As confidentially submitted to the Securities and Exchange Commission on June 29, 2020 as Amendment No. 1 to the draft Registration Statement. **Registration No. 333-**

# UNITED STATES 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

(State or other jurisdiction of incorporation or organization)

3841 (Primary Standard Industrial Classification Code Number)

45-1306615 (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

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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.  $\Box$ 

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.  $\Box$ 

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.  $\Box$ 

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): Accelerated filer  $\square$ Non-accelerated filer  $\square$ 

Large accelerated filer  $\square$ 

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	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee
Common stock, \$0.001 par value per share	\$	\$

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

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.

Smaller reporting company 🗵

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.

, 2020

# SUBJECT TO COMPLETION, DATED

Shares ACUTUS MEDICAL

Common Stock

This is the initial public offering of shares of common stock of Acutus Medical, Inc.

We are offering shares of our common stock. Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price per share will be between \$ and \$ . We intend to apply to list our common stock on The Nasdaq Global Market under the symbol "AFIB."

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 18.

	Per	
	Share	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) See "Underwriting" for additional disclosure regarding the estimated 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	, 2020.

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.

J.P. Morgan

**BofA Securities** 

William Blair

BTIG

**Canaccord Genuity** 

, 2020

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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 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.

Until , 2020 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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### PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere 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 sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes included elsewhere in this prospectus. 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 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 frequencies 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, 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 wellestablished therapy for the large and rapidly growing patient population, with clear and substantial reimbursement in developed markets. We estimate that in 2019 there were over 50 million individuals worldwide with arrhythmias and approximately 1.1 million ablation procedures globally, reflecting a \$5.7 billion global market that has grown 13% 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 complex arrhythmias and creation of durable ablation lesions remains challenging with long, unpredictable procedure times and inconsistent outcomes. For example, data from large, multi-center trials of cardiac ablation have demonstrated that approximately 30 to 50% of ablations for atrial fibrillation result in arrhythmia recurrence within the first 12 months of the initial ablation procedure. Currently marketed mapping systems are not able to quickly and consistently identify the source of the arrhythmia in more complex cases, which can contribute to these unsatisfactory outcomes. Current competitive mapping systems sequentially collect data, point-by-point, by contacting the heart surface at multiple locations throughout the chamber. This is a time-consuming process that

often takes 15 to 20 minutes per map. Additionally, because contact-based mapping relies on a fixed timing reference to sequence the data points, it precludes these systems from being able to quickly and reliably identify the drivers and maintainers of unstable arrhythmias, such as atrial fibrillation, many types of supraventricular tachycardias and certain ventricular arrhythmias.

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

We believe that by creating high definition, clinically accurate activation maps of all types of arrhythmias, our AcQMap System offers physicians better decision-making tools 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 gold-tip, irrigated, radiofrequency force sensing ablation catheters and control unit which we expect to commercialize once we obtain regulatory approval. We anticipate CE Mark approval and commercial launch of our AcQBlate force sensing ablation catheters and control unit in Europe in the second half of 2020, and we plan to commence an investigational device exemption, or IDE, trial for U.S. Food and Drug Administration, or FDA, premarket approval, or PMA approval, in the United States within the same time frame. We currently anticipate FDA PMA approval, and the U.S. commercial launch, of our AcQBlate force sensing ablation catheters and control unit in late 2022. 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.

Early versions of our AcQMap System and certain related accessory products have been used in the United States since May 2018 and Western Europe since July 2016 in a limited, pilot launch capacity, where our focus was on optimizing workflow and validating our value proposition. We fully commenced the launch of our commercial-grade console and software products in the first quarter of 2020. Critical to our launch were a series of recent strategic transactions and regulatory approvals, including: FDA 510(k) clearance and CE Mark of our second-generation AcQMap console and SuperMap software suite; the addition of an integrated family of transseptal crossing and steerable introducer systems to our product portfolio through our acquisition of Rhythm Xience, Inc., or Rhythm Xience; and the acquisition of our AcQBlate Force sensing product line from Biotronik. Since our full launch, we have continued to enhance our product portfolio and global presence by entering into bi-lateral distribution agreements with Biotronik in May 2020, which added a full suite of diagnostic and ablation catheters to our product portfolio and significantly expanded our international distribution and market development capabilities. 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 catheters 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 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.

During the year ended December 31, 2019, we generated revenue of \$2.8 million and a net loss of \$97.0 million (which included \$15.0 million in payments attributable to the product line we acquired from Biotronik pursuant to a license and distribution agreement), compared to revenue of \$2.2 million and a net loss of \$47.9 million during the year ended December 31, 2018. During the quarter ended March 31, 2020 we generated revenue of \$1.6 million and a net loss of \$18.1 million, compared to revenue of \$0.8 million and a net loss of \$14.7 million during the quarter ended March 31, 2019. As of December 31, 2019 and March 31, 2020, our installed base of AcQMap consoles and workstations placed into service at customer sites was 27 and 31 units, respectively. Since our full commercial launch through June 26, 2020, we have installed 20 AcQMap consoles and workstations. 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. The 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. See the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" for more information.

# **Our Competitive Strengths**

We believe the continued growth of our company will be driven by our:

- paradigm-shifting intracardiac mapping system offering significant advantages relative to the current standard of care;
- broad and expanding product portfolio;
- attractive value proposition for hospitals, physicians, patients and payors;
- large, rapidly growing and underpenetrated market with established reimbursement;
- efficient commercial model;
- pure-play electrophysiology-focus;
- deep technology-driven competitive advantage supported by a robust patent portfolio, trade secrets and know-how, and in-licensed and acquired technology; and
- highly experienced senior management team with broad cardiovascular industry expertise.

# **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. If left untreated, arrhythmias can result in debilitating symptoms, heart failure, stroke and sudden cardiac death.

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

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 475,000 cardiac ablation procedures globally for atrial fibrillation in 2019, representing a current market size of approximately \$3.4 billion in disposable product revenue. We believe this market is significantly underpenetrated. 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, 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 516,000 ablation procedures worldwide for SVTs in 2019, reflecting a market size of approximately \$1.7 billion in disposable product revenue. 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. If left untreated, VTs and PVCs can lead to heart failure, ventricular fibrillation and sudden cardiac death. We estimate that there were approximately 90,000 global ablation procedures for ventricular arrhythmias in 2019, reflecting a market size of approximately \$620 million in disposable product revenue. 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.

# 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. 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.

# Cardiac Ablation

Cardiac ablation involves identifying and destroying tissue in the heart that is responsible for initiating and/or maintaining an arrhythmia. 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. Currently marketed mapping systems then collect data point-by-point through contact with the chamber wall to create a map of the anatomy and electrical activation pathways. This map is used to determine the tissue area that is likely causing the arrhythmia. Once the area of interest is identified, an ablation catheter is inserted that 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 arrhythmias and durable ablation remains challenging with long, unpredictable procedure times and inconsistent outcomes. For example, data from large, multi-center trials of ablation therapy, including STOP AF and STAR AF II, have demonstrated that approximately 30 to 50% of ablations for atrial fibrillation result in recurrence within 12 months of the initial ablation procedure. We believe a primary reason for this is the inability of currently marketed mapping systems to reliably identify where to ablate and when ablation is complete.

### Limitations of Current Mapping Systems

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.

The challenges associated with contact-based mapping systems have limited the penetration of cardiac ablation therapy to a small portion of patients with AF, SVTs, VTs and PVCs. These challenges include:

- lengthy, unpredictable procedure times driving inefficient resource utilization;
- impracticality in the use of an iterative treatment approach (map, treat, re-map, adjust therapy, etc.);
- inability to quickly and reliably identify unstable arrhythmias including AF, certain VTs, PVCs and many types of SVTs (including those SVTs that occur during the procedure as a result of ablations for AF);
- inability to address 40-60% of SVT patients who also have AF;
- AF recurrence rates of 30–50% within 12 months of initial ablation procedure; and
- the potential to cause ventricular arrhythmias due to contact with the chamber wall.

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.

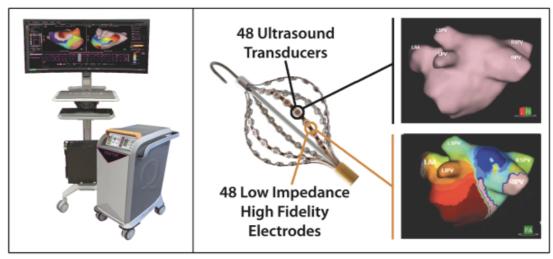
#### **Our Solution**

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, as depicted in the graphic below.



(Left): Our AcQMap console and workstation. (Middle): Our AcQMap 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.

### 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 arming them with an optimal solution to better customize therapy.

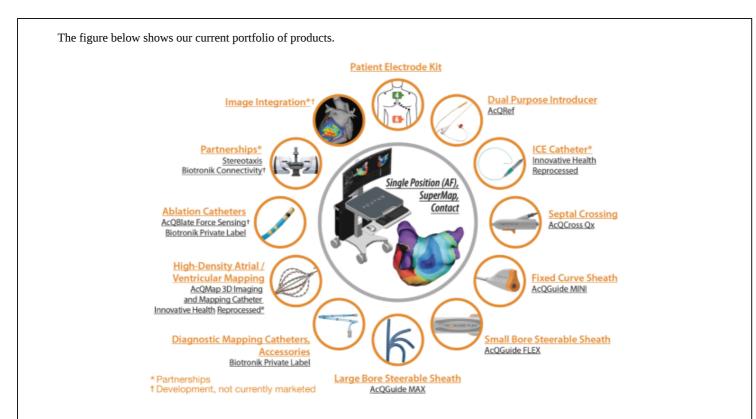
*Excellent Clinical Outcomes.* Our UNCOVER AF post-market approval trial, which assessed the effectiveness of the AcQMap System in identifying patient-specific targets for ablation, demonstrated favorable freedom from AF outcomes. The results are particularly favorable in the context of other landmark 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 gold-tip, irrigated, radiofrequency force sensing ablation catheters and control unit which we expect to commercialize once we obtain regulatory approval. We anticipate CE Mark approval and commercial launch of our AcQBlate force sensing ablation catheters and control unit in Europe in the second half of 2020, and we plan to commence an IDE trial for FDA PMA approval in the United States within the same time frame. We currently anticipate FDA PMA approval, and the U.S. commercial launch, of our AcQBlate force sensing ablation catheters and control unit in late 2022.

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.





# 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*. 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. Similarly, we believe that the speed of our iterative mapping approach will ultimately result in shorter and more predictable procedure duration.

*Hospitals*. We believe our products will improve hospital workflow efficiency which will allow hospitals to better utilize their operating room capacity and fixed overhead as well as increase their return on capital.

*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 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.
- 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" and the "Acutus" logo, "Acutus Medical" and the "Acutus Medical" logo, "AcQMap" and the "AcQMap" logo, "AcQBlate" and the "AcQBlate" logo, "AcQGuide" and the "AcQGuide" logo, "AcQRef" and the "AcQRef" logo, "AcQCross" and the "AcQCross" logo, "SuperMap" and the "SuperMap" logo and "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  $^{TM}$  or  $^{I\!R}$  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 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) the last day of the fiscal year following the fifth anniversary of the consummation of this offering; (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 nonaffiliates is less that \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less that \$100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less that \$700.0 million measured on the last business day of our second fiscal quarter.

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), based on the assumed initial public offering price of \$ per share (which is the midpoint of the estimated price range set forth on the cover page of this prospectus) and after deducting the estimated 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, to support the conduct of our ongoing clinical trials and research and development activities, and 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.					
Proposed Nasdaq trading symbol	"AFIB"					

The number of shares of common stock that will be outstanding after this offering is based on 168,068,784 shares of our common stock (including all shares of our convertible preferred stock on an as-converted basis) outstanding as of March 31, 2020, and excludes:

- 4,955,017 shares of our common stock issuable upon the exercise of warrants to purchase shares of our common stock outstanding as of March 31, 2020, with a weighted-average exercise price of \$0.02 per share;
- 4,346,557 shares of our common stock issuable upon the exercise of warrants to purchase shares of convertible preferred stock outstanding as of March 31, 2020, which will be automatically converted into warrants to purchase shares of our common stock immediately prior to the completion of this offering, with a weighted-average exercise price of \$1.714 per share;
- 26,704,989 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of March 31, 2020, with a weighted-average exercise price of \$1.13 per share;

- 5,518,463 shares of our common stock issuable upon the vesting and settlement of outstanding restricted stock units, or RSUs, as of March 31, 2020, of which part; and
  - shares of our common stock reserved for future grants under our stock-based compensation plans, consisting of:
  - 2,970,421 shares of our common stock reserved for future grants under our 2011 Equity Incentive Plan, or our 2011 Plan, which shares will be added to the shares to be reserved under our 2020 Equity Incentive Plan, or our 2020 Plan, which will become effective immediately prior to the effective date of this registration statement,
  - shares of our common stock reserved for future grants under our 2020 Plan, which will become effective immediately
    prior to the effective date of this registration statement, including shares of our common stock issuable upon the
    exercise of options to purchase shares of our common stock granted to certain of our executive officers, directors and new
    employees pursuant to our 2020 Plan, with a grant date of the effective date of this registration statement and with an exercise
    price equal to the initial public offering price, as well as any automatic increases in the number of shares of our common stock
    reserved for future issuance pursuant to this plan, and
  - shares of our common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, or our 2020 ESPP, which will become effective immediately prior to the effective date of this registration statement, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to this plan.

