitals receive a Medicare outpatient payment based on the APC group assigned to the physician service or procedure performed, which are described by Current Procedure Terminology, or CPT, codes. CPT codes are specific to the approach, the technique used and the specific anatomy in which the procedure is performed. For diagnosis and treatment of cardiac arrhythmias, the main drivers of APC assignment are anatomical location and the diagnostic or therapeutic devices that are used in the procedure. The table below lists the three major APC groups under which cardiac ablation procedures are reimbursed.

Our portfolio of access, diagnostic and therapeutic tools can be used separately and in conjunction with competitor products within all three APC groups. The majority of procedures where our products would be used are Level 3 EP Procedures.

The table below describes outpatient payments for electrophysiology for U.S. hospitals in 2021.

C-APC	APC Description	National Medicare Rate
5211	Level 1 EP procedures	$ 1,113
5212	Level 2 EP Procedures	$ 6,078
5213	Level 3 EP Procedures	$ 21,464

Hospital Inpatient

CMS reimbursement for the facility in the inpatient setting is determined according to the hospital inpatient prospective payment system, or IPPS. Payment is set by the applicable Medicare Severity Diagnosis Related Group, or MS-DRG, which groups patients by similar diagnoses and/or performed procedures. The IPPS payment covers the entire admission, including any secondary procedures.

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In the inpatient setting, diagnosis and ablation of complex cardiac arrhythmias is assigned to one of the two MS-DRGs listed in the table below, depending on whether there are major complications associated with the procedure. These MS-DRGs are the same for procedures that address atrial and ventricular tachycardias as well as atrial fibrillation.

The table below describes the proposed inpatient payments for electrophysiology for U.S. hospitals for 2021.

MS-DRG	Description	2021 National Average Reimbursement
273	Percutaneous intracardiac procedures with major complications	$ 24,664
274	Percutaneous intracardiac procedures without major complications	$ 21,117

Physician Payment

In addition to reimbursement for the facility, CMS also reimburses the physician for their time spent performing the procedure according to the Medicare Physician Fee Schedule, or PFS. The PFS is based on the amount of work dedicated to the procedure and is updated annually.

CPT code 93656 is the standard code for AF ablation procedures and is associated with a proposed payment of $1,074 per procedure according to the 2020 PFS. In addition to this code, CPT code 93655 can also be reported when two distinctly different arrhythmia foci are treated. CPT code 93655 is associated with a payment of $407 in 2021. In addition, CPT code 93657 can be reported, in combination with CPT code 93656, up to two times per case for catheter ablation of the left or right atrium for the treatment of AF after completion of PVI. CPT code 93657 is associated with a payment of $407 according to the 2021 PFS.

Commercial Third-Party Payors

Commercial third-party payors often refer to CMS coverage policies and payment limitations in setting their own reimbursement rates, while also relying on their own methods and approval process apart from CMS determinations. While reimbursement for cardiac ablation procedures is well established across commercial payors, there is no uniform policy in the United States. Therefore, coverage and reimbursement can differ significantly from payor to payor.

International

Outside of the United States, market acceptance of medical devices depends partly upon the availability of reimbursement within the prevailing healthcare payment system. Reimbursement levels vary significantly by country and, within some countries, by region. Reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans, and combinations of both. Cardiac ablation for arrhythmias is a standard of care in developed international markets and reimbursement generally exists for electrophysiology procedures, though levels vary considerably by country. We designed our commercial strategy to utilize a direct sales force in certain developed markets in Western Europe where reimbursement for electrophysiology procedures is sufficient to support utilization of our AcQMap System and associated products.

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 single products 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:

- 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;
- expand our sales force across key markets to increase physician awareness;
- 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.

Biotronik Agreements

In July 2019, we entered into a license and distribution agreement with Biotronik and VascoMed GmbH (who we refer to together as the Biotronik Parties), whereby we acquired certain assets and licensing rights (including distribution rights) related to force sensing ablation catheters and electronic equipment and accessories. We refer to this agreement as the Biotronik License Agreement.

Further, in May 2020, we entered into more expansive bi-lateral distribution agreements with Biotronik, where we acquired the right to distribute a range of Biotronik's therapeutic and diagnostic electrophysiology products, and Biotronik agreed to distribute our AcQMap System and related disposable products. We refer to these agreements as the Bi-Lateral Distribution Agreements and this relationship with Biotronik as the Acutus/Biotronik Global Alliance for Electrophysiology.

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Biotronik License Agreement

Pursuant to the Biotronik License Agreement, we acquired certain manufacturing equipment and other assets and obtained from the Biotronik Parties a license under certain patents and technology to develop, commercialize, distribute and manufacture our AcQBlate Force sensing ablation catheters, which we manufacture at our facility in Carlsbad and sell in the United States, Canada, certain markets in Western Europe and Asia and internationally under our private label. In addition, under the Biotronik License Agreement, we obtained from the Biotronik Parties a license under certain patents and technology to develop, commercialize, distribute and manufacture our Qubic Force control unit, which is designed for the visualization of contact force measured by our AcQBlate Force sensing ablation catheters. Upon regulatory approvals, Biotronik will initially manufacture our Qubic Force control unit as a contract manufacturer. We can, however, elect to have the Biotronik Parties transfer the responsibility for the manufacture and supply of our Qubic Force control unit to us with 24 months' advance notice. We also obtained a non-exclusive license to distribute a range of Biotronik's branded electronic electrophysiology products, including the Qubic RF Generator and Pulse Stimulator and Qiona Pump and related accessories, which are used in connection with ablation procedures.

With respect to our AcQBlate Force Sensing Ablation System, our license from the Biotronik Parties is exclusive in the United States and co-exclusive with the Biotronik Parties outside the United States in the field of radiofrequency, or RF, or direct current ablation with optically based contact force sensing for cardiac applications. With respect to Biotronik's branded electronic electrophysiology products, our license is non-exclusive and has a term of five years outside the United States and the full term of the Biotronik License Agreement within the United States.

Pursuant to the Biotronik License Agreement, we are responsible for developing, obtaining and maintaining regulatory approval for our AcQBlate Force sensing ablation catheters and our Qubic Force control unit with the FDA and our European Union Notified Body, DQS-MED, Frankfurt, Germany, or DQS, including the performance of any necessary clinical trials.

In consideration for the rights granted to us under 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. In addition, we paid Biotronik a $2.0 million milestone payment following receipt of marketing approval for the sale of our AcQBlate Force sensing ablation catheters in Europe in December 2020. The Biotronik License Agreement also requires that we pay the Biotronik Parties certain milestone payments as follows: (i) $5.0 million upon the receipt of marketing approval for the sale of our AcQBlate Force sensing ablation catheters in the United States and (ii) $3.0 million upon the first commercial sale of our AcQBlate Force sensing ablation catheters in the United States. We are also required to pay the Biotronik Parties unit-based royalties on any sales we make of our AcQBlate Force sensing ablation catheters of $40 per unit beginning in 2020 and decreasing incrementally to $26 per unit for sales in and after 2034.