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

- a 1-for- reverse split of our capital stock which was effected on , 2020;
- the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 161,155,827 shares of our common stock immediately prior to the completion of this offering;
- the automatic conversion of all outstanding warrants to purchase shares of our convertible preferred stock outstanding into warrants to purchase an aggregate of 4,346,557 shares of our common stock immediately prior to the completion of this offering;
- no exercise of outstanding options or warrants or settlement of outstanding RSUs;
- no exercise by the underwriters of their option to purchase up to an additional shares of our common stock in this offering; and
- the adoption, filing and effectiveness of our amended and restated certificate of incorporation and amended and restated bylaws immediately prior to the completion of this offering.

We refer to our Series A convertible preferred stock, Series B convertible preferred stock, Series C convertible preferred stock and Series D convertible preferred stock as our convertible preferred stock in this prospectus, as well as for financial reporting purposes and in the financial tables included in this prospectus, as more fully explained in Note 13 to our consolidated financial statements included elsewhere in this prospectus.

# 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, 2019 and 2018 from our audited consolidated financial statements included elsewhere in this prospectus. We have derived the summary consolidated statements of operations and comprehensive loss data for the consolidated balance sheet data as of March 31, 2020 from our unaudited interim consolidated financial statements included elsewhere in this prospectus. You should read this data together with our consolidated financial statements and related notes included elsewhere in this prospectus and the information in the sections titled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." 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 included to replace the consolidated financial statements and related notes and 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 any other period and our interim results are not necessarily indicative of the results to be expected for the full year ending December 31, 2020.

	Three Months Ended March 31,			Year I Decem				
(in thousands, except share and per share data)	thousands, except share and per share data) 2020 2019 (unaudited)		2019	2019			2018	
Consolidated Statements of Operations and Comprehensive Loss Data:		(unau	dited)					
Revenue <sup>(2)</sup>	\$	1,583	\$	787	\$	2,836	\$	2,166
Costs and operating expenses:	ψ	1,505	Ψ	/0/	Ψ	2,050	Ψ	2,100
Cost of products sold(1)		3,194		2,176		9,243		7,510
Research and development <sup>(1)</sup>		7,973		4,377		23,029		19,077
Research and development—license acquired						15,000		
Selling, general and administrative <sup>(1)</sup>		10,235		4,093		26,847		13,330
Impairment of property and equipment						786		
Change in fair value of contingent consideration		(2,219)		—		500		
Total costs and operating expenses		19,183		10,646		75,405		39,917
Loss from operations	(	(17,600)		(9,859)		(72,569)		(37,751)
Other income (expense):								
Change in fair value of warrant liability and embedded derivative		581		841		(1,919)		(4,298)
Loss on issuance of convertible notes and warrants		—		—				(924)
Loss on debt extinguishment				_		(1,447)		
Interest income		275		65		1,164		297
Interest expense		(1,354)		(5,742)		(22,268)		(5,231)
Total other income (expense), net		(498)		(4,836)		(24,470)		(10,156)
Loss before income taxes	(	(18,098)		(14,695)	_	(97,039)		(47,907)
Income tax benefit		_		_		_		_
Net loss	\$ (	(18,098)	\$	(14,695)	\$	(97,039)	\$	(47,907)
Net loss per common share, basic and diluted <sup>(3)</sup>	\$	(2.66)	\$	(2.30)	\$	(14.85)	\$	(9.03)
Weighted-average shares outstanding, basic and diluted <sup>(3)</sup>	6,8	312,226	6,	385,612	6	,534,469	5	5,307,392
Pro forma net loss per common share, basic and diluted (unaudited) <sup>(3)</sup>	\$				\$			
Pro forma weighted-average shares outstanding, basic and diluted (unaudited) (3)								

(1) The following table sets forth the stock-based compensation expense included in our consolidated results of operations for the three months ended March 31, 2020 and 2019 and the years ended December 31, 2019 and 2018:

(in thousands)		Three Months Ended March 31,						Year Ended December 31,		
		2020		2019		2019	2018			
	-	(unaudited)					_			
Cost of products sold	9	5 108	\$	52	\$	209	\$	215		
Research and development		211	_	142		656		564		
Selling, general and administrative		1,422	2	365		2,129		1,292		
Total stock-based compensation expense	9	5 1,741	\$	559	\$	2,994	\$	2,071		

(2) The following table sets forth our revenue for disposables and systems/service for the three months ended March 31, 2020 and 2019 and the years ended December 31, 2019 and 2018:

	Three Mor Marc	nths Ended ch 31,			Ended ber 31,
(in thousands)	2020	2019		2018	
	 (unau	dited)		_	
Disposables	\$ 1,057	\$ 782	\$ 2,8	17	\$ 2,160
Systems/service	 526	5		19	6
Total revenue	\$ 1,583	\$ 787	\$ 2,8	36	\$ 2,166

(3) See Note 16 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per common share, basic and diluted pro forma net loss per common share and the weighted-average number of shares used in the computation of the per share amounts.

	As of March 31, 2020				
	Actual	Pro Forma (1) As Adjusted(2)(3)			
(in thousands)	(unaudited)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	\$ 49,880	\$	\$		
Working capital <sup>(4)</sup>	38,363				
Total assets	87,106				
Contingent consideration, short- and long-term	6,900				
Common and preferred stock warrant liability	8,338				
Long-term debt	38,398				
Convertible preferred stock	260,555				
Accumulated deficit	(277,132)				
Total stockholders' equity (deficit)	(242,222)				

(1) The pro forma consolidated balance sheet data gives effect to: (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 161,155,827 shares of common stock immediately prior to the completion of this offering, as if such conversion had occurred on March 31, 2020; (ii) the automatic conversion of all of our outstanding warrants to purchase convertible preferred stock into warrants to purchase shares of our common stock, and the related reclassification of our common and preferred stock warrant liability to stockholders' equity (deficit) immediately prior to the completion of this offering; and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, which will be in effect immediately prior to the completion of this offering.

(2) The pro forma as adjusted consolidated balance sheet data gives effect to: (i) the pro forma items described in footnote (1) above; and (ii) the issuance and sale by us of shares of our common stock in this offering at the assumed initial public offering price of \$ per share (which is the midpoint of the estimated price range set forth on the cover page of this prospectus) and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) The pro forma as adjusted consolidated balance sheet data is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) each of our pro forma as adjusted cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity (deficit) by \$ million, 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 estimated underwriting discounts and

commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares of common stock offered by us would increase (decrease) each of our pro forma as adjusted cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity (deficit) by \$ million, assuming the assumed initial public offering price of \$ per share remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Working capital is defined as total current assets less total current liabilities. See our consolidated financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

(4)

### **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, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus, 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 and began commercializing our products in 2016. 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 U.S. Food and Drug Administration, or FDA, 510(k) clearance or premarket approval, 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 March 31, 2020, we have sold our products directly in the United States, Belgium, the Czech Republic, Denmark, France, Germany, Great Britain, Italy, the Netherlands 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 three months ended March 31, 2020 and the years ended December 31, 2019 and December 31, 2018, 51%, 74% and 79%, 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 of 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 2019, our headcount increased by 67%, and we released five new disposable products, two hardware products, including a major generational update to our AcQMap System, and 15 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 nob 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 produce economically, successfully commercialized or widely accepted in the marketplace. The expenses or losses associated with unsuccessful pro

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.

While third-party payors currently cover and provide reimbursement for procedures using our currently cleared or approved products, we can give no assurance that these third-party payors will continue to provide

coverage and adequate reimbursement for the procedures using our products, to permit hospitals and doctors to offer procedures using our products to patients requiring treatment, or that current reimbursement levels for procedures using our products will continue. If sufficient coverage and reimbursement is not available for the procedures using our products, in either the United States or internationally, the demand for our products and our revenue will be adversely affected. Furthermore, although we believe there is potential to improve on the current reimbursement profile for our products in the future, the overall amount of reimbursement available for procedures intended to diagnose and treat complex heart arrhythmias could remain at current levels or decrease in the future. Failure by hospitals and other users of our products to obtain and maintain coverage and adequate reimbursement for the procedures using our products would materially adversely affect our business, financial condition and results of operations.

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

# Our operations and financial results have been, and will continue to be, adversely impacted by the COVID-19 pandemic in the United States and the rest of the world.

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

The COVID-19 pandemic and the measures imposed to contain this pandemic disrupted and are expected to continue to impact our business. For example, 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 may impact certain of our operations over the near term and long term. Moreover, beginning in March 2020, access to hospitals and other customer sites has been restricted to essential personnel, which has 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. Moreover, hospitals and other therapeutic centers have suspended many elective procedures, resulting in a significantly reduced volume of procedures using our products. In addition, all clinical trials in Europe have been suspended with follow-ups for clinical trials done via telecom, and we believe enrollment timing in our planned clinical trials will be slowed due to COVID-19 driven delayed access to enrollment sites. As the COVID-19 pandemic continues to spread around the globe, the impact may be prolonged and we may experience additional disruptions that could severely impact our business, including:

• significant interruptions to, or temporary closures of, our operations, including our manufacturing facility or our commercial organization;

- adverse effects of the COVID-19 pandemic on macroeconomic conditions as well as within the economies and financial markets of specific regions in which our products are marketed;
- continued depressed demand for installations of our AcQMap console and workstation and for our disposable products during a prolonged delay in physicians performing elective procedures using our products, or due to focusing their resources elsewhere;
- continued or increased delays or difficulties in enrolling patients in our clinical trials or the interruption or delay of key clinical trial activities, such as clinical trial site monitoring, due to limitations on access to trial sites or limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in resources that would otherwise be focused on the conduct of our business, including because of sickness or the desire to avoid contact with large groups of people or as a result of government-imposed shelter-in-place or similar working restrictions;
- difficulties in recruitment of qualified sales and marketing personnel and mappers during a period in which we are seeking to significantly expand our commercial organization; and
- interruption in global shipping that may affect the shipment of our products or the transport of clinical trial materials.

We are still assessing the impact that COVID-19 may have on our ability to effectively conduct our business operations as planned and there can be no assurance that we will be able to avoid a material impact on our business from the spread of COVID-19 or its consequences, including disruption to our business and downturns in business sentiment generally or in our industry. As a result of the interruptions to our business due to COVID-19, we have enacted a cash conservation program, which includes delaying certain non-critical capital expenditures and other projects, implementing a hiring freeze and temporary compensation and headcount reductions throughout our organization.

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 global outbreak of COVID-19 continues to rapidly evolve. The magnitude of the impact of the COVID-19 pandemic on our productivity, results of operations and financial position, and its disruption to our business and our clinical programs and timelines, will depend, in part, on the length and severity of these restrictions and on our ability to conduct business in the ordinary course.

# 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 2019 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 53% and 65% of our revenue in 2019, 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 facilities become 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 2022, 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 facilities;
- 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 facilities 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 approval at each site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials.

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

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

- enrollment in our clinical trials may be slower than we anticipate, or we may experience high screen failure rates in our clinical trials, resulting in significant delays;
- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing which may be expensive and time-consuming;
- trial results may not meet the level of statistical significance required by the FDA or other regulatory authorities;

- the FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans;
- the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;
- there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities;
- there may be delays in obtaining institutional review board 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 institutional review boards, 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.

#### 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.

#### 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 system and product line and Qubic Force device from Biotronik pursuant to the Biotronik License Agreement. However, we have limited experience in acquiring other businesses, products or technologies. The process of integrating an acquired company, business or technology may create unforeseen operating challenges, risks and expenditures, including that the acquisitions do not advance our corporate strategy, that we get an unsatisfactory return on our investment, that the acquisitions distract management, or that we may have difficulty: (i) integrating an acquired company's accounting, financial reporting, management information and information security, human resource and other administrative systems to permit effective management; (ii) integrating the controls, procedures and policies at companies we acquire into our internal control over financial reporting; and (iii) transitioning the acquired company's operations, suppliers and customers to us. It may take longer than expected to realize the full benefits from these acquisitions, such as increased revenue, enhanced efficiencies or increased market share, or the benefit may ultimately be smaller than we expected. Moreover, if any of our acquisitions or investments increase our international operations, it would expose us to additional risks relating to operating outside the United States, including increased operational and regulatory risks. Our failure to address these risks or other problems encountered in connection with our past or future acquisitions and investments could cause us to fail to realize the anticipated benefits of such acquisitions or investments, incur unanticipated liabilities and harm our business generally. If an acquired business, product or technology fails to meet our expectations or results in unanticipated costs and expenses, our business, financial condition and results of operations may suffer.

We also cannot assure you that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product or technology in a cost-effective and non-disruptive manner. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment. In addition, under our Credit Agreement, dated as of May 20, 2019, with the lenders from time to time party thereto, Wilmington Trust, National Association, as administrative agent, and OrbiMed Royalty Opportunities II, LP, or ORO II, as origination agent, or the 2019 Credit Agreement, we may require the prior written consent of such agents and the required lenders prior to consummating any acquisition or investment.

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

# The terms of our 2019 Credit Agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

On May 20, 2019, we entered into the 2019 Credit Agreement. The 2019 Credit Agreement provided us with a senior term loan facility in aggregate principal amount of \$70.0 million, of which \$40.0 million in aggregate principal amount is outstanding as of March 31, 2020. Of the remaining \$30.0 million, \$20.0 million is

available for borrowing by us on or prior to December 31, 2020, subject to our achievement of specified trailing revenue levels, and \$10.0 million will no longer be available for borrowing as of June 30, 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 three months ended March 31, 2020 and the years ended December 31, 2019 and 2018, approximately 51%, 74% and 79%, 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, 2019, we had U.S. federal and state net operating loss, or NOL, carryforwards of approximately \$199.9 million and \$32.5 million, respectively. We may use these NOLs to offset against taxable income for U.S. federal and state income tax purposes. If not utilized, our U.S. federal NOLs (and our state NOLs in conforming states) arising in taxable years beginning before 2018 will begin to expire in 2031. Deductibility of U.S. federal NOLs arising in taxable years beginning after 2017 and used in taxable years beginning after 2020 is limited to 80% of our taxable income before the deduction for such NOLs. Additionally, Section 382 of the Internal Revenue Code of 1986, as amended, may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We have not conducted a 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.

#### 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 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 everincreasing 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.

# 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 and Massachusetts, 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 it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. State laws and regulations are not necessarily preempted by the Health Insurance Portability and Accountability Act of 1996, or HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, we have to comply with the stricter provisions. In addition tas been misused. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity and liability. Legal requirements relating to the collection, storage, handling, and transfer of personal information and personal data continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement, sanctions and increased costs of compliance.

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 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 these laws, it may lead to regulatory enforcement actions, which can result in monetary penalties of up to  $\xi$ 20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties.

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.

#### 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.

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

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

### Risks Related to Our Financial Position and Need for Additional Capital

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

We have incurred net losses since our inception in March 2011. For the three months ended March 31, 2020 and the year ended December 31, 2019, we had a net loss of \$18.1 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 we expect to continue to incur additional net losses for at least the next several years. As a result of these losses, as of March 31, 2020 and December 31, 2019, we had an accumulated deficit of \$277.1 million and \$259.0 million, respectively. Prior to this offering, 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 businesses 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 or that, if operations 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, 2020 and December 31, 2019, we had \$49.9 million and \$71.8 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.

# The report of our independent registered public accounting firm for the year ended December 31, 2019 includes a "going concern" explanatory paragraph.

The report of our independent registered public accounting firm on our consolidated financial statements as of and for the year ended December 31, 2019 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. If we are unable to raise sufficient capital when needed, our business, financial condition and results of operations will be materially and adversely affected, and we will need to significantly modify our operational plans to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements. The inclusion of a going concern explanatory paragraph by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

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

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

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

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

- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals 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 approval.

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, untiled 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 to customers, may not in all cases meet all of the criteria for statutory exception or regulatory safe harbor protection from anti-kickback liability. In October 2019, the federal government published two proposed regulations that would create 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; even if these regulations are eventually finalized, the impact of the proposed regulations on our operations is not yet clear.
- federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or

fraudulent claim for purposes of the federal civil False Claims Act. Actions under the federal civil False Claims Act may be brought by the government or as a qui tam action by a private individual in the name of the government. These individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial financial settlements with the federal government under the federal civil False Claims Act for a variety of alleged improper activities, including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non-reimbursable uses and interactions with prescribers and other customers, including those that may have affected their billing or coding practices and submission of claims to the federal government. Federal civil False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory monetary penalties for each false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and medical device companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings.

- HIPAA, which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;
  - HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or 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 that perform certain services for them or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We believe we are not a covered entity or typically a business associate for purposes of HIPAA;

the federal Physician Payments Sunshine Act, also known as Open Payments, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions, to the CMS information related to payments or other "transfers of value" made to physicians, as defined by such law, 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, certified nurse anesthetists and certified nurse-midwives; and

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

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

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

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If we or our employees are found to have violated any of the above laws, we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. 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. 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. Defending against any such actions can be costly, time-consuming and may require significant personnel resources, and may have a material adverse effect on our business, financial condition and results of operations.

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

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

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

There remain judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act, and we

expect such challenges and amendments to continue. For example, since January 2017, President Trump has 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 has 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, includes a provision repealing, 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." In December 2018, CMS published a new final rule further permitting collections and payments to and from certain Affordable Care Act gualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the TCJA. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall of 2020.

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. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030 unless additional Congressional action is taken. 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 and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control product costs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability.

Various new healthcare reform proposals are emerging at the federal and state level. It is also possible that additional governmental action is taken to address the COVID-19 pandemic. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

We are subject to numerous, and sometimes conflicting, legal regimes in the countries in which we operate, including on matters as diverse as health and safety standards, marketing and promotional activities, anticorruption, import/export controls, content requirements, trade restrictions, tariffs, taxation, sanctions, immigration, internal and disclosure control obligations, securities regulation, anti-competition, data privacy and labor relations. This includes in emerging markets where legal systems may be less developed or familiar to us. We strive to abide by and maintain compliance with these laws and regulations. Compliance with diverse legal requirements is costly, time-consuming and requires significant resources. Violations of one or more of these

regulations in the conduct of our business could result in significant fines, criminal sanctions against us or our officers, prohibitions on doing business and damage to our reputation. Violations of these regulations in connection with the performance of our obligations to our customers also could result in liability for significant monetary damages, fines and/or criminal prosecution, unfavorable publicity and other reputational damage, restrictions on our ability to process information and allegations by our customers or distributors that we have not performed our contractual obligations. Due to the varying degrees of development of the legal systems of the countries in which we operate, local laws might be insufficient to protect our rights.

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

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

Material modifications to the intended use or technological characteristics of any of our products will require new 510(k) clearances, premarket approvals or CE Mark grants, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA cleared device or service that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

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

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

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

If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall

which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

In addition, we are subject to medical device reporting regulations that require us to report to the FDA or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction recurred. Failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to the FDA's satisfaction, can subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

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

Under 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 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 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 or sell access to our solutions would likely adversely affect our business.

We have implemented policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, the U.K. Bribery Act, 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, 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 is the patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag

behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

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

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

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

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

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

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

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

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

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

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks and competing technologies, may have applied for or obtained, or may in the

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

Even if we believe 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 proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. Uncertainties resulting from the initiation and continuation of patent and other intellectual property litigation or other proceedings could have a material adverse effect on our business, financial condition and results of operations.

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

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

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

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

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

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

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

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect and some courts are less willing or unwilling to protect trade secrets. To

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

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

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

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

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

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trademarks and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and trademarks at risk of being invalidated or interpreted narrowly and our patent or trademark applications at risk, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, many countries, including India, China and certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property

rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

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

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

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

Recent 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 recently 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**

# There has been no prior market for our common stock, the market price for our common stock may be volatile or may decline regardless of our operating performance, an active public trading market may not develop or be sustained following this offering, and you may not be able to resell our common stock at or above the initial public offering price.

There has been no public market for our common stock prior to this offering. The initial public offering price for our common stock will be determined through negotiations between the underwriters and us and may vary from the market price of our common stock following this offering. You may not be able to resell your shares at or above the initial public 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 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 or 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.

Although we intend to apply to list our common stock on The Nasdaq Global Market, we cannot assure you that a trading market for our common stock will develop, or, if a trading market does develop, that it 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.

# 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.

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

The market price of our common stock may be 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.

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

The initial 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 , 2020 and upon the issuance and sale of shares of common stock by us at the assumed initial public offering price of \$ per share (which is the midpoint of the estimated price range set forth on the cover page of this prospectus) if you purchase our common stock in this offering, you will suffer immediate dilution of approximately \$ 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 future dilution. A total of shares of common stock have been reserved for future issuance under our stock-based compensation plans, including our 2020 Plan and our 2020 ESPP. 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."

# 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 articles of incorporation that will be in effect immediately prior to the completion of this offering authorize us to issue up to shares of our common stock and up to shares of preferred stock with such rights and preferences as included in our 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 for up to five years following the completion of this offering. 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
- the last day of the fiscal year ending after the fifth anniversary of the completion of this offering.

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 of our second fiscal quarter.

# 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 will rely 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.

# 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 will continue to have substantial influence over us after this offering 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 March 31, 2020, our directors, executive officers and holders of more than 5% of our common stock beneficially owned, as a group, 73.7% 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, approximately % 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 March 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 consummation 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, except that any shares held by our affiliates, as that term is defined under Rule 144 of the Securities Act, or Rule 144, including our directors, executive officers and other affiliates, may be sold only in compliance with the limitations described in the section titled "Shares Eligible for Future Sale."

The shares held by certain directors and officers and their affiliates immediately following the consummation of this offering will represent approximately % of our total outstanding shares of common stock following this offering, based on the number of shares outstanding as of March 31, 2020. Such shares will be "restricted securities" within the meaning of Rule 144 and subject to certain restrictions on resale following the consummation of this offering. Restricted securities may be sold in the public market only if they are registered under the Securities Act or are sold pursuant to an exemption from registration such as Rule 144, as described in the section titled "Shares Eligible for Future Sale."

In connection with this offering, we, our directors and executive officers, and holders of substantially all of our common stock prior to this offering 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 180 days after the date of this prospectus, except with the prior written consent of certain representatives of the underwriters. See the section titled "Underwriting" for a description of these lock-up agreements.

Upon the expiration of the contractual lock-up agreements pertaining to this offering, up to an additional shares will be eligible for sale in the public market, of which are held by directors, executive officers and other affiliates and 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 approximately % 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 2020 Plan and our 2020 ESPP 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 shares of our common stock and shares of our common stock have been reserved for future issuance under our 2020 Plan and our 2020 ESPP, 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.

# 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.

As a public company, we will be 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 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 and in this prospectus, our business and financial condition will 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.

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

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

#### 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 ablation catheters and Qubic Force device 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."

# 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. If we are not able to remediate the material weakness and otherwise 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 will 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.

In connection with the audits of our consolidated financial statements included elsewhere in this prospectus, we and our independent registered public accounting firm identified a material weakness related to our financial statement closing process, primarily related to a lack of appropriately designed and implemented controls over the review and approval of manual journal entries and the related supporting journal entry calculations. Under standards established by the Public Company Accounting Oversight Board, a material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected and corrected on a timely basis.

We are working to remediate the material weakness and are taking steps to strengthen our internal control over financial reporting. In order to do so, we have taken and plan to take the following actions: (i) the hiring of additional finance and accounting personnel over time to augment our accounting staff and to provide more resources for complex accounting matters and financial reporting; and (ii) further developing and implementing formal policies, processes and documentation procedures relating to our financial reporting. The actions that we

are taking are subject to ongoing executive management review, and will also be subject to audit committee oversight. If we are unable to successfully remediate the material weakness, or if in the future, we identify further material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated.

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. 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 the second annual report following the completion of this offering. 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 will be 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.

# Our amended and restated bylaws that will become effective immediately prior to the completion of this offering 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 that will become effective immediately prior to the completion of this offering 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 will be authorized to issue and designate shares of our preferred stock in additional series without stockholder approval.

Our amended and restated certificate of incorporation will authorize 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.

## SPECIAL NOTES REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements 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 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," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "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 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 forwardlooking statements in this prospectus 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. 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. 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 that we reference in this prospectus and have 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.

# MARKET, INDUSTRY AND OTHER DATA

This prospectus contains 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. 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 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.

# **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.

# **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), based on the assumed initial public offering price of \$ per share (which is the midpoint of the estimated price range set forth on the cover page of this prospectus) and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) 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 estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by \$ million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering price or the number of shares by these amounts would have a material effect on our uses of the 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 to support the conduct of our ongoing clinical trials, 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.

# CAPITALIZATION

The following table sets forth our cash, cash equivalents and marketable securities and capitalization as of March 31, 2020 on:

- an actual basis;
- a pro forma basis, giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 161,155,827 shares of our common stock immediately prior to the completion of this offering, as if such conversion had occurred on March 31, 2020, (ii) the automatic conversion of all outstanding warrants to purchase shares of our convertible preferred stock into warrants to purchase shares of our common stock, and the related reclassification of our common and preferred stock warrant liability to stockholders' equity (deficit) immediately prior to the completion of this offering, and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, which will be in effect immediately prior to the completion of this offering; and
- a pro forma as adjusted basis to give further effect to our issuance and sale of shares of common stock in this offering at the assumed initial public offering price of \$ per share (which is the midpoint of the estimated price range set forth on the cover page of this prospectus) and after deducting the estimated 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 included elsewhere 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."

	A		
(in thousands, except share and per share data)	Actual	<u>Pro Forma</u> (unaudited)	Pro Forma <u>As Adjusted</u>
Cash, cash equivalents and marketable securities	\$ 49,880	\$	\$
Long-term debt	\$ 38,398	\$	\$
Common and preferred stock warrant liability	8,338		
Convertible preferred stock, \$0.001 par value per share; 172,064,796 shares authorized, 161,155,827 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro			
forma as adjusted	260,555	—	
Stockholders' equity (deficit):			
Preferred stock, \$0.001 par value per share; no shares authorized, issued or outstanding, actual; shares authorized, pro forma and pro forma as adjusted; no shares issued or outstanding, pro			
forma and pro forma as adjusted	—	_	_
Common stock, \$0.001 par value per share; 220,000,000 shares authorized, 6,912,957 shares issued and outstanding, actual; shares authorized, shares issued and outstanding, pro forma;			
shares authorized, shares issued and outstanding, pro forma as adjusted	7		
Additional paid-in capital	34,987		
Accumulated deficit	(277,132)		
Accumulated other comprehensive (loss) income	(84)		
Total stockholders' equity (deficit)	(242,222)		
Total capitalization	\$ 65,069	\$	\$

The pro forma 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 (decrease) in the assumed initial public offering price of \$ per share (which is the midpoint of the estimated price range set forth on the cover page of this prospectus) would increase (decrease) each of our pro forma as adjusted cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders' equity (deficit) and total capitalization 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 estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares of common stock offered by us would increase (decrease) each of our pro forma as adjusted cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by \$ million, assuming the assumed initial public offering price of \$ per share remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimate deducting the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters' option to purchase additional shares is exercised in full, our pro forma as adjusted cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders' equity (deficit), total capitalization and shares outstanding as of March 31, 2020 would be \$ million, \$ million, \$ million and , respectively.