Under the Biotronik License Agreement, if we undergo a change in control with certain competitors of the Biotronik Parties, 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, the milestone payments described above 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). See "Risk Factors—Risks Related to Our Common Stock and this Offering—Provisions in our organizational documents or agreements with third parties could delay or prevent a change of control." Starting from the effective date of the Biotronik License Agreement and ending on the earlier of: (i) six years following the effective date of the Biotronik License Agreement and (ii) a change in control of us involving certain competitors of the Biotronik Parties, neither party nor their affiliates are allowed to commercialize competitive ablation catheters in the field of the license.

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The term of the Biotronik License Agreement is 10 years, but the term automatically renews for successive five-year periods until we give prior written notice of our desire not to renew. The Biotronik License Agreement may be terminated by either party in the event of a material breach or upon specified insolvency events of the other party. However, if the Biotronik Parties terminate the Biotronik License Agreement due to a material breach by us that was not related to our payment obligations under the agreement, then we would retain a non-exclusive license to our AcQBlate Force Sensing Ablation System, subject to the Biotronik Parties' rights to terminate such license under specific conditions.

Bi-Lateral Distribution Agreements

Pursuant to our Bi-Lateral Distribution Agreements, we obtained a non-exclusive license to distribute a range of Biotronik's therapeutic electrophysiology products and accessories (including the AlCath family of RF ablation catheters) in the United States, Canada, China, Hong Kong and multiple Western European countries under our own private label. Moreover, if an 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, we will obtain an exclusive distribution right in such territories for the applicable products for a term of up to five years commencing on the date of regulatory approval if we cover the cost of the required IDE or other clinical trial and we conduct such study within a specified period. We also obtained a non-exclusive license to distribute a range of Biotronik's diagnostic electrophysiology products and accessories under our own private label in each of the foregoing territories.

Pursuant to the Bi-Lateral Distribution Agreements, Biotronik has also agreed to distribute our products, including our AcQMap System, our Qubic Force control unit and our disposable products (including our AcQBlate Force sensing ablation catheters) and accessories in Germany, Japan, Mexico, Switzerland and multiple countries in Asia-Pacific, Eastern Europe, the Middle East and South America. In connection therewith, we granted to Biotronik an exclusive, non-transferable right to commercialize and distribute these products in such countries. We also granted Biotronik a co-exclusive right to commercialize and distribute these products in Hong Kong. Biotronik is required to use our branding with respect to the AcQMap console and workstation, but retains the right to distribute our disposable products and accessories under its private label.

Under the Bi-Lateral Distribution Agreements, each party is responsible for manufacturing and supplying its own products to the other party, though initially Biotronik will be responsible for manufacturing our Qubic Force control unit pursuant to the Biotronik License Agreement. The agreements also provide for the collaboration of the parties in commercialization, marketing and sales efforts, as well as responsibility for obtaining regulatory approvals.

The term of the Bi-Lateral Distribution Agreements is initially seven years, which may be renewed for successive three-year periods. In addition, the non-distributing party may terminate each of the Biotronik Distribution Agreements, on a country-by-country basis, if the distributing party does not meet specified performance metrics for such country following a specified ramp-up period. The Bi-Lateral Distribution Agreements also provides that if either party chooses to distribute a product that is competitive to one of the other party's products within the other party's territory, the other party has the right to remove that specific product from the applicable Bi-Lateral Distribution Agreement. 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. If we undergo a change in control and terminate Biotronik's right to distribute our products in one or more territories, we (or the entity acquiring us) may become obligated to pay Biotronik specified compensation for Biotronik's development of our products in such territories. See "Risk Factors—Risks Related to Our Common Stock and this Offering—Provisions in our organizational documents or agreements with third parties could delay or prevent a change of control."

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License Agreements

Exclusive Patent License Agreement—Christoph Scharf

In May 2011, we entered into an Exclusive Patent License Agreement with Christoph Scharf, or Dr. Scharf, as amended in September 2011, whereby we acquired an exclusive, irrevocable, perpetual, transferable, sublicensable worldwide license under certain patents and pending patent applications and related technology claiming methods, devices and technology related to recording electrical activity of organ tissues to make, have made, use, sell, offer for sale and import any products and practice and exploit any method, process or procedure in connection therewith. We are obliged to use commercially reasonable efforts to develop and sell products covered by the licensed patents, and following the first commercial sale of any such product, we must use commercially reasonable efforts to meet the market demand for such product. In exchange for our license, we are required to pay Dr. Scharf low single-digit percentage royalties on net sales by us, our affiliates or sublicensees of any products covered by a valid claim in the licensed patents for the term of the license, subject to certain reductions. The term of the license agreement continues, on a country-by-country and product-by-product basis, until the expiration of the last to expire valid claim in the licensed patents that cover such product in such country. We may terminate the license agreement after providing written notice to Dr. Scharf.

Exclusive Patent License Agreement—University of Minnesota

In April 2014, we entered into an Exclusive Patent License Agreement with the Regents of the University of Minnesota, or the University of Minnesota, as amended in October 2014, pursuant to which we received an exclusive, sublicenseable license under certain patents and pending patent applications claiming methods, devices and technology related to cardiac imaging technology to make, have made, use, offer to sell or sell, offer to lease or lease, import or otherwise offer to dispose or dispose of products for all uses, in all countries where there are issued and unexpired patents or patent applications subsisting. Our license is subject to certain reserved rights by the U.S. government and the University of Minnesota's retained non-exclusive right to practice the licensed intellectual property for teaching, research and educational purposes. We are obliged to use commercially reasonable efforts to commercialize products covered by the license as soon as practicable and maximize sales of any such products. In consideration for our license, we reimbursed the University of Minnesota certain patent-related expenses incurred in connection with prosecution and maintenance of the licensed patents and patent applications, and paid University of Minnesota a specified upfront payment. We are also required to pay the University of Minnesota a specified annual maintenance and administrative fees, certain regulatory and commercial milestone payments up to $235,000, and a low single-digit percentage royalties on net sales of products covered by our license, subject to a minimum annual royalty beginning at $15,000 and increasing to $50,000 in the seventh year of the agreement. Further, we are obligated to pay the University of Minnesota between a range of 15% and 25% of revenue (other than royalties) that we or our affiliates receive from sublicensees as a result of the grant of a sublicense under the rights granted under the license agreement.

The term of the license agreement expires on the date on which no licensed patents are active and no licensed patent applications are pending. The University of Minnesota may terminate the license agreement for our uncured material breach or insolvency, or if we challenge the validity or enforceability of any patents or patent applications licensed under the license agreement.