The number of shares of common stock that will be outstanding after this offering on a pro forma and pro forma as adjusted basis is based on 168,068,784 shares of our common stock (including all shares of our convertible preferred stock on an as-converted basis) outstanding as of March 31, 2020, and excludes:

- 4,955,017 shares of our common stock issuable upon the exercise of warrants to purchase shares of our common stock outstanding as of March 31, 2020, with a weighted-average exercise price of \$0.02 per share;
- 4,346,557 shares of our common stock issuable upon the exercise of warrants to purchase shares of convertible preferred stock outstanding as of March 31, 2020, which will be automatically converted into warrants to purchase shares of our common stock immediately prior to the completion of this offering, with a weighted-average exercise price of \$1.714 per share;
- 26,704,989 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of March 31, 2020, with a weighted-average exercise price of \$1.13 per share;
- 5,518,463 shares of our common stock issuable upon the vesting and settlement of outstanding RSUs as of March 31, 2020, of which units will vest upon the effectiveness of the registration statement of which this prospectus forms a part; and
  - shares of our common stock reserved for future grants under our stock-based compensation plans, consisting of:
  - 2,970,421 shares of our common stock reserved for future grants under our 2011 Plan, which shares will be added to the shares to be reserved under our 2020 Plan, which will become effective immediately prior to the effective date of this registration statement,
  - shares of our common stock reserved for future grants under our 2020 Plan, which will become effective immediately prior to the effective date of this registration statement, including shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted to certain of our executive officers, directors and new employees pursuant to our 2020 Plan, with a grant date of the effective date of this registration statement and with an exercise price equal to the initial public offering price, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to this plan, and

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shares of our common stock reserved for future issuance under our 2020 ESPP, which will become effective immediately prior to the effective date of this registration statement, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to this plan.

#### 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 initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of March 31, 2020 was \$(258.2) million, or \$(37.36) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and convertible preferred stock, which is not included within our stockholders' equity (deficit). Historical net tangible book value per share represents historical net tangible book value (deficit) divided by the number of shares of our common stock outstanding as of March 31, 2020.

Our pro forma net tangible book value as of March 31, 2020 was \$ million, or \$ per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 161,155,827 shares of our common stock immediately prior to the completion of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of March 31, 2020, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 161,155,827 shares of our convertible preferred stock into an aggregate of 161,155,827 shares of our convertible preferred stock into an aggregate of 161,155,827 shares of our common stock immediately prior to the completion of this offering.

After giving further effect to our sale of shares of common stock in this offering at the assumed initial public offering price of \$ per share (which is the midpoint of the estimated price range set forth on the cover page of this prospectus) and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of million, or approximately \$ per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$ to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors purchasing common stock in this offering price per share paid by new investors.

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

\$
\$

The dilution information discussed above is illustrative only and may change based on the actual initial public offering price and other terms of this offering. Each \$1.00 increase in the assumed initial public offering price of \$ per share (which is the midpoint of the price range set forth on the cover page of this prospectus) would increase our pro forma as adjusted net tangible book value by \$ per share and the dilution per share to

new investors 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 estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each \$1.00 decrease in the assumed initial public offering price of \$ per share would decrease our pro forma as adjusted net tangible book value by \$ per share and the dilution per share to new investors 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 estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each increase of 1.0 million in the number of shares of common stock offered by us would increase our pro forma as adjusted net tangible book value by \$ per share and the dilution per share to new investors in this offering by \$ per share, assuming the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each decrease of 1.0 million in the number of shares of common stock offered by us would decrease our pro forma as adjusted net tangible book value by \$ per share and the dilution per share to new investors in this offering by \$ per share, assuming the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of March 31, 2020, on a pro forma as adjusted basis as described above, the difference between existing stockholders and investors purchasing shares in this offering with respect to the number of shares of common stock purchased from us, the total consideration paid to us, and the weighted-average price per share paid, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Pu	urchased	Total Cons	deration	Weighted- Average Price Per
	Number	Percent	Amount	Percent	Share
Existing stockholders before this offering		%	\$	%	\$
Investors purchasing shares in this offering					\$
Total		100.0%	\$	100.0%	

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, the number of shares of our common stock held by existing stockholders would be reduced to % of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in the offering would be increased to % of the total number of shares outstanding after this offering.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share (which is the midpoint of the estimated price range set forth on the cover page of this prospectus) would increase (decrease) the total consideration paid by new investors by \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) the total consideration paid by new investors by \$ million, assuming no change in the assumed initial public offering price.

The foregoing tables and calculations (other than the historical net tangible book value calculation) are based on the 168,068,784 shares of our common stock (including all shares of our convertible preferred stock on an as-converted basis) outstanding as of March 31, 2020, and excludes:

4,955,017 shares of our common stock issuable upon the exercise of warrants to purchase shares of our common stock outstanding as of March 31, 2020, with a weighted-average exercise price of \$0.02 per share;

- 4,346,557 shares of our common stock issuable upon the exercise of warrants to purchase shares of convertible preferred stock outstanding as of March 31, 2020, which will be automatically converted into warrants to purchase shares of our common stock immediately prior to the completion of this offering, with a weighted-average exercise price of \$1.714 per share;
- 26,704,989 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of March 31, 2020, with a weighted-average exercise price of \$1.13 per share;
- 5,518,463 shares of our common stock issuable upon the vesting and settlement of outstanding RSUs as of March 31, 2020, of which units will vest upon the effectiveness of the registration statement of which this prospectus forms a part; and
  - shares of our common stock reserved for future grants under our stock-based compensation plans, consisting of:
  - 2,970,421 shares of our common stock reserved for future grants under our 2011 Plan, which shares will be added to the shares to be reserved under our 2020 Plan, which will become effective immediately prior to the effective date of this registration statement,
    - shares of our common stock reserved for future grants under our 2020 Plan, which will become effective immediately prior to the effective date of this registration statement, including shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted to certain of our executive officers, directors and new employees pursuant to our 2020 Plan, with a grant date of the effective date of this registration statement and with an exercise price equal to the initial public offering price, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to this plan, and
    - shares of our common stock reserved for future issuance under our 2020 ESPP, which will become effective immediately prior to the effective date of this registration statement, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to this plan.

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.

## SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth our selected historical consolidated financial data as of and for the periods indicated. We have derived the selected consolidated statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2018 and the consolidated balance sheet data as of December 31, 2019 and 2018 from our audited consolidated financial statements included elsewhere in this prospectus. We have derived the selected consolidated statements of operations and comprehensive loss data for the three months ended March 31, 2020 and 2019 and the consolidated balance sheet data as of March 31, 2020 from our unaudited interim consolidated financial statements included elsewhere in this prospectus. You should read this data together with our consolidated financial statements and related notes included elsewhere in this prospectus and the information in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The selected 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 elsewhere in this prospectus 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, 2020.

	Three Months Ended March 31,			Year End December				
(in thousands, except share and per share data)		2020 (unau	dited)	2019		2019		2018
Consolidated Statements of Operations and Comprehensive Loss Data:	(unuutred)							
Revenue(2)	\$	1,583	\$	787	\$	2,836	\$	2,166
Costs and operating expenses:								
Cost of products sold <sup>(1)</sup>		3,194		2,176		9,243		7,510
Research and development <sup>(1)</sup>		7,973		4,377		23,029		19,077
Research and development—license acquired		—				15,000		—
Selling, general and administrative(1)		10,235		4,093		26,847		13,330
Impairment of property and equipment		—		—		786		—
Change in fair value of contingent consideration		(2,219)				500		
Total costs and operating expenses		19,183		10,646		75,405		39,917
Loss from operations		(17,600)		(9,859)		(72,569)		(37,751)
Other income (expense):								
Change in fair value of warrant liability and embedded derivative		581		841		(1,919)		(4,298)
Loss on issuance of convertible notes and warrants		—				—		(924)
Loss on debt extinguishment		—				(1,447)		—
Interest income		275		65		1,164		297
Interest expense		(1,354)	_	(5,742)		(22,268)		(5,231)
Total other income (expense), net		(498)		(4,836)		(24,470)		(10,156)
Loss before income taxes		(18,098)		(14,695)		(97,039)		(47,907)
Income tax benefit		_		_		_		_
Net loss	\$	(18,098)	\$	(14,695)	\$	(97,039)	\$	(47,907)
Net loss per common share, basic and diluted(3)	\$	(2.66)	\$	(2.30)	\$	(14.85)	\$	(9.03)
Weighted-average shares outstanding, basic and diluted(3)	6,	812,226	6	,385,612	6	6,534,469	5	,307,392
Pro forma net loss per common share, basic and diluted (unaudited)(3)	\$				\$			
Pro forma weighted-average shares outstanding, basic and diluted (unaudited)(3)					_			

(1) The following table sets forth the stock-based compensation expense included in our consolidated results of operations for the three months ended March 31, 2020 and 2019 and the years ended December 31, 2019 and 2018:

	1	Three Months Ended March 31,			Year Ended December 31,			
(in thousands)		2020	2	019		2019		2018
		(unaud	lited)					
Cost of products sold	\$	108	\$	52	\$	209	\$	215
Research and development		211		142		656		564
Selling, general and administrative		1,422		365		2,129		1,292
Total stock-based compensation expense	\$	1,741	\$	559	\$	2,994	\$	2,071

(2) The following table sets forth our revenue for disposables and systems/service for the three months ended March 31, 2020 and 2019 and the years ended December 31, 2019 and 2018:

	Three Months Ended March 31,			Year E Decemb				
(in thousands)		2020	2	019		2019		2018
	(unaudited)							
Disposables	\$	1,057	\$	782	\$	2,817	\$	2,160
Systems/service		526		5		19		6
Total revenue	\$	1,583	\$	787	\$	2,836	\$	2,166

(3) See Note 16 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per common share, basic and diluted pro forma net loss per common share and the weighted-average number of shares used in the computation of the per share amounts.

	As of March 31,	As of Dec	ember 31,
	<u>2020</u> (unaudited)	2019	2018
(in thousands)	. ,		
Consolidated Balance Sheet Data:			
Cash, cash equivalents and marketable securities	\$ 49,880	\$ 71,803	\$ 17,745
Working capital (deficit) <sup>(1)</sup>	38,363	50,546	(2,923)
Total assets	87,106	105,455	25,948
Contingent consideration, short- and long-term	6,900	13,900	
Common and preferred stock warrant liability	8,338	8,919	6,842
Long-term debt	38,398	38,244	14,591
Convertible preferred stock	260,555	253,358	118,319
Accumulated deficit	(277,132)	(259,034)	(161,995)
Total stockholders' deficit	(242,222)	(225,811)	(131,824)

(1) Working capital (deficit) is defined as total current assets less total current liabilities. See our consolidated financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

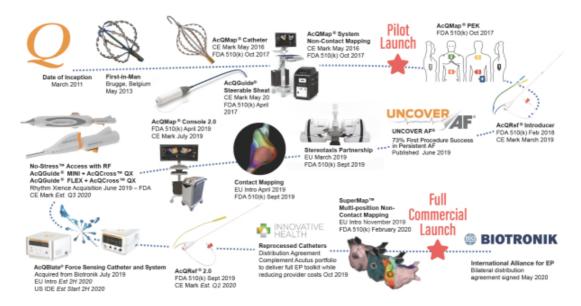
#### Overview

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

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

We were incorporated in the State of Delaware on March 25, 2011 and are headquartered in Carlsbad, California. Early versions of our AcQMap System and certain related accessory products have been used in the United States since May 2018 and Western Europe since July 2016 in a limited, pilot launch capacity, where our focus was on optimizing workflow and validating our value proposition. We fully commenced the launch of our commercial-grade console and software products in the first quarter of 2020. Critical to our launch were a series of recent strategic transactions and regulatory approvals, including: FDA 510(k) clearance and CE Mark of our second-generation AcQMap console and SuperMap software suite; the addition of an integrated family of transseptal crossing and steerable introducer systems to our product portfolio through our acquisition of Rhythm Xience, Inc., or Rhythm Xience; and the acquisition of our AcQBlate Force sensing product line from Biotronik SE & Co. KG, or 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:



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

As of June 23, 2020, our commercial organization consisted of 60 individuals with substantial applicable medical device, sales and clinical experience, including sales managers, sales representatives and mappers. 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.

Our revenue has historically consisted predominantly of sales of our disposable products (principally our mapping catheters 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 purchase. In addition, we have also generated a small portion of our revenue from service agreements with our customers.

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. In addition, 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 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, radiofrequency, or RF, generators and irrigation pumps, Innovative Health for reprocessed diagnostic catheters and MedFact for robotic navigation enabled ablation catheters.

As of March 31, 2020, we have completed three clinical trials that collectively evaluated 223 subjects across 16 centers in multiple countries. 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 investigational device exemption, or IDE, trials to support regulatory approval of our AcQBlate Force ablation catheters. Our ongoing and planned trials are anticipated to involve an aggregate of over 700 subjects in at least 35 centers in the United States and internationally. We expect to provide data readouts from these ongoing and planned trials at various points in time through 2023.