Master License Agreement—Heraeus Medical Components LLC

In June 2015, we entered into a Master License Agreement with Biotectix, LLC, as amended and assumed by Heraeus Medical Components LLC, or Heraeus, in August 2017, pursuant to which Heraeus agreed to develop a coating for use in our catheters, incorporating certain intellectual property licensed from us and SurModics, Inc., or SurModics. Pursuant to the Master License Agreement, we and Heraeus granted each other non-exclusive, royalty-free worldwide licenses under our respective technology rights to research and develop coated products.

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Following our request to initiate commercial sales in 2016, Heraeus agreed to supply us with coating materials for the production of our coated catheters. We are required to provide Heraeus binding forecasts of purchase orders for coating materials used in our catheters, and we pay for such coating materials supplied by Heraeus on a per unit basis. In addition, we are required to pay tiered low single-digit percentage royalties on net sales of our catheters incorporating the coating supplied by Heraeus, subject to certain reductions and an annual minimum royalty of $25,000 per year. We are also obliged to pay a one-time commercial milestone payment of $500,000.

At our request and for a specified transfer fee, Heraeus will be required to transfer certain technology and intellectual property to enable us to manufacture the coated catheter. Upon any such request and our payment of a specified license initiation fee, Heraeus will automatically grant us a non-exclusive, royalty-bearing, sublicenseable (subject to certain limitations) worldwide license under certain other intellectual property (which includes intellectual property owned by SurModics) to make, have made, use, offer to sell, sell, and import our catheters using the coating, and to use SurModics reagents and materials in such catheters to the extent covered by the licensed intellectual property.

In the event of a supply failure by Heraeus, Heraeus will grant us a non-exclusive, non-transferable right to make the coating materials and provide technology transfer therefor.

To the extent that any such coating materials we make or have made contain any of SurModics' reagents, SurModics will be our exclusive supplier of such reagents, and our right to transfer any such reagents to a third-party manufacturer for the manufacture of the coating material will be subject to such manufacturer entering into a confidentiality agreement with SurModics to protect its confidential information.

The term of the Master License Agreement expires upon the expiration of the last-to-expire licensed patent, and upon expiration, all licenses granted to us shall become fully paid and irrevocable. We may terminate the Master License Agreement for any reason upon nine months' advanced written notice. Either party may terminate the agreement after providing written notice upon the other party's uncured material breach or insolvency. If a party terminates this agreement within nine months of its own change of control, such party shall make a payment of $250,000 to the other party. For more information regarding the risks related to our reliance on Heraeus and SurModics for the production of a component of our products, please see "Risk Factors—Risks Related to Our Business and Products—The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business."

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.

Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our technology, inventions, improvements and products that are important to the development and implementation of our business. Our patent portfolio covers mapping, anatomy reconstruction, multiple energy modalities for ablation therapy as well as cardiac access and is intended to cover our products and components thereof, their methods of use and processes for their manufacture, including device, apparatus and method claims. Within mapping, our intellectual property portfolio includes patent claims directed to contact and non-contact charge density mapping, multi-transducer ultrasound reconstruction of cardiac anatomy which generates static and dynamic images that

enable the assessment of cardiac function/output, determination of wall thickness and visualization of adjacent structures. Within cardiac access, our intellectual property portfolio includes patent claims directed to endovascular access to all chambers of the heart. We also rely on trade secrets and know-how to protect our technology and product candidates, including our AcQMap System.

As of December 31, 2020, our patent portfolio included 30 solely owned or exclusively licensed U.S. patents and 24 solely owned or exclusively licensed pending U.S. patent applications (including four solely owned Patent Cooperation Treaty, or PCT, applications and one solely owned provisional U.S. patent applications). In addition, we solely owned or exclusively licensed 44 issued patents and 47 pending patent applications in jurisdictions outside the United States. Of our 71 pending patent applications, four have been allowed. Of our 30 owned and exclusively licensed U.S. patents, 28 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 2040, 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.

Pending PCT patent applications are not eligible to become issued patents until, among other things, we file such PCT applications as national stage patent application(s) within 30, or as applicable 31, months in the countries or regions in which we seek patent protection, depending on the country or region. If we do not timely file any national stage patent applications, we may lose our priority date with respect to any such PCT patent applications and any patent protection on the inventions disclosed in such PCT patent applications. Provisional patent applications are not eligible to become issued patents, but can become the basis of PCT and U.S. non-provisional patent applications, if such PCT or U.S. non-provisional applications are filed within 12 months of filing the related provisional patent application. If we do not timely file any non-provisional patent applications, we will lose our priority date and might be unable to obtain any patent protection on the inventions disclosed in any such provisional patent application.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. We cannot be sure that our pending patent applications that we have filed or may file in the future will result in issued patents, and we can give no assurance that any patents that have issued or might issue in the future will protect our current or future products, will provide us with any competitive advantage, and will not be challenged, invalidated or circumvented.

We also rely, in some circumstances, on trade secrets relating to our technology and products. However, trade secrets and proprietary information can be difficult to protect. We seek to protect our trade secrets and proprietary information, in part, by confidentiality agreements and proprietary invention assignment agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in the measures we take to protect and preserve our trade secrets and proprietary information, there may be instances in which they may not provide meaningful protection. Such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

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.

In the United States, we generally ship our proprietary products from Carlsbad to our customers in the United States, but also may sell our products directly to our hospital customers through our sales representatives, who deliver such products to hospital customers in the field. Internationally, we ship our proprietary products from Carlsbad to our Belgian subsidiary. Product is then placed on the market by being shipped to customers and distributors pursuant to purchase orders. The third-party manufacturers whose products we offer as part of our product portfolio ship products, either directly to our customers or to our Carlsbad or Brussels, Belgium facilities, pursuant to purchase orders we place with them.

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.

The FDA monitors compliance with the QSR through periodic inspections of our facilities and may include our suppliers' facilities as well. DQS-MED monitors compliance with the MDD requirements through both annual scheduled audits and periodic unannounced audits of our manufacturing facilities as well as our contract manufacturers' facilities.

Our failure, or the failure of our suppliers or third-party manufacturers, to maintain acceptable quality requirements could result in the shutdown of our manufacturing operations or the recall of our products, which would harm our business. In the event that one of our suppliers or third-party manufacturers fails to maintain acceptable quality requirements, we may have to qualify a new supplier and could experience a material adverse effect to manufacturing and manufacturing delays as a result.

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Government Regulation

U.S. Food & 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.

Device Classification

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 includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the General Controls for Medical Devices, which require compliance with the applicable portions of the QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, preclinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device trials. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

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 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 institutional review boards 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 institutional review board 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

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the FDCA, to a legally marketed predicate device.

A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. 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 is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA process, or seek reclassification of the device through the de novo process. A manufacturer can also submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k)

clearance or, depending on the modification, could require a PMA application or de novo classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacture documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained.

The PMA Process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (e.g., major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from preclinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device

specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval trial or post-market surveillance, whereby the applicant conducts a follow-up trial or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also require post-market surveillance for certain devices cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use.

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 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 FDA to enable export to countries other than those designated in the statutory provisions. The petitioning process can be difficult, and 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 European Union Directive 93/42/EEC, also known as the Medical Device Directive, or 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, similarly 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 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.

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In 2017, the European Parliament passed the Medical Devices Regulation, which repeals and replaces the EU Medical Devices Directive. 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 in vitro diagnostic devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation will however 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. Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve 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
- strengthen 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 our products have already been certified under the existing regulatory framework, the MDR 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) MDR, 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 Certificates of Conformity. Furthermore, the regulation introduces UDI, i.e., a bar code that must be placed on the label of the device or on its packaging, and manufacturers will be obligated to file adverse effects reports via the Eudamed platform in case there is an increase in the frequency or severity of incidents related to the medical device.

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 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 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. 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 Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit, 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 obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device 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. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, also established federal protection for the privacy and security of health information. Under HIPAA, the Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of protected health information used or disclosed by "Covered Entities," including certain healthcare providers and their "Business Associates" and covered subcontractors. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and covered providers. The privacy regulations, among other things, protect medical records and other protected health information by limiting their use and release, giving patients the right to access their medical records and limiting most disclosures of health information to the minimum amount necessary to accomplish an intended purpose. The HIPAA security standards require the adoption of administrative, physical and technical safeguards and the adoption of written security policies and procedures. HIPAA also requires Covered Entities to execute Business Associate Agreements with their Business Associates who need access to protected health information in order to provide services for or on behalf of the Covered Entities. In addition, companies that would not otherwise be subject to HIPAA may become contractually obligated to follow HIPAA requirements through agreements with Covered Entities and Business Associates, and some of our customers may require us to agree to these provisions.

In addition, HIPAA and other federal privacy regulations, such as Section 5 of the Federal Trade Commission Act, there are a number of state laws regarding the privacy and security of health information and personal data that apply to us. The compliance requirements of these laws, including additional breach reporting requirements, and the penalties for violation vary widely, and new privacy and security laws in this area are evolving. Requirements of these laws and penalties for violations vary widely.

If we or our operations are found to be in violation of HIPAA, HITECH or their implementing regulations, we may be subject to significant penalties, including civil and criminal penalties, fines, and exclusion from participation in federal or state healthcare programs, and the curtailment or restructuring of our operations. HITECH increased the civil and criminal penalties that may be imposed against Covered Entities, their Business Associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

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.

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Anti-Kickback Statutes

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

The definition of "remuneration" has been broadly interpreted to include anything of value, including, for example, gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payment of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered businesses, the statute has been violated. In addition, 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. codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the Federal False Claims Act. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection.

The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy an applicable statutory exception or regulatory safe harbor may result in increased scrutiny by government enforcement authorities such as the Office of Inspector General, or OIG, of HHS.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of recipients for healthcare products or services reimbursed by any source, not only government healthcare programs, and may apply to payments made directly by the patient.

Government officials have continued their enforcement efforts related to the marketing of healthcare services and products, among other activities, and continue to bring cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Federal False Claims Act

The federal False Claims Act, or FCA, imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The *qui tam* provisions of the FCA allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the FCA and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the FCA, and many of these state laws apply where a claim is submitted to any third-party payor and not only a federal healthcare program.

When an entity is determined to have violated the FCA, it may be required to pay up to three times the actual damages sustained by the government, plus significant civil fines and penalties. As part of any settlement, the government may require the entity to enter into a corporate integrity agreement, which imposes certain compliance, certification and reporting obligations. There are many potential bases for liability under the FCA. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. For example, the federal government has used the FCA to assert liability on the basis of kickbacks, or in instances in which manufacturers have provided billing or coding advice to providers that the government considered to be inaccurate. In these cases, the manufacturer faces liability for "causing" a false claim. In addition, the federal government has prosecuted companies under the FCA in connection with off-label promotion of products. Our activities relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products and the sale and marketing of our products may be subject to scrutiny under these laws.

While we are unaware of any current matters, we are unable to predict whether we will be subject to actions under the FCA or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

Civil Monetary Penalties

The federal Civil Monetary Penalty Law imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim 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, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

Open Payments

The Physician Payments Sunshine Act, known as "Open Payments" and enacted as part of the Affordable Care Act, requires certain pharmaceutical and medical device manufacturers of products covered by Medicare, Medicaid or the Children's Health Insurance Program to report annually to HHS: payments and transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to the CMS. Beginning in 2022, applicable manufacturers also will be required to report such 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. Failure to submit required information in a timely, complete and accurate manner may result in significant civil monetary penalties. We are subject to Open Payments and the information we disclose may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals.

Foreign Corrupt Practices Act

The 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.

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 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.

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."

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 changed 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. Moreover, the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. On December 22, 2017, President Trump signed the Tax Cuts and Jobs Act into law, which, among other things, removed penalties for not complying with the individual mandate to carry health insurance, effective as of January 1, 2019.

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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. The 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 will remain 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. 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. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. 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. Procedure reimbursement in the United States is often based on the site of service for the procedure as described below. 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.

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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. 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.

Employees and 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, 2020, we had 291 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.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purpose of our incentive share plan is to attract, retain and motivate selected employees, consultants and directors through the granting of incentive share-based compensation awards and cash-based performance bonus awards.

Mission, Vision, 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:

Mission

Provide patient-focused solutions for the electrophysiology community that help people live better lives

Our Vision

Become the worldwide leader in guided ablation therapy for cardiac arrhythmias

Cultural Values

- 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.

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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. 87 employees, or 30% 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.

Facilities

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, 2021, 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.

Legal Proceedings

From time to time, we are involved in various legal proceedings arising from the normal course of our business activities. We are not presently a party to any litigation the outcome of which, we believe, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, cash flows, or financial condition. We have 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.

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DESCRIPTION OF CAPITAL STOCK

The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation and 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, amended and restated bylaws and amended and restated investors rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

General

Our amended and restated certificate of incorporation authorizes 260,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of convertible preferred stock, par value $0.001 per share.

Based on 28,113,165 shares of common stock outstanding as of March 31, 2021, there will be shares of common stock outstanding upon the closing of this offering. As of March 31, 2021, we had 93 stockholders of record, and there were 3,846,360 shares of common stock subject to outstanding options and restricted stock units.

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 convertible 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 convertible 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 convertible 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.

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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. As of March 31, 2021, there were no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Options

As of March 31, 2021, we had outstanding options to purchase an aggregate of 3,379,575 shares of our common stock, with a weighted-average exercise price of $13.45 per share.