For the three months ended March 31, 2020 and the year ended December 31, 2019, we generated revenue of \$1.6 million and \$2.8 million, respectively, of which 51% and 74%, respectively, was from customers located outside of the United States. Since our inception, we have generated significant losses. Our net loss was \$18.1 million and \$97.0 million for the three months ended March 31, 2020 and the year ended December 31, 2019 (which included \$15.0 million in payments attributable to the product line we acquired from Biotronik pursuant to the Biotronik License Agreement), respectively. As of March 31, 2020 and December 31, 2019, we had an accumulated deficit of \$277.1 million and \$259.0 million, respectively, and working capital of \$38.4 million and \$50.5 million, respectively. Prior to this offering, 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.

We intend to continue to make significant investments in our sales and marketing organization. We believe increasing the number of sales representatives and expanding our international marketing programs will help facilitate further adoption of our products among existing customer accounts as well as broaden awareness of our products to new accounts. We also expect to continue to make substantial investments in our ongoing clinical trials and in additional clinical trials that are designed to provide clinical evidence of the safety and effectiveness of our existing and future generations of products. We expect to continue to make investments in research and development and regulatory affairs to develop future generations of products based on our technology, supported with appropriate regulatory submissions. We 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. We will also incur costs as a public company that we have not previously incurred or have previously incurred at lower rates, including increased costs for employee-related expenses, director and officer insurance premiums, audit and legal fees, investor relations fees, fees to members of our board of directors and expenses for compliance with public-company reporting requirements under the Exchange Act and rules implemented by the SEC, as well as Nasdaq rules. Because of these and other factors, we expect to continue to incur substantial net losses and negative cash flows from operations for at least the next several years.

#### **Biotronik Agreements**

#### **Biotronik License Agreement**

In July 2019, we entered into the Biotronik License Agreement with Biotronik and VascoMed GmbH, or VascoMed (who we refer to together as the Biotronik Parties), whereby we acquired certain manufacturing equipment and obtained from the Biotronik Parties a license under certain patents and technology to develop, commercialize, distribute and manufacture our AcQBlate Force ablation catheters and Qubic Force device. We refer to this transaction as the Biotronik Asset Acquisition. Pursuant to the Biotronik License Agreement, we paid Biotronik a \$3.0 million upfront fee at the time the agreement was signed, as well as a technology transfer fee consisting of \$7.0 million in cash in December 2019 and \$5.0 million in shares of our Series D convertible preferred stock in February 2020.

The Biotronik License Agreement also requires that we pay the Biotronik Parties certain milestone payments as follows: (i) \$2.0 million upon receipt of marketing approval for the sale of our AcQBlate Force ablation catheters in Europe; (ii) \$5.0 million upon the receipt of marketing approval for the sale of our AcQBlate Force ablation catheters; and (iii) \$3.0 million upon the first commercial sale of our AcQBlate Force ablation catheters in the United States; and (iii) \$3.0 million upon the first commercial sale of our AcQBlate Force 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 ablation catheters following commercialization.

#### **Bi-Lateral Distribution Agreements**

In May 2020, we entered into more expansive bi-lateral distribution agreements with Biotronik. We refer to these agreements as the Bi-Lateral Distribution Agreements and our relationship with Biotronik as the Acutus/Biotronik Global Alliance for Electrophysiology. 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 a term of up to five years commencing on the date of regulatory approval if we cover the cost of the 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 in each of the foregoing territories under our own private label.

Pursuant to the Bi-Lateral Distribution Agreements, Biotronik has also agreed to distribute our products, including our AcQMap System, our Qubic Force device and our disposable products (including our AcQBlate Force catheters) and accessories in Germany, Japan, Mexico, Switzerland and multiple countries in Asia-Pacific, Eastern Europe, the Middle East and South America. We also granted Biotronik a co-exclusive right to 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. Each party will pay to the other party specified transfer prices on the sale of the other party's products under the Bi-Lateral Distribution Agreements and, accordingly, will earn a distribution margin on the sale of the other party's products.

For a further description of our agreements with Biotronik, see the section titled "Business—Biotronik Agreements."

#### **Key Business Metric**

We regularly review a number of operating and financial metrics, including the following key business metric, to evaluate our business, measure our performance, identify trends affecting our business, formulate financial projections and make strategic decisions. We believe that the following metric is representative of our

current business. However, we anticipate this metric may change or may be substituted for additional or different metrics as our business grows and as we introduce new products.

#### **Installed Base**

Once an AcQMap console and workstation is established in a customer account, our revenue from that account becomes predominantly recurring in nature and derived from the sale of our portfolio of disposable products used with our system. We believe our installed base is one of the key indicators of our ability to drive customer adoption of our products. We define our installed base as the cumulative number of AcQMap consoles and workstations placed into service at customer sites, all of which to date were originally placed without charge to the customer. 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 purchase. Our installed base as of March 31, 2020 and 2019 and December 31, 2019 and 2018 is set forth in the table below:

		As of					
	N	larch 31,	Decemb	er 31,			
	2020	2020 2019		2018			
Installed base:							
United States	13	6	10	5			
International	18	17	17	16			
Total	31	23	27	21			

Growth in our quarterly installed base can fluctuate due to a number of factors, including the commercial effectiveness of our sales representatives and strategic partners such as Biotronik, and the procurement and budgeting cycles of many of our customers, especially those where unused funds may be forfeited or future budgets may be reduced if purchases are not made by their fiscal year end. We also believe the timing of installations has been impacted and will continue to be impacted by the timing of product introductions and transitions. In addition, the growth of our market in certain geographic regions and our continued efforts to service these regions impact unit volumes quarter to quarter.

#### **Factors Affecting Our Performance**

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

- *Market Acceptance*. The growth of our business will depend substantially on our ability to increase our installed base. Once an AcQMap console and workstation is established in a customer account, our revenue from that account becomes predominantly recurring in nature and derived from the sale of our portfolio of disposable products used with our system. Our ability to increase our installed base will depend on our ability to gain broader acceptance of our AcQMap System by continuing to make physicians and other hospital staff aware of the benefits of the AcQMap System, thereby generating increased demand for system installations and the frequency of use of our disposable products. Although we are attempting to increase our installed base through our established relationships and focused sales efforts, we cannot provide assurance that our efforts will be successful.
  - **Commercial Organization Size and Effectiveness.** As of June 23, 2020, our commercial organization consisted of 60 individuals with substantial applicable medical device, sales and clinical experience, including sales managers, sales representatives and mappers. We intend to continue to make significant investments in our commercial organization by increasing the number of our sales representatives, sales managers and mappers, as well as by expanding our global marketing and training programs, to

help facilitate further adoption of our products among existing and new customer accounts. The rate at which we grow our commercial organization and the speed at which newly hired personnel become effective can impact our revenue growth or our costs incurred in anticipation of such growth.

*Strategic Partnerships and Acquisitions*. We have in the past, and may in the future, enter into strategic partnerships and acquire complementary businesses, products or technologies. For example, we have entered into strategic partnerships with Innovative Health and Stereotaxis and, most recently, we entered into our Global Alliance for Electrophysiology with Biotronik in May 2020. In addition, we added an integrated family of transseptal crossing and steerable introducer systems to our product portfolio through our acquisition of Rhythm Xience in June 2019 and acquired our AcQBlate Force sensing product line from Biotronik in July 2019. Our strategic partnerships and acquisitions have helped us establish a global sales presence delivering a broad portfolio of highly differentiated electrophysiology products. Our ability to grow our revenue will depend substantially on our ability to leverage our strategic partnerships and acquisitions to achieve distribution at a global scale, broaden our product portfolio and enable and accelerate global connectivity.

**Continued Investment in Innovation**. Our business strategy relies significantly on innovation to develop and introduce new products and to differentiate our products from our competitors. For example, in 2019, our research and development team released five new disposable products, two hardware products, including a major generational update to our AcQMap System, and 15 software updates. We expect our research and development expenditures to increase as we make additional investments to support our growth strategies. We plan to increase our research and development expenditures with internal initiatives, as well as potentially licensing or acquiring technology from third parties. We also expect expenditures associated with our manufacturing organization to grow over time as production volume increases and we bring new products to market. Our internal and external investments will be focused on initiatives that we believe will offer the greatest opportunity for growth and profitability. With a significant investment in research and development, a strong focus on innovation and a well-managed innovation process, we believe we can continue to innovate and grow. Introducing additional, innovative products is also expected to help support our existing installed base and help drive demand for additional installations of our system. If, however, our future innovations are not successful in meeting customers' needs or prove to be too costly relative to their perceived benefit, we may not be successful. Moreover, as cost of products sold, operating expenses and capital expenditures fluctuate over time, we may experience short-term, negative impacts to our results of operations and cash flows, but we are undertaking such investments in the belief that they will contribute to long-term growth.

**Product and Geographic Mix; Timing.** Our financial results, including our gross margins, may fluctuate from period to period due to a variety of factors, including: average selling prices; production volumes; the cost of direct materials; the timing of customer orders or medical procedures and the timing and number of system installations; the number of available selling days in a particular period, which can be impacted by a number of factors such as holidays or days of severe inclement weather in a particular geography; the mix of products sold and the geographic mix of where products are sold; the level of reimbursement available for our products; discounting practices; manufacturing costs; product yields; headcount; and cost-reduction strategies. For example, gross margins on the sale of our products by Biotronik in other parts of the world. Moreover, gross margins on the sale of our products are generally higher than gross margins on the sale of products we source through our strategic partnerships with third parties. Future selling prices and gross margins for our products may fluctuate due to a variety of other factors, including the introduction by others of competing products or the attempted integration by third parties of capabilities similar to ours into their existing products. We aim to mitigate downward pressure on our selling prices by increasing the value proposition offered by our products through innovation. While we have not yet experienced significant seasonality in our results, it is not uncommon in our industry to experience seasonally weaker revenue during the summer months and end-of-year holiday season.

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- **Regulatory Approvals/Clearances and Timing and Efficiency of New Product Introductions**. We are seeking FDA clearance and CE Mark for the use of our AcQBlate Force ablation catheters and Qubic Force device in the United States and Europe, as well as regulatory clearance or approval of our other pipeline products in the United States and in international markets. Our ability to grow our revenue will depend on our obtaining necessary regulatory approvals or clearances for our products. In addition, as we introduce new products, we expect to build our inventory of components and finished goods in advance of sales, which may cause quarterly fluctuations in our results of operations.
- *Competition*. Our industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. Our most significant competitors are large, well-capitalized companies. We must continue to successfully compete considering our competitors' existing and future products and related pricing and their resources to successfully market to the physicians who could use our products. Publications of clinical results by us, our competitors and other third parties can also have a significant influence on whether, and the degree to which, we are able to gain market share and increase utilization of our products.
- COVID-19 Pandemic. Beginning in early March 2020, the COVID-19 pandemic and the measures imposed to contain this pandemic disrupted and are expected to continue to impact our business. For example, 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 may impact certain of our operations over the near term and long term. Moreover, beginning in March 2020, access to hospitals and other customer sites has been restricted to essential personnel, which has negatively impacted our ability to install our AcQMap consoles and workstations in new accounts and for our sales representatives and mappers to promote the use of our products with physicians. Moreover, hospitals and other therapeutic centers have suspended many elective procedures, resulting in a significantly reduced volume of procedures using our products. In addition, all clinical trials in Europe have been suspended with follow-ups for clinical trials done via telecom, and we believe enrollment timing in our planned clinical trials will be slowed due to COVID-19 driven delayed access to enrollment sites. As a result of the interruptions to our business due to COVID-19, we have enacted a cash conservation program, which includes delaying certain non-critical capital expenditures and other projects and implementing a hiring freeze and temporary compensation and headcount reductions throughout our organization. Although the 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, the magnitude of the impact of the COVID-19 pandemic on our productivity, results of operations and financial position, and its disruption to our business and our clinical programs and timelines, will depend, in part, on the length and severity of these restrictions and on our ability to conduct business in the ordinary course. Quarantines, shelter-in-place and similar government orders have also impacted, and may continue to impact, our third-party manufacturers and suppliers, and could in turn adversely impact the availability or cost of materials, which could disrupt our supply chain.

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

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

#### **Components of Results of Operations**

#### Revenue

Our revenue consists of: (i) revenue from the sale of our disposable products; and (ii) systems and service revenue. In the United States and select markets in Western Europe where we have developed a direct selling presence, we install our AcQMap console and workstation with our customer accounts and then generate revenue from the sale of our disposable products to these accounts for use with our system. In other international markets, we leverage our partnership with Biotronik to install our AcQMap console and workstation with customer accounts and then generate revenue from Biotronik's sale of our disposable products for use with our system. Our currently marketed disposable products include access sheaths, transseptal crossing tools, diagnostic and mapping catheters, ablation catheters and accessories.

Our revenue has historically consisted predominantly of sales of our disposable products (principally our mapping catheters 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 second-generation 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 purchase. When a sale of a second-generation AcQMap system is made, the sale includes installation of the equipment, software updates and maintenance, and equipment service. Evaluation contracts are not accounted for as sales under ASC 606, *Revenue from Contracts with Customers*. In addition, we also generate a small portion of our revenue from service agreements. Revenue is recognized when the customer obtains control of the promised goods or services, generally at a point in time, and is recognized in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. For the three months ended March 31, 2020 and the years ended December 31, 2019 and 2018, approximately 51%, 74% and 79%, respectively, of our sales were denominated in currencies other than U.S. dollars, primarily in Euros and the British Pound Sterling, or GBP. Our revenue is subject to fluctuation based on the foreign currency in which our products are sold.