Warrants

The following table sets forth information about outstanding warrants to purchase shares of our stock as of March 31, 2021.

Class of Stock Underlying Warrants	Number of Shares of Stock Exercisable Prior to this Offering	Number of Shares of Common Stock Underlying Warrants on an As-Converted Basis	Weighted-Average Exercise Price Per Share Prior to this Offering	Weighted-Average Exercise Price Per Share on an As-Converted Basis
Common stock, par value $0.001 per share	824,608	824,608	$ 9.10	$ 9.10

The warrants to purchase shares of our common stock will expire upon the earlier of the expiration date set forth in each warrant, which are various dates between January 2025 and May 2029, our acquisition, or a sale of all or substantially all our assets.

Restricted Stock Units

As of March 31, 2021, we had 466,785 outstanding restricted stock units, which were subject to performance and time-based vesting conditions.

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 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) August 10, 2023 (the date that is three years after the completion of our IPO); (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 the IPO 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 is 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 shall terminate on the date of the 2021 annual meeting, the term of the initial Class II directors shall terminate on the date of the 2022 annual meeting, and the term of the initial Class III directors shall terminate on the date of the 2023 annual meeting. At each annual meeting of stockholders beginning in 2021, 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 provide that, except as otherwise required by law, special meetings of the stockholders may be called only by our board of directors.

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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 do 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 will be 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, 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. In addition, this exclusive forum 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.

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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 Select 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.

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SHARES ELIGIBLE FOR FUTURE SALE

Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after the completion of this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Upon completion of this offering, based on the number of shares of our capital stock outstanding as of March 31, 2021, we will have a total of shares of common stock outstanding. Of these outstanding shares, all the shares of common stock sold in this offering, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable, unless the shares are held by any of our "affiliates" as such term is defined in Rule 144.

Certain of the remaining outstanding shares of our common stock held by existing stockholders immediately prior to the completion of this offering are "restricted securities" as defined in Rule 144. Restricted securities may be sold in the public market only if they are registered or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which rules are summarized below.

Lock-Up Agreements

In connection with this offering, all of our directors and executive officers and certain funds affiliated with certain of our directors have agreed, subject to limited exceptions, not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common shares or such other securities for a period of 90 days after the date of this prospectus without the prior written consent of Goldman Sachs & Co. LLC. See the section titled "Underwriting" for additional information.

Following the lock-up period set forth above, and assuming that Goldman Sachs & Co. LLC does not release any parties from such lock-up agreements entered into in connection with this offering, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

Rule 144

In general, under Rule 144 as currently in effect, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell those shares without complying with any of the requirements of Rule 144.

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In general, under Rule 144, as currently in effect, and upon expiration of the lock-up agreements described above, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares; or
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144.

Registration Rights

The holders of up to approximately 12.2 million outstanding shares of our common stock are entitled to certain rights with respect to the registration of such shares under the Securities Act. The registration of these shares of our common stock under the Securities Act would result in these shares becoming eligible for sale in the public market without restriction under the Securities Act immediately upon the effectiveness of such registration, subject to the Rule 144 limitations applicable to affiliates. See the section titled "Description of Capital Stock—Registration Rights" for a description of these registration rights.

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MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following are the material U.S. federal income and estate tax consequences of the ownership and disposition of our common stock acquired in this offering by a "Non-U.S. Holder" that does not own, and has not owned, actually or constructively, more than 5% of our common stock. You are a Non-U.S. Holder if for U.S. federal income tax purposes you are a beneficial owner of our common stock that is:

- a nonresident alien individual;
- a foreign corporation; or
- a foreign estate or trust.

You are not a Non-U.S. Holder if you are a nonresident alien individual present in the United States for 183 days or more in the taxable year of disposition, or if you are a former citizen or former resident of the United States for U.S. federal income tax purposes. If you are such a person, you should consult your tax adviser regarding the U.S. federal income tax consequences of the ownership and disposition of our common stock.

If you are a partnership (including an entity or arrangement treated as a partnership) for U.S. federal income tax purposes, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner, your activities and certain determinations made at the partner level.

This discussion is based on the Code, administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations, changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein, possibly with retroactive effect. This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the effect of the Medicare contribution tax on net investment income or the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment; banks, insurance companies, and other financial institutions; brokers, dealers or traders in securities; "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax; tax-exempt organizations or governmental organizations; persons deemed to sell our common stock under the constructive sale provisions of the Code; persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; tax-qualified retirement plans; "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and persons subject to special tax accounting rules as a result of any item of gross income with respect to the stock being taken into account in an applicable financial statement.

This discussion does not address any tax consequences arising under the laws of any state, local or foreign jurisdiction. Prospective holders are urged to consult their tax advisers with respect to the particular tax consequences to them of owning and disposing of our common stock, including the consequences under the laws of any state, local or foreign jurisdiction.

Dividends

As discussed under "Dividend Policy" above, we do not currently expect to make distributions on our common stock. In the event that we do make distributions of cash or other property, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed our current and accumulated earnings and profits, they will constitute a return of capital, which will first

reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of our common stock, as described below under "—Gain on Disposition of Our Common Stock."

Dividends paid to you generally will be subject to U.S. federal withholding tax at a 30% rate or a reduced rate specified by an applicable income tax treaty. In order to obtain a reduced rate of withholding, you will be required to provide a properly executed Internal Revenue Service ("IRS") Form W-8BEN or W-8BEN-E (or other applicable form) certifying your entitlement to benefits under a treaty.

If dividends paid to you are effectively connected with your conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base maintained by you in the United States), you will generally be taxed on the dividends in the same manner as a "United States person" as defined under the Code, or a U.S. person. In this case, you will be exempt from the withholding tax discussed in the preceding paragraph, although you will be required to provide a properly executed IRS Form W-8ECI in order to claim an exemption from withholding. Instead, the effectively connected dividends will generally be subject to regular U.S. income tax as if you were a U.S. person. If, for U.S. federal income tax purposes, you are treated as a corporation, effectively connected dividends may also be subject to an additional "branch profits tax" imposed at a rate of 30% (or a lower treaty rate).

You should consult your tax adviser with respect to other U.S. tax consequences of the ownership and disposition of our common stock, including the possible imposition of a branch profits tax at a rate of 30% (or a lower treaty rate) if you are a corporation.

Gain on Disposition of Our Common Stock

Subject to the discussions below under "—Information Reporting and Backup Withholding" and "—FATCA," you generally will not be subject to U.S. federal income or withholding tax on gain realized on a sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with your conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by you in the United States); or
- we are or have been a "United States real property holding corporation," as defined in the Code, at any time within the five-year period preceding the disposition or your holding period, whichever period is shorter, and our common stock has ceased to be regularly traded on an established securities market as defined by applicable Treasury regulations.