#### Costs and Operating Expenses

# Cost of Products Sold

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

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

products are generally higher than gross margins on the sale of products we source through our strategic partnerships with third parties. Future selling prices and gross margins for our products may fluctuate due to a variety of other factors, including the introduction by others of competing products or the attempted integration by third parties of capabilities similar to ours into their existing products. We aim to mitigate downward pressure on our selling prices by increasing the value proposition offered by our products through innovation.

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 our gross margins to increase over the long term to the extent we are successful in increasing our sales volume and are therefore able to leverage our fixed costs. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which, if successful, we believe will reduce costs and enable us to increase our gross margins. Such manufacturing cost improvement efforts may involve moving production of key subassemblies in house, volume driven supplier cost reductions and process redesigns. While we expect gross margins to increase over the long term, they will likely fluctuate from quarter to quarter as we continue to introduce new products and adopt new manufacturing processes and technologies.

## Research and Development Expenses

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

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

We expect our research and development expenses to increase in absolute dollars for the foreseeable future, though they may vary from period to period as a percentage of revenue, as we hire additional research and development personnel, as well as continue to develop new products, enhance existing products and technologies and perform activities related to obtaining additional regulatory approvals or clearances.

#### Research and Development Expenses—License Acquired

In July 2019, we entered into the Biotronik License Agreement with the Biotronik Parties in connection with the Biotronik Asset Acquisition. In accordance with Accounting Standards Codification, or ASC, 805, *Business Combinations*, the Biotronik Asset Acquisition was accounted for as an asset acquisition as substantially all of the \$15.0 million in value transferred to Biotronik was allocated to intellectual property. On the acquisition date, the products licensed had not yet received regulatory approval and the intellectual property did not have an alternative use. Accordingly, the \$15.0 million paid to Biotronik was immediately charged to research and development expenses—license acquired in our consolidated statement of operations and comprehensive loss. Additional contingent milestone payments of up to \$10.0 million are to be made to the Biotronik Parties upon certain regulatory approvals and first commercial sale, as described above. In further consideration of the rights granted, beginning with our first commercial sale of the first force sensing ablation catheter within the licensed product line, we will also make per unit royalty payments. We have determined that as of the acquisition date and as of March 31, 2020 and December 31, 2019, the contingent milestone and royalty payments are not probable and estimable and therefore have not been recorded as a liability. Upon regulatory approval of our force sensing ablation catheter in Europe, the milestone payments will be capitalized and amortized, and the royalty payments will be recorded as cost of products sold as sales of catheters are recognized.

# Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and employee-related costs (including stock-based compensation) for personnel in sales, executive, finance and other administrative

functions, allocated rent and facilities costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services, marketing costs and insurance costs.

We expect our selling, general and administrative expenses to increase in absolute dollars for the foreseeable future, though they may vary from period to period as a percentage of revenue, as we expand our sale force and increase the number of our mappers, increase our professional education and physician training, as well as to support our expanded infrastructure and incur increased costs associated with operating as a public company. These increases are expected to include increased costs for fees to members of our board of directors, increased employee-related expenses, and increased director and officer insurance premiums, audit and legal fees, investor relations fees and expenses for compliance with public company reporting requirements under the Exchange Act and rules implemented by the SEC, as well as stock exchange rules.

### Other Income (Expense)

#### Change in Fair Value of Warrant Liability

We accounted for certain of our freestanding warrants to purchase shares of our common stock and preferred stock as liabilities at fair value. We accounted for certain features of our convertible notes issued in 2018, or the 2018 Convertible Notes (which were converted into shares of our Series D convertible preferred stock in 2019), that were determined to be an embedded derivative requiring bifurcation and separate accounting at fair value. The warrants and embedded derivative were subject to re-measurement at each balance sheet date with gains and losses reported in our consolidated statements of operations and comprehensive loss.

#### Loss on Issuance of Convertible Notes and Warrants

We recorded a loss on the issuance of the 2018 Convertible Notes and warrants for the excess fair value of the automatic conversion feature of the notes after allocating the gross proceeds of the 2018 Convertible Notes to the fair value of the warrants and the beneficial conversion feature held by the noteholders.

#### Loss on Debt Extinguishment

During 2019, we prepaid the entire principal amount of our loan under our loan and security agreement with Oxford Finance LLC, or the 2018 Term Loan. We recorded a loss on debt extinguishment for the write off of deferred financing fees, the prepayment penalty and related fees upon our prepayment of this loan.

#### Interest Income

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

#### Interest Expense

Interest expense relates to our: (i) Credit Agreement with Orbimed Royalty Opportunities II, LP and Deerfield Private Design Fund II, L.P., or the 2019 Credit Agreement; (ii) 2018 Term Loan, which was repaid during 2019; (iii) 2018 Convertible Notes; and (iv) convertible notes issued in 2019, or the 2019 Convertible Notes. Our 2018 Convertible Notes and our 2019 Convertible Notes were converted into shares of our Series D convertible preferred stock during 2019.

# Results of Operations for the Three Months Ended March 31, 2020 and 2019

The results of operations presented below should be reviewed in conjunction with our consolidated financial statements and related notes included elsewhere in this prospectus. The following table sets forth our results of operations for the three months ended March 31, 2020 and 2019:

	Three Mor Marc	nths Ended			
		h 31.	Change		
	2020	2019	\$	%	
(dollars in thousands)	(unau	dited)			
Revenue(2)	\$ 1,583	\$ 787	\$ 796	101%	
Costs and operating expenses:					
Cost of products sold <sup>(1)</sup>	3,194	2,176	1,018	47%	
Research and development	7,973	4,377	3,596	82%	
Selling, general and administrative <sup>(1)</sup>	10,235	4,093	6,142	150%	
Change in fair value of contingent consideration	(2,219)		(2,219)	*	
Total operating expenses	19,183	10,646	8,537	80%	
Loss from operations	(17,600)	(9,859)	(7,741)	79%	
Other income (expense):					
Change in fair value of warrant liability and embedded derivative	581	841	(260)	(31%)	
Interest income	275	65	210	323%	
Interest expense	(1,354)	(5,742)	4,388	(76%)	
Total other income (expense), net	(498)	(4,836)	4,338	(90%)	
Loss before income taxes	(18,098)	(14,695)	(3,403)	23%	
Income tax benefit	—	_	—	%	
Net loss	\$(18,098)	\$(14,695)	\$(3,403)	23%	
Other comprehensive income (loss):					
Unrealized gain (loss) on marketable securities	(27)	1	(28)	(2800%)	
Foreign currency translation adjustment	(27)	(14)	(13)	93%	
Comprehensive loss	\$(18,152)	\$(14,708)	\$(3,444)	23%	

\* Not meaningful.

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

	Three Mo Ended Mar	
	2020	2019
(in thousands)	(unaudit	ed)
Cost of products sold	\$ 108	\$ 52
Research and development	211	142
Selling, general and administrative	1,422	365
Total stock-based compensation expense	<u>\$ 1,741</u>	\$ 559

(2) The following table sets forth our revenue for disposables and systems/service for the three months ended March 31, 2020 and 2019:

		Three Months Ended March 31,				
	202	0	2019			
(in thousands)		(unaudited)				
Disposables	\$ 1	,057 \$	5 782			
Systems/service		526	5			
Total revenue	\$ 1	,583 \$	5 787			

#### Revenue

Revenue was \$1.6 million for the three months ended March 31, 2020, compared to \$0.8 million for the three months ended March 31, 2019. This increase of \$0.8 million, or 101%, was primarily attributable to \$0.5 million of AcQMap systems sales and a \$0.3 million increase in purchase volume of our disposable products used in electrophysiology procedures as a result of a higher installed base, as well as slightly higher average selling prices on certain of our disposable products.

Revenue, classified by the major geographic areas in which our products are shipped, was \$0.8 million for the United States and \$0.8 million for all other countries in the three months ended March 31, 2020, compared to \$0.2 million for the United States and \$0.6 million for all other countries for the comparative period in 2019.

#### **Costs and Operating Expenses**

#### Cost of Products Sold

Cost of products sold was \$3.2 million for the three months ended March 31, 2020, compared to \$2.2 million for the three months ended March 31, 2019. This increase of \$1.0 million, or 47%, was primarily attributable to \$0.5 million due to an increase in sales volume, \$0.3 million due to increased manufacturing overhead and direct labor resources to support our full commercial launch and a \$0.3 million increase in warranty and field service expense to support the higher installed base. Gross margin was negative 102% for the three months ended March 31, 2020 compared to negative 176% for the three months ended March 31, 2019. This improvement in gross margin was primarily attributable to increased sales volume of our disposable products.

#### Research and Development Expenses

Research and development expenses were \$8.0 million for the three months ended March 31, 2020, compared to \$4.4 million for the three months ended March 31, 2019. This increase of \$3.6 million, or 82%, was primarily attributable to \$1.4 million in increased compensation and related costs from higher headcount, and \$1.8 million in increased materials and supplies costs related to higher engineering project spending.

#### Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$10.2 million for the three months ended March 31, 2020, compared to \$4.1 million for the three months ended March 31, 2019. This increase of \$6.1 million, or 150%, was primarily attributable to \$4.4 million in increased compensation and related costs due to our investment in our commercial organization in support of our full commercial launch in the United States in the first quarter of 2020, \$0.9 million in increased consulting expenses and \$0.7 million in increased general marketing expenses.

#### Change in Fair Value of Contingent Consideration

For the three months ended March 31, 2020, we recorded a change in fair value of contingent consideration of \$2.2 million for the decrease in the fair value of the contingent consideration for the acquisition of Rhythm Xience.

#### Other Income (Expense)

Other expense, net was \$0.5 million for the three months ended March 31, 2020, compared to \$4.8 million for the three months ended March 31, 2019. This decrease of \$4.3 million, or 90%, was primarily attributable to a decrease of \$4.4 million in interest expense primarily related to the 2019 Credit Agreement and 2018 Convertible Notes.

# Results of Operations for the Years Ended December 31, 2019 and 2018

The results of operations presented below should be reviewed in conjunction with our consolidated financial statements and related notes included elsewhere in this prospectus. The following table sets forth our results of operations for the years ended December 31, 2019 and 2018:

	Year I Decem		Change		
(dollars in thousands)	2019	2018	\$	%	
Revenue <sup>(2)</sup>	\$ 2,836	\$ 2,166	\$ 670	31%	
Costs and operating expenses:					
Cost of products sold(1)	9,243	7,510	1,733	23%	
Research and development(1)	23,029	19,077	3,952	21%	
Research and development—license acquired	15,000	—	15,000	100%	
Selling, general and administrative <sup>(1)</sup>	26,847	13,330	13,517	101%	
Impairment of property and equipment	786	—	786	100%	
Change in fair value of contingent consideration	500	—	500	100%	
Total costs and operating expenses	75,405	39,917	35,488	89%	
Loss from operations	(72,569)	(37,751)	(34,818)	92%	
Other income (expense):					
Change in fair value of warrant liability and embedded derivative	(1,919)	(4,298)	2,379	(55%)	
Loss on issuance of convertible notes and warrants	—	(924)	924	(100%)	
Loss on debt extinguishment	(1,447)	—	(1,447)	100%	
Interest income	1,164	297	867	292%	
Interest expense	(22,268)	(5,231)	(17,037)	326%	
Total other income (expense), net	(24,470)	(10,156)	(14,314)	141%	
Loss before income taxes	(97,039)	(47,907)	(49,132)	103%	
Income tax benefit	—	—		%	
Net loss	\$(97,039)	\$(47,907)	\$(49,132)	103%	
Other comprehensive income (loss):					
Unrealized gain (loss) on marketable securities	46	(1)	47	(4700%)	
Foreign currency translation adjustment	(96)	(43)	(53)	123%	
Comprehensive loss	\$(97,089)	\$(47,951)	\$(49,138)	102%	

(1) The following table sets forth the stock-based compensation expense included in our results of operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
(in thousands)	2019	2018
Cost of products sold	\$ 209	\$ 215
Research and development	656	564
Selling, general and administrative	2,129	1,292
Total stock-based compensation expense	\$ 2,994	\$ 2,071

(2) The following table sets forth our revenue for disposables and systems/service for the years ended December 31, 2019 and 2018:

	Year Ended	Year Ended December 31,	
(in thousands)	2019	2018	
Disposables	\$ 2,817	\$ 2,160	
Systems/service	19	6	
Total revenue	\$ 2,836	\$ 2,166	

#### Revenue

Revenue was \$2.8 million for the year ended December 31, 2019, compared to \$2.2 million for the year ended December 31, 2018. This increase of \$0.7 million, or 31%, was primarily attributable to an increase in purchase volume of our disposable products used in electrophysiology procedures as a result of a higher installed base, as well as slightly higher average selling prices on certain of our disposable products. Substantially all of our revenue for the years ended December 31, 2019 and 2018 was generated from sales of our disposable products.

Revenue, classified by the major geographic areas in which our products are shipped, was \$0.7 million for the United States and \$2.1 million for all other countries in 2019, compared to \$0.5 million for the United States and \$1.7 million for all other countries in 2018.

#### Costs and Operating Expenses

#### Cost of Products Sold

Cost of products sold was \$9.2 million for the year ended December 31, 2019, compared to \$7.5 million for the year ended December 31, 2018. This increase of \$1.7 million, or 23%, was primarily attributable to increased manufacturing overhead and direct labor resources in anticipation of our full commercial launch, charges taken for excess and obsolete inventory reserves associated with our first-generation AcQMap console and for growth in sales volume. Gross margin was negative 226% for the year ended December 31, 2019 compared to negative 247% for the year ended December 31, 2018. This improvement in gross margin was primarily attributable to increased sales volume of our disposable products, but partially offset by the aforementioned inventory reserve charges.

#### Research and Development Expenses

Research and development expenses were \$23.0 million for the year ended December 31, 2019, compared to \$19.1 million for the year ended December 31, 2018. This increase of \$4.0 million, or 21%, was primarily attributable to \$1.8 million in increased compensation and related costs from higher headcount, and \$1.2 million in increased materials and supplies costs related to higher engineering project spending.

#### Research and Development Expenses-License Acquired

Research and development expenses—license acquired were \$15.0 million for the year ended December 31, 2019, related to the Biotronik Asset Acquisition, where we acquired intellectual property. Since the acquired intellectual property had no alternative use and was for products that have not yet received regulatory approval, the intellectual property was immediately charged to research and development expenses—license acquired.

#### Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$26.8 million for the year ended December 31, 2019, compared to \$13.3 million for the year ended December 31, 2018. This increase of \$13.5 million, or 101%, was primarily attributable to \$7.8 million in increased compensation and related costs due to our investment in our commercial organization in support of our full commercial launch in the United States in the first quarter of 2020, \$3.8 million in increased consulting expenses and \$0.8 million in increased general marketing expenses.

#### Impairment of Property and Equipment

For the year ended December 31, 2019, we recorded an impairment of property and equipment related to the first generation of our AcQMap System that was no longer in service. The impairment is the result of an analysis that indicated it was probable the undiscounted cash flows derived from the assets would not exceed their book value during their remaining useful life.

#### Change in Fair Value of Contingent Consideration

For the year ended December 31, 2019, we recorded a change in fair value of contingent consideration of \$0.5 million for the increase in the fair value of the contingent consideration for the acquisition of Rhythm Xience.

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

Other expense, net was \$24.5 million for the year ended December 31, 2019, compared to \$10.2 million for the year ended December 31, 2018. This increase of \$14.3 million, or 141%, was primarily attributable to \$17.0 million in increased interest expense primarily related to the 2019 Credit Agreement and 2018 Convertible Notes and a \$1.4 million loss on debt extinguishment related to costs and fees associated with the repayment of the 2018 Term Loan, partially offset by a decrease in the change in fair value of the warrant and embedded derivative liabilities.

#### Liquidity and Capital Resources

We have incurred significant operating losses and negative cash flows from operations since our inception, and we anticipate that we will incur significant losses for at least the next several years. As of March 31, 2020 and December 31, 2019, we had cash, cash equivalents and marketable securities of \$49.9 million and \$71.8 million, respectively. For the three months ended March 31, 2020 and the years ended December 31, 2019 and 2018, our net losses were \$18.1 million, \$97.0 million and \$47.9 million, respectively, and our net cash used in operating activities was \$17.6 million, \$56.0 million and \$33.8 million, respectively. We had an accumulated deficit of \$277.1 million and \$259.0 million as of March 31, 2020 and December 31, 2019, respectively.

Prior to this offering, 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. In June and July 2019, we completed an equity financing pursuant to which we issued 79,740,085 shares of Series D convertible preferred stock in a private placement. The Series D convertible preferred stock issuance was comprised of: (i) 39,789,158 shares at \$1.714 per share for cash proceeds of \$66.6 million, net of fees of \$1.6 million; and (ii) 18,325,558 shares at \$1.3712 per share (including a 20% discount) for the conversion of our 2018 Convertible Notes (and related accrued interest) and 21,625,369 shares at \$1.714 per share for the conversion of our 2019 Convertible Notes (and related accrued interest), in an aggregate amount of \$68.5 million, including the fair value of the embedded derivative of \$6.3 million relating to the 20% discount for the conversion of the 2018 Convertible Notes.

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.

Our primary uses of capital are, and we expect will continue to be, investment in our commercial organization and related expenses, clinical research and development services, laboratory and related supplies, legal and other regulatory expenses, general administrative costs and working capital. In addition, we have acquired, and may in the future seek to acquire or invest in, additional businesses, products or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. For example, in June 2019, we acquired Rhythm Xience, a medical device company specializing in the design and manufacture of transseptal crossing and steerable introducer systems, for \$3.0 million in cash. The cash payment did not include the potential \$17.0 million in earn out consideration to be paid based on the achievement of certain regulatory milestones and revenue milestones. In February 2020, we issued to the former owners of Rhythm Xience 1,166,861 shares of our Series D convertible preferred stock and paid them \$2.6 million in connection with the regulatory and revenue milestones earned to date. In addition, pursuant to the Biotronik License Agreement, we paid Biotronik a \$3.0 million upfront fee at the time the agreement was signed, as well as a technology transfer fee consisting of \$7.0 million in cash in December 2019 and \$5.0 million in shares of our Series D convertible preferred stock in February 2020. We are required to pay the Biotronik Parties up to \$10.0 million upon the achievement of various regulatory and sales-related milestones, as well as unit-based royalties on any sales of force sensing catheters. We will also incur costs as a public company that we have not previously incurred or have previously incurred at lower rates.

Our consolidated financial statements included elsewhere in this prospectus have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to our ability to continue as a going concern. At present, without taking into consideration any proceeds from this offering, we do not have enough cash on hand to cover our costs for the next 12 months. In order to proceed with our business plan, we will need to raise substantial additional funds. However, based on our current operating plan, 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.

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.

### **Debt Obligations**

During 2019, we repaid our 2018 Term Loan and our 2018 Convertible Notes and our 2019 Convertible Notes were converted into shares of our Series D convertible preferred stock.

On May 20, 2019, we entered into the 2019 Credit Agreement. The 2019 Credit Agreement provided us with a senior term loan facility in aggregate principal amount of \$70.0 million, of which we borrowed \$40.0 million upon closing. Of the remaining \$30.0 million, \$20.0 million is available for borrowing by us on or prior to December 31, 2020, subject to our achievement of specified trailing revenue levels, and \$10.0 million will no longer be available for borrowing as of June 30, 2020. The 2019 Credit Agreement bears interest per annum at 7.75% plus LIBOR for such interest period, and the principal amount of term loans outstanding under the 2019 Credit Agreement is due on May 20, 2024. The 2019 Credit Agreement can be prepaid but is subject to prepayment penalties. The 2019 Credit Agreement provides for final payment fees of an additional \$4.6 million that are due upon prepayment, on the maturity date or upon acceleration.

Our obligations under the 2019 Credit Agreement are secured by substantially all of our assets, including our intellectual property, and is guaranteed by our subsidiary. The 2019 Credit Agreement contains customary affirmative and restrictive covenants, including with respect to our ability to enter into fundamental transactions, incur additional indebtedness, grant liens, pay any dividend or make any distributions to our holders, make investments and merge or consolidate with any other person or engage in transactions with our affiliates, but does not include any financial covenants, other than a minimum liquidity requirement.

In connection with our entry into the 2019 Credit Agreement, we issued liability-classified warrants with a fair value of \$0.9 million to purchase 4,084,014 shares of our Series C convertible preferred stock at \$1.714 per share. These warrants were subsequently automatically converted into warrants to purchase an equal number of shares of our Series D convertible preferred stock at a price of \$1.714 per share.

### Cash Flows

The following table shows a summary of our cash flows for the three months ended March 31, 2019 and 2018 and the years ended December 31, 2019 and 2018 (in thousands):

	Three Months Ended March 31,			Year Ended December 31,			
	2020		2019		2	019	2018
		(unau	ıdited)				
Net cash used in operating activities	\$	(17,558)	\$	(9,584)	\$ (5	5,986)	\$ (33,780)
Net cash provided by (used in) investing activities		31,717		8,077	(7	70,430)	(4,742)
Net cash (used in) provided by financing activities		(2,584)		—	12	26,339	37,414
Effect of exchange rate changes on cash, cash equivalents and restricted cash		(27)		(14)		(96)	(43)
Net change in cash, cash equivalents and restricted cash	\$	11,548	\$	(1,521)	\$	(173)	\$ (1,151)

### **Operating Activities**

During the three months ended March 31, 2020, operating activities used \$17.6 million of cash, an increase of \$8.0 million from the three months ended March 31, 2019. This increase was primarily attributable to a \$3.4 million increase in net loss and a \$5.5 million decrease of non-cash items, primarily driven by a decrease of \$4.7 million in amortization of debt issuance costs and a decrease of \$2.2 million in the fair value of the contingent consideration. This increase was partially offset by a \$0.9 million increase in the cash provided by operating assets and liabilities, primarily resulting from a larger increase in accounts payable balances, and by a larger increase in inventory balances from December 31, 2019 to March 31, 2020, as compared to December 31, 2018 to March 31, 2019.

During the year ended December 31, 2019, operating activities used \$56.0 million of cash, an increase of \$22.2 million from the year ended December 31, 2018. This increase was primarily attributable to a \$49.1 million increase in net loss and a \$3.7 million increase in the use of cash from operating assets and liabilities, primarily resulting from: (i) a \$5.4 million increase in the inventory balance from December 31, 2018 to December 31, 2018 to December 31, 2019, as compared to a relatively consistent inventory balance from December 31, 2017 to December 31, 2018, partially offset by (ii) a \$2.4 million increase in accounts payable balance from December 31, 2018 to December 31, 2019, as compared to a relatively consistent accounts payable balance from December 31, 2018 to December 31, 2019, as compared to a relatively consistent accounts payable balance from December 31, 2018 to December 31, 2019, as compared to a relatively consistent accounts payable balance from December 31, 2018 to December 31, 2019, as compared to a relatively consistent accounts payable balance from December 31, 2018 to December 31, 2019, as compared to a relatively consistent accounts payable balance from December 31, 2018 to December 31, 2019, as compared to a relatively consistent accounts payable balance from December 31, 2018 to December 31, 2019, as compared to a relatively consistent accounts payable balance from December 31, 2018 to December 31, 2019, as compared to a relatively consistent accounts payable balance from December 31, 2018 to December 31, 2019, as compared to a relatively consistent accounts payable balance from December 31, 2018 to December 31, 2019, as compared to a relatively consistent accounts payable balance from December 31, 2018 to December 31, 2019 to December 31, 2018 to December

### Investing Activities

During the three months ended March 31, 2020, investing activities provided \$31.7 million of cash, an increase of \$23.6 million from the three months ended March 31, 2019. This increase was attributable to an increase of maturities of marketable securities of \$17.2 million and sales of marketable securities of \$8.1 million, partially offset by a \$1.7 million increase in purchases of property and equipment.

During the year ended December 31, 2019, investing activities used \$70.4 million of cash, an increase of \$65.7 million from the year ended December 31, 2018. This increase was primarily attributable to a \$54.4 million increase in purchases of marketable securities, a \$10.0 million payment for the Biotronik Asset Acquisition, \$3.0 million of cash paid, net of cash acquired, for the Rhythm Xience acquisition and a \$1.4 million increase in purchase of property and equipment, partially offset by a \$3.1 million increase in the maturities of marketable securities.

#### Financing Activities

During the three months ended March 31, 2020, financing activities used \$2.6 million of cash, an increase of \$2.6 million from the three months ended March 31, 2019. This increase resulted from the payment of contingent consideration related to the Rhythm Xience acquisition for the achievement of certain regulatory milestones and revenue targets.

During the year ended December 31, 2019, financing activities provided \$126.3 million of cash, an increase of \$88.9 million from the year ended December 31, 2018. This increase was primarily attributable to \$66.6 million from the issuance of shares of our Series D convertible preferred stock in June and July 2019 and \$40.0 million resulting from the closing of the 2019 Credit Agreement, partially offset by a \$16.6 million increase in debt repayments related to the repayment of the 2018 Term Loan and payments of issuance and extinguishment costs.

#### **Contractual Obligations and Commitments**

The following table summarizes our contractual obligations and commitments as of December 31, 2019 (in thousands):

	Payments Due by Period					
		Less than				e than
	Total	1 Year	1-3 Years	3-5 Years	5 Y	ears
Principal payments on long-term debt(1)	\$40,000	\$ —	\$ —	\$40,000	\$	—
Exit fees for long-term debt(1)	4,550		—	4,550		—
Interest payments on long-term debt <sup>(2)</sup>	18,370	4,168	8,314	5,888		—
Operating leases(3)	3,233	1,013	2,118	102		—
Purchase obligations(4)	12,288	12,283	5	—		—
Total	\$78,441	\$17,464	\$10,437	\$50,540	\$	_

- On May 20, 2019, we entered into the 2019 Credit Agreement. The 2019 Credit Agreement provides us with a senior term loan facility in aggregate principal amount of \$70.0 million, of which we borrowed \$40.0 million upon closing. Of the remaining \$30.0 million, \$20.0 million is available for borrowing by us on or prior to December 31, 2020, subject to our achievement of specified trailing revenue levels, and \$10.0 million will no longer be available for borrowing as of June 30, 2020. The principal amount of term loans outstanding under the 2019 Credit Agreement is due on May 20, 2024. Principal payments and exit fees associated with the term loan are included in the above table. (1)
- Interest payments are based on the variable interest rate of 10.25% in effect as of December 31, 2019 applied to the principal balance outstanding as of December 31, 2019, and (2)
- considering the contractual repayment schedule in the 2019 Credit Agreement assuming the debt will be outstanding until maturity. We lease approximately 50,800 square feet of office space for our corporate headquarters and manufacturing facility in Carlsbad, California under a noncancelable operating lease that expires on December 31, 2022. We have a renewal option for an additional five-year term upon the expiration date of this lease, which has been excluded from the calculation of the (3)right-of-use asset as it is not reasonably certain to be exercised. Additionally, we lease approximately 3,900 square feet of office space in Zaventem, Belgium under a noncancelable operating lease that expires on December 31, 2021. We have a renewal option for an additional three-year term upon the expiration date of this lease, which has been included in the calculation of the right-of-use asset as it is reasonably certain to be exercised.
- As of December 31, 2019, we had \$12.3 million of open purchase orders. All of our purchase orders may be cancelled without significant penalty. (4)

In addition, we enter into agreements in the normal course of business with contract research organizations for clinical trials and with vendors for preclinical trials and other services and products for operating purposes which are cancelable at any time by us, generally upon 30 days prior written notice. These payments are not included in this table of contractual obligations.