We will be a United States real property holding corporation at any time that the fair market value of our "United States real property interests," as defined in the Code and applicable Treasury regulations, equals or exceeds 50% of the aggregate fair market value of our worldwide real property interests and our other assets used or held for use in a trade or business (all as determined for U.S. federal income tax purposes). We believe that we are not, and do not anticipate becoming, a United States real property holding corporation.

If you recognize gain on a sale or other disposition of our common stock that is effectively connected with your conduct of a trade or business in the United States (and if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by you in the United States), you will generally be taxed on such gain in the same manner as a U.S. person. You should consult your tax adviser with respect to other U.S. tax consequences of the ownership and disposition of our common stock, including the possible imposition of a branch profits tax at a rate of 30% (or a lower treaty rate) if you are a corporation.

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Information Reporting and Backup Withholding

Information returns are required to be filed with the IRS in connection with payments of dividends on our common stock. Unless you comply with certification procedures to establish that you are not a U.S. person, information returns may also be filed with the IRS in connection with the proceeds from a sale or other disposition of our common stock. You may be subject to backup withholding on payments on our common stock or on the proceeds from a sale or other disposition of our common stock unless you comply with certification procedures to establish that you are not a U.S. person or otherwise establish an exemption. Your provision of a properly executed applicable IRS Form W-8 certifying your non-U.S. status will permit you to avoid backup withholding. Amounts withheld under the backup withholding rules are not additional taxes and may be refunded or credited against your U.S. federal income tax liability, if any, provided the required information is timely furnished to the IRS.

FATCA

Provisions of the Code commonly referred to as "FATCA" require withholding of 30% on payments of dividends on our common stock and, subject to the discussion of proposed U.S. Treasury regulations below, of gross proceeds of dispositions of our common stock to "foreign financial institutions" (which is broadly defined for this purpose and in general includes investment vehicles) and certain other non-U.S. entities unless various U.S. information reporting and due diligence requirements (generally relating to ownership by U.S. persons of interests in or accounts with those entities) have been satisfied, or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. In addition, regulations proposed by the U.S. Treasury Department (the preamble to which indicates that taxpayers may rely on the regulations pending their finalization) would eliminate the requirement under FATCA of withholding on gross proceeds. If FATCA withholding is imposed, a beneficial owner that is not a foreign financial institution generally may obtain a refund of any amounts withheld by filing a U.S. federal income tax return (which may entail significant administrative burden). You should consult your tax adviser regarding the effects of FATCA on your investment in our common stock.

Federal Estate Tax

Individual Non-U.S. Holders (as specifically defined for U.S. federal estate tax purposes) and entities the property of which is potentially includible in such an individual's gross estate for U.S. federal estate tax purposes (for example, a trust funded by such an individual and with respect to which the individual has retained certain interests or powers), should note that, absent an applicable treaty exemption, our common stock will be treated as U.S.-situs property subject to U.S. federal estate tax.

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UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC is acting as the representative.

Underwriters	Number of Shares
Goldman Sachs & Co. LLC	
Total	

The underwriters will be committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days from the date of this prospectus. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional shares from us.

	No Exercise	Full Exercise
Per Share	$	$
Total	$	$

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately $. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to $.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

Shares sold by the underwriters to the public will initially be offered at the public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the public offering price. After the initial offering of the shares, the representative may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our executive officers and directors and certain of our stockholders have agreed or will agree with the underwriters, subject to certain exceptions, not to dispose of or hedge any of our or their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 90 days after the date of this prospectus, except with the prior written consent of Goldman Sachs & Co. LLC. This agreement does not apply to any existing employee benefit plans. See the section of this prospectus titled "Shares Eligible for Future Sale" for a discussion of certain transfer restrictions.

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Our common stock is listed on The Nasdaq Global Select Market under the symbol “AFIB”.

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of our common stock. As a result, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on The Nasdaq Global Select Market, in the over-the-counter market or otherwise.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

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European Economic Area

In relation to each Member State of the European Economic Area (each a Relevant State), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant State at any time:

- to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

- to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

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Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (1) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong), or the Companies Ordinance, or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the Securities and Futures Ordinance, or (2) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (3) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (1) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, under Section 274 of the SFA, (2) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (3) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore, or Regulation 32.

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Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Solely for the purposes of its obligations pursuant to Section 309B of the SFA, we have determined, and hereby notify all relevant persons (as defined in the CMP Regulations 2018), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This offering document does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This offering document contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this offering document is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

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Dubai International Financial Centre

This offering document relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This offering document is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth in this prospectus and has no responsibility for the offering document. The securities to which this offering document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this offering document you should consult an authorized financial advisor.

Switzerland

We have not and will not register with the Swiss Financial Market Supervisory Authority, or FINMA, as a foreign collective investment scheme pursuant to Article 119 of the Federal Act on Collective Investment Scheme of 23 June 2006, as amended, or CISA, and accordingly the securities being offered pursuant to this prospectus have not and will not be approved, and may not be licensable, with FINMA. Therefore, the securities have not been authorized for distribution by FINMA as a foreign collective investment scheme pursuant to Article 119 CISA and the securities offered hereby may not be offered to the public (as this term is defined in Article 3 CISA) in or from Switzerland. The securities may solely be offered to "qualified investors," as this term is defined in Article 10 CISA, and in the circumstances set out in Article 3 of the Ordinance on Collective Investment Scheme of 22 November 2006, as amended, or CISO, such that there is no public offer. Investors, however, do not benefit from protection under CISA or CISO or supervision by FINMA. This prospectus and any other materials relating to the securities are strictly personal and confidential to each offeree and do not constitute an offer to any other person. This prospectus may only be used by those qualified investors to whom it has been handed out in connection with the offer described in this prospectus and may neither directly or indirectly be distributed or made available to any person or entity other than its recipients. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in Switzerland or from Switzerland. This prospectus does not constitute an issue prospectus as that term is understood pursuant to Article 652a and/or 1156 of the Swiss Federal Code of Obligations. We have not applied for a listing of the securities on the SIX Swiss Exchange or any other regulated securities market in Switzerland, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the listing rules of the SIX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SIX Swiss Exchange.

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LEGAL MATTERS

Davis Polk & Wardwell LLP, Menlo Park, California will pass upon the validity of the shares of common stock offered by this prospectus. Cooley LLP, San Diego, California is acting as counsel for the underwriters.

EXPERTS

The consolidated financial statements of Acutus Medical, Inc. as of December 31, 2020 and 2019, and for each of the years in the two-year period ended December 31, 2020, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not include all of the information contained in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. You should refer to the registration statement and its exhibits for additional information. Whenever we make references in this prospectus to any of our contracts, agreements or other documents, such references are not necessarily complete and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

You can read our SEC filings, including the registration statement and its exhibits, at the SEC's web site at www.sec.gov.

We are subject to the information reporting requirements of the Exchange Act, and we file annual, quarterly and special reports, proxy statements and other information with the SEC. These reports, proxy statements and other information are available at the website of the SEC referred to above. We also maintain a website at www.acutusmedical.com where you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessible through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus. We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC (Commission File No. 001-39430):

- Our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 19, 2021;
- the information contained in our Definitive Proxy Statement on Schedule 14A filed with the SEC on April 29, 2021 and incorporated into Part III of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020;
- Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, filed with the SEC on May 13, 2021;

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- Our Current Reports on Form 8-K filed with the SEC on February 9, 2021, March 18, 2021 and May 12, 2021; and
- The description of our common stock which is registered under Section 12 of the Exchange Act, in our registration statement on Form 8-A, filed on August 5, 2020, including any amendment or reports filed for the purposes of updating this description.

Notwithstanding the statements in the preceding paragraphs, no document, report or exhibit (or portion of any of the foregoing) or any other information that we have "furnished" to the SEC pursuant to the Exchange Act shall be incorporated by reference into this prospectus.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus, including exhibits to these documents. You should direct any requests for documents to Acutus Medical, Inc., 2210 Faraday Ave., Suite 100, Carlsbad, CA 92008.

You also may access these filings on our website at www.acutusmedical.com. We do not incorporate the information on our website into this prospectus or any supplement to this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus or any supplement to this prospectus).

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

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Pursuant to 17 C.F.R. Section 200.83

Shares

Common Stock

Prospectus

Goldman Sachs & Co. LLC

, 2021

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimates except the Securities and Exchange Commission's registration fee, Financial Industry Regulatory Authority, Inc.'s filing fee and the Nasdaq listing fee.

	Amount Paid or to Be Paid
SEC registration fee	$
FINRA filing fee	
Nasdaq listing fee	
Printing and engraving expenses	
Legal fees and expenses	
Accounting fees and expenses	
Transfer agent and registrar fees	
Miscellaneous expenses	
Total	$

Item 14. Indemnification of Officers and Directors

Section 145 of the Delaware General Corporation Law provides, in effect, that any person made a party to any action by reason of the fact that he is or was a director, officer, employee or agent of ours may, and in certain cases must, be indemnified by us against, in the case of a non-derivative action, judgments, fines, amounts paid in settlement, and reasonable expenses (including attorneys' fees) incurred by him as a result of such action, and in the case of a derivative action, against expenses (including attorneys' fees), if in either type of action he acted in good faith and in a manner he reasonably believed to be in or not opposed to our best interests. This indemnification does not apply: (i) in a derivative action, to matters as to which it is adjudged that the director, officer, employee or agent is liable to us, unless upon court order it is determined that, despite such adjudication of liability, but in view of all the circumstances of the case, he is fairly and reasonably entitled to indemnity for expenses; and (ii) in a non-derivative action, to any criminal proceeding in which such person had no reasonable cause to believe his conduct was unlawful.

Article VIII of our amended and restated certificate of incorporation provides for the indemnification of directors to the fullest extent permissible under Delaware law.

We have entered into indemnification agreements with certain of our directors, executive officers and others, in addition to indemnification provided for in our bylaws. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

The Underwriting Agreement (Exhibit 1.1 hereto) provides for indemnification by the underwriters of us and our executive officers and directors, and by us of the underwriters for certain liabilities, including liabilities arising under the Securities Act.

We have purchased and intend to maintain insurance on behalf of any person who is or was a director or officer against any loss arising from any claim, including claims relating to, among other things, public securities

matters, asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

See also the undertakings set out in response to Item 17 herein.

Item 15. Recent Sales of Unregistered Securities

We have issued and sold the following securities since January 1, 2018:

(i) In June 2018, we issued warrants exercisable for up to 501,946 shares of our common stock at a price of $0.10 per share to five accredited investors (including certain holders of 5% or more of our capital stock and entities affiliated with certain of our directors).

(ii) In June 2018, we issued $22,815,231 in principal amount of convertible promissory notes to a total of eight accredited investors (including certain holders of 5% or more of our capital stock, entities affiliated with certain of our directors and Christoph Scharf, M.D., one of our directors until his resignation on June 10, 2020), which notes were subsequently amended and converted into an aggregate of 1,884,565 shares of our Series D convertible preferred stock at a price of $13.33 per share.

(iii) In July 2018, we issued warrants exercisable for up to 26,998 shares of our Series C convertible preferred stock at a price of $16.67 per share. These warrants were subsequently automatically converted to warrants to purchase up to 26,998 shares of our Series D convertible preferred stock at a price of $16.67 per share.

(iv) In May 2019, we issued warrants exercisable for up to 419,992 shares of our Series C convertible preferred stock at a price of $16.67 per share to two accredited investors (including certain holders of 5% or more of our capital stock and entities affiliated with certain of our directors). These warrants were subsequently automatically converted to warrants to purchase up to 419,992 shares of our Series D convertible preferred stock at a price of $16.67 per share.

(v) In May 2019, we issued $37,000,000 in principal amount of convertible promissory notes to a total of seven accredited investors (including certain holders of 5% or more of our capital stock and entities affiliated with certain of our directors), which notes were subsequently converted into an aggregate of 2,223,913 shares of our Series D convertible preferred stock at a price of $16.67 per share.

(vi) In June 2019, we sold an aggregate of 4,091,819 shares of our Series D convertible preferred stock at a price of $16.67 per share for an aggregate purchase price of $68,198,650.

(vii) On June 18, 2019, we entered into an acquisition agreement under which we acquired all of the stock of Rhythm Xience, Inc. Pursuant to that agreement, in February 2020 we issued 119,993 shares of our Series D convertible preferred stock with an implied value of $2,197,199 to the former owners of Rhythm Xience, Inc. in connection with the achievement of certain regulatory and revenue milestones.

(viii) On July 2, 2019 we entered into a license agreement with Biotronik SE & Co. KG and VascoMed GmbH. Pursuant to that agreement, we issued 273,070 shares of our Series D convertible preferred stock, with an implied value of $5,000,000, to Biotronik in February 2020.

(ix) From January 1, 2018 through August 5, 2020, we granted to certain employees, consultants and directors options to purchase an aggregate of 2,998,107 shares of our common stock under our 2011 Plan and 2020 Plan at exercise prices ranging from $9.72 to $18.00 per share.

(x) From January 1, 2018 through August 5, 2020, we issued an aggregate of 213,190 shares of our common stock upon the exercise of options granted under our 2011 Plan and 2020 Plan, at exercise prices ranging from $1.85 to $13.38 per share, for an aggregate exercise price of $792,196.

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None of the foregoing transactions involved any underwriters, underwriting discounts, or commissions, or any public offering. The sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving a public offering or transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under such Rule 701. The recipients of securities in each such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and warrants issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits.