Further, the agreement to acquire Rhythm Xience requires us to pay the former owners of Rhythm Xience up to \$15.0 million in additional cash earn out consideration based on the achievement of certain regulatory and revenue milestones. In February 2020, we issued to the former owners of Rhythm Xience 1,166,861 shares of our Series D convertible preferred stock and paid them \$2.6 million in connection with the regulatory and revenue milestones earned to date. In addition, pursuant to the Biotronik License Agreement, we issued to Biotronik \$5.0 million in shares of our Series D convertible preferred stock in February 2020, and we are required to pay the Biotronik Parties up to \$10.0 million upon the achievement of various regulatory and sales-related milestones, as well as unit-based royalties on any sales of force sensing catheters.

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

As of March 31, 2020 and December 31, 2019, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined in the SEC rules and regulations.

### **Critical Accounting Policies and Estimates**

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

While our significant accounting policies are more fully described in the Note 2 to our consolidated financial statements included elsewhere in this prospectus, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

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

We adopted ASC 606 effective January 1, 2018, using the full retrospective method.

In the United States and select markets in Western Europe where we have developed a direct selling presence, we install our AcQMap console and workstation with our customer accounts and then generate revenue from the sale of our disposable products to these accounts for use with our system. In other international markets, we leverage our partnership with Biotronik to install our AcQMap console and workstation with customer accounts and then generate revenue from Biotronik's sale of our disposable products to these accounts. Once an AcQMap console and workstation is established in a customer account, our revenue from that account becomes predominantly recurring in nature and derived from the sale of our portfolio of disposable products used with our system. Our currently marketed disposable products include access sheaths, transseptal crossing tools, diagnostic and mapping catheters, ablation catheters and accessories.

Our revenue has historically consisted predominantly of sales of our disposable products (principally our mapping catheters and related access sheaths, and to a lesser extent our transseptal crossing tools, ablation catheters and other accessories), as we have generally loaned our 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 secondgeneration 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 purchase. When a sale of a second-generation AcQMap system is made, the sale includes installation of the equipment, software updates and maintenance, and equipment service. Evaluation contracts are not accounted for as sales under ASC 606. In addition, we also generate a small portion of our revenue from service agreements. We provide our disposable products in exchange for consideration, which occurs when a customer submits a purchase order and we provide our disposable products at the agreed upon prices in the invoice. Generally, for our first-generation AcQMap console and workstation, customers purchased disposable products using separate purchase orders after the equipment has been installed at no upfront fee with no binding agreement or requirement to purchase any disposable products. We have elected the practical expedient and accounting policy election to account for the shipping and handling as activities to fulfill the promise to transfer the disposable products and not as a separate performance obligation.

Our contracts generally only include fixed consideration, with no discounts, rebates, returns or other forms of variable consideration. Our customers are generally required to pay within 30 to 60 days.

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

The installation and delivery of the AcQMap system is satisfied at a point in time when the installation is complete, which is when our customers can benefit and has control of the system. Our software updates and equipment service performance obligations are satisfied evenly over time as our customers simultaneously receives and consumes the benefits of our performance for these services throughout the service period.

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

Our contracts with customers generally have an expected duration of one year or less, therefore we have elected the practical expedient in ASC 606 to not disclose information about our remaining performance obligations. Any incremental costs to obtain contracts are recorded as selling, general and administrative expense as incurred due to the short duration of our contracts.

### Stock-Based Compensation

We account for all stock-based payments to employees and non-employees, including grants of stock options, restricted stock awards, or RSAs, and restricted stock units with non-market performance and service conditions, or PSUs, to be recognized in our consolidated financial statements, based on their respective grant date fair values. We estimate the fair value of stock option grants using the Black-Scholes option pricing model. The RSAs and PSUs are valued based on the fair value of our common stock on the date of grant. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. We expense stock-based compensation related to stock options and RSAs over the requisite service period. As the PSUs have a performance condition, compensation expense is recognized for each vesting tranche over the respective requisite service period of each tranche if and when we deem it probable that the performance conditions will be satisfied. We may recognize a cumulative true-up adjustment related to PSUs once a condition becomes probable of being satisfied if the related service period had commenced in a prior period. Forfeitures are recorded as they occur.

The determination of the grant date fair value of options using an option pricing model is affected principally by our estimated fair value of shares of our common stock and requires management to make a number of other assumptions, including the expected term of the option, the expected volatility of the underlying shares, the risk-free interest rate and the expected dividend yield. The assumptions used in our Black-Scholes option-pricing model represent management's best estimates at the time of measurement. These estimates are complex, involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future. These assumptions are estimated as follows:

- Fair Value of Common Stock. See the subsection titled "-Fair Value of Common Stock" below.
- *Expected Term.* The expected term represents the period that our options are expected to be outstanding. We calculated the expected term using the simplified method for options based on the average of each option's vesting term and the contractual period during which the option can be exercised, which is typically 10 years following the date of grant.
- *Expected Volatility.* The expected volatility was based on the historical share volatility of several comparable publicly traded companies over a period of time equal to the expected term of the options, as we do not have any trading history to use the volatility of our own common stock. The comparable companies were chosen based on their size, stage in life cycle and area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *Risk-Free Interest Rate.* The risk-free interest rate was based on the yields of U.S. Treasury securities with maturities appropriate for the term of the award.
- *Expected Dividend Yield*. We have not paid dividends on our common stock nor do we expect to pay dividends in the foreseeable future. Therefore, we used an expected dividend yield of zero.

### Fair Value of Common Stock

There has been no public market for our common stock to date. As such, the estimated fair value of our common stock and underlying stock options has been determined at each grant date by our board of directors, with input from management, based on the information known to us on the grant date and upon a review of any

recent events and their potential impact on the estimated per share fair value of our common stock. As part of these fair value determinations, our board of directors obtained and considered valuation reports prepared by a third-party valuation firm in accordance with the guidance outlined in the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

In determining the fair value of our common stock prior to this offering, multiple factors were considered in selecting an appropriate valuation approach, including, without limitation: (i) does the valuation method reflect our going-concern and/or expected time to liquidity status; (ii) does the valuation method assign value to the junior instruments, unless a future exit scenario is being analyzed whereby no cash is being distributed to the junior instruments based on equity class-specific rights; and (iii) is the complexity of the method appropriate based on our stage of development at the date of the valuation. The valuation methods evaluated and utilized, as appropriate, included the Option Pricing Method, or OPM, Scenario-Based Method and Hybrid Method. The OPM is a forward-looking method that considers our current equity value and allocates our total equity value to the various equity classes considering a continuous distribution of outcomes, rather than focusing on distinct future scenarios. The Scenario-Based Method is a forward-looking method that considers of equity across a range of future exit scenario, discounted to the applicable valuation date at an appropriate rate of return for each equity class. This method may include a simplified scenario analysis, a relative value scenario analysis or a full scenario analysis, also known as the Probability-Weighted Expected Return Method, or PWERM. The Hybrid Method is a hybrid of the OPM and the Scenario-Based Method.

Prior to June 2018, we determined the estimated fair value of our common stock using the OPM given the uncertainty associated with both the timing and type of any future exit scenario. The OPM is an allocation method that considers the current value of equity and then allocates that equity value to the various equity classes considering the rights and preferences of the individual equity classes. The OPM treated our common stock and convertible preferred stock as call options on our total equity value, with exercise prices based on the liquidation preferences of the convertible preferred stock. The OPM utilized the Black-Scholes model to price the call options, and considered the various terms of the stockholder agreements that would affect the distributions to each class of equity upon a liquidity event, including the level of seniority among the classes of equity, dividend policy, conversion ratios and cash allocations. When determining our total equity value, a Market Approach using the Market Value of Invested Capital and Adjusted Enterprise Value Method was determined to be appropriate. The Market Value of Invested Capital was determined based on the performance of a set of guideline comparable companies, known as the Guideline Publicly-Traded Companies Method, or GPTCM, and a book value of invested capital multiple that considered all of the guideline public companies' various financial characteristics. The Adjusted Enterprise Value Method utilized our equity value, as determined by our most recent prior valuation and adjusted the value based on changes in the market. Our overall equity value was then inferred by weighting the Market Value of Invested Capital and Adjusted Enterprise Value Method equally. Since our shares are not publicly traded, a discount for lack of marketability, or DLOM, was then applied to the freely traded/marketable value.

From June 2018 to March 2019, we determined the estimated fair value of our common stock using the OPM applying both an Income Approach and Market Approach when determining our total equity value. The Income Approach utilized the discounted cash flow, or DCF, method to value our business enterprise. The DCF method required estimation of future economic benefits and the application of an appropriate discount rate to risk-adjust the projected cash flows to a single present value. The Market Approach consisted of identifying transactions involving companies with characteristics similar to us. Based on the identified transactions, measures were developed for calculating value predicated on the prices and operating metrics specific to the transactions. The Market Approach utilized the GPTCM and a Guideline Transactions Method, or GTM. Under the GPTCM and GTM, valuation multiples were calculated from the market data and operating metrics of the guideline companies/transactions. The selected multiples were evaluated and adjusted based on our strengths and weaknesses relative to the companies/transactions being analyzed. The selected multiples were ultimately applied to our operating metrics to calculate indications of value. A DLOM was also then applied.

Beginning in March 2019, we determined the estimated fair value of our common stock using the Hybrid Method, which incorporated the OPM and the PWERM Scenario-Based Method, estimating the probability-weighted value across multiple scenarios by using the OPM to estimate the allocation of value within one or more of those scenarios. The Hybrid Method was utilized given there was transparency into one or more near-term potential exits but there existed uncertainty regarding what would occur if the near-term exit plans did not materialize. Under the PWERM, the values of the various equity interests were estimated based upon an analysis of future values for our company, assuming various potential future outcomes. Share value was based upon the probability-weighted present value of expected future investment returns, considering each of the possible future outcomes available to us, as well as the rights of each share class. The future outcomes modeled included an initial public offering, a merger or sale, a dissolution or continued operation as a private company until a later exit date. To estimate our total equity value, a combination of the Backsolve Methodology ("backsolving" the implied enterprise value based on the price paid for each new preferred security sold), a DCF analysis and a GPTCM analysis was used for scenario options, based on the fact pattern that existed as of the particular valuation date. After deriving the indicated values of equity under the scenario options, the present value of the class specific equity allocations were calculated. After calculating the present values as applicable to the scenario options, the probability of each scenario occurring was multiplied by the indications of value under each scenario. The sum of the probability-weighted values for our common stock was then divided by our total common stock outstanding as of the relevant valuation date.

In addition to considering the results of these third-party valuation reports, our board of directors used assumptions based on various objective and subjective factors, combined with management judgment, to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- external market conditions affecting the life sciences research and development industry and trends within the industry;
- our stage of development and business strategy;
- our financial condition and operating results, including our levels of available capital resources and forecasted results;
- developments in our business;
- the progress of our research and development efforts;
- equity market conditions affecting comparable public companies; and
- general market conditions and the lack of marketability of our common stock.

Application of these approaches involves the use of estimates, judgment and assumptions that are highly complex and subjective, such as those regarding our expected future revenue, expenses and future cash flows, discount rates, market multiples, the selection of comparable companies and the probability of possible future events. Changes in any or all of these estimates and assumptions or the relationships between the assumptions impact our valuations as of each valuation date and may have a material impact on the valuation of our common stock.

Once a public trading market for our common stock has been established in connection with the closing of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the closing price of our common stock as reported on the date of grant.

During the three months ended March 31, 2020, we granted options to purchase 8,431,411 shares of our common stock, with a weighted-average exercise price of \$1.52 per share. We did not grant any stock-based

awards in the second quarter of 2020. As of , 2020, based on the assumed initial public offering price of \$ per share (which is the midpoint of the estimated price range set forth on the cover page of this prospectus), the aggregate intrinsic value of our outstanding stock options was \$ million, with \$ million related to vested stock options. As of , 2020, we had \$ million of unrecognized stock-based compensation which is expected to be recognized over a weighted-average period of approximately years.

### Fair Value Measurements

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

### Warrant Liability

We account for certain common stock warrants and convertible preferred stock warrants outstanding as a liability, in accordance with ASC 815, *Derivatives and Hedging*, at fair value and adjust the instruments to fair value at each reporting period. The fair value of these warrants have been estimated using a Monte Carlo simulation in 2018 and first quarter of 2019 and as an output of the Hybrid Method for the remaining quarters of 2019. The underlying equity included in the Monte Carlo simulation and the Hybrid Method was determined based on the equity value implied from preferred stock transactions and from examination of income and market approaches