See the Exhibit Index immediately preceding the signature page hereto for a list of exhibits filed as part of this registration statement on Form S-1, which Exhibit Index is incorporated herein by reference.

(b) Financial Statement Schedules.

All other schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or related notes.

Item 17. Undertakings

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(i) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(ii) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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EXHIBIT INDEX

Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit	Filing Date
1.1*	Form of Underwriting Agreement				
2.1^	Acquisition Agreement, dated May 31, 2019, among the Registrant, Rhythm Xience, Inc., the sellers listed on Schedule I thereto and Harold Wodlinger, as the Sellers' Agent	S-1	333-239873	2.1	July 15, 2020
3.1	Amended and Restated Certificate of Incorporation	8-K	001-39430	3.1	August 10, 2020
3.2	Amended and Restated Bylaws	8-K	001-39430	3.2	August 10, 2020
4.1	Specimen Common Stock Certificate	S-1/A	333-239873	4.2	July 30, 2020
4.2	Amended and Restated Investors' Rights Agreement	S-1	333-239873	4.1	July 15, 2020
4.4	Form of warrant to purchase common stock dated January 30, 2015, issued by the Registrant to various parties, together with a schedule of material differences	S-1	333-239873	4.3	July 15, 2020
4.5	Form of warrant to purchase common stock dated June 7, 2018, issued by the Registrant to various parties, together with a schedule of material differences	S-1	333-239873	4.4	July 15, 2020
4.6	Form of warrant to purchase common stock dated July 31, 2018, issued by the Registrant to various parties, together with a schedule of material differences	S-1	333-239873	4.5	July 15, 2020
4.7	Form of warrant to purchase common stock dated May 20, 2019, issued by the Registrant to various parties, together with a schedule of material differences	S-1	333-239873	4.6	July 15, 2020
5.1*	Opinion of Davis Polk & Wardwell LLP				
10.1	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")	S-1	333-239873	10.1	July 15, 2020
10.2	Pledge and Security Agreement, dated May 20, 2019, between the Registrant and Wilmington Trust, National Association	S-1	333-239873	10.2	July 15, 2020
10.3#	License and Distribution Agreement, dated July 2, 2019, among the Registrant, Biotronik SE & Co. KG and VascoMed GmbH	S-1	333-239873	10.3	July 15, 2020

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Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit	Filing Date
10.4#	Bi-Lateral Distribution Agreement, dated May 11, 2020, between the Registrant and Biotronik SE & Co. KG (Acutus as distributor)	S-1	333-239873	10.4	July 15, 2020
10.5#	Bi-Lateral Distribution Agreement, dated May 11, 2020, between the Registrant and Biotronik SE & Co. KG (Biotronik as distributor)	S-1	333-239873	10.5	July 15, 2020
10.6	License Agreement, dated May 10, 2011, between the Registrant and Dr. Christoph Scharf	S-1	333-239873	10.6	July 15, 2020
10.7	First Amendment to License Agreement, dated September 30, 2011, between the Registrant and Dr. Christoph Scharf	S-1	333-239873	10.7	July 15, 2020
10.8#	Master License Agreement, dated March 11, 2014, between the Registrant and Biotectix, LLC	S-1	333-239873	10.8	July 15, 2020
10.9#	Exclusive Patent License Agreement, dated April 21, 2014, between the Registrant and Regents of the University of Minnesota	S-1	333-239873	10.9	July 15, 2020
10.10	First Amendment to Exclusive Patent License Agreement, dated October 20, 2014, between the Registrant and Regents of the University of Minnesota	S-1	333-239873	10.10	July 15, 2020
10.11	Lease Agreement, dated January 22, 2015, as amended, between the Registrant and Carlsbad 2210, LLC	S-1	333-239873	10.11	July 15, 2020
10.12†	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers	S-1	333-239873	10.12	July 15, 2020
10.13†	2011 Equity Incentive Plan, as amended, and forms of agreement thereunder	S-1	333-239873	10.13	July 15, 2020
10.14†	2020 Equity Incentive Plan and forms of agreement thereunder	S-1/A	333-239873	10.14	July 30, 2020
10.15†	2020 Employee Stock Purchase Plan	S-1/A	333-239873	10.15	July 30, 2020
10.16†	Executive Incentive Compensation Plan	S-1	333-239873	10.16	July 15, 2020
10.17†	Executive Chairman Agreement between the Registrant and Scott Huennekens	S-1	333-239873	10.17	July 15, 2020
10.18†	Restricted Stock Unit Award Agreement between the Registrant and Scott Huennekens	S-1	333-239873	10.18	July 15, 2020
10.19†	Employment Agreement between Registrant and Vince Burgess	S-1	333-239873	10.19	July 15, 2020

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Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit	Filing Date
10.20†	Employment Agreement between Registrant and Steven McQuillan	S-1	333-239873	10.21	July 15, 2020
10.21†	Employment Agreement between Registrant and David Roman	10-K	001-39430	10.22	March 19, 2021
10.22	Amendment No. 1 to Credit Agreement, dated June 7, 2019	10-K	001-39430	10.24	March 19, 2021
10.23	Amendment No. 2 and Waiver to the Credit Agreement, dated October 21, 2020	10-K	001-39430	10.25	March 19, 2021
21.1	Subsidiaries of the Registrant	10-K	001-39430	21.1	March 19, 2021
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm				
23.2*	Consent of Davis Polk & Wardwell LLP (included in Exhibit 5.1)				
24.1*	Power of Attorney (included on signature page)				

* To be filed by amendment.
† Indicates management contract or compensatory plan.
# Portions of the exhibit have been omitted as the Registrant has determined that: (i) the omitted information is not material; and (ii) the omitted information would likely cause competitive harm to the Registrant if publicly disclosed.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Carlsbad, State of California, on , 2021.

ACUTUS MEDICAL, INC.

By: _____
Vince Burgess
President, Chief Executive Officer and Director

POWER OF ATTORNEY

We, the undersigned officers and directors of Acutus Medical, Inc., hereby severally constitute and appoint Vince Burgess, David H. Roman and Tom Sohn, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
Vince Burgess	President, Chief Executive Officer and Director (Principal Executive Officer)	,2021
David H. Roman	Chief Financial Officer (Principal Financial and Accounting Officer)	, 2021
R. Scott Huennekens	Chairman of the Board	, 2021
David Bonita, M.D.	Director	, 2021
Daniella Cramp	Director	, 2021
Andrew ElBardissi, M.D.	Director	, 2021
Jim Hinrichs	Director	, 2021

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Signature	Title	Date
Shahzad Malik, MB BChir	Director	, 2021
Shaden Marzouk, M.D.	Director	, 2021
John Sheridan	Director	, 2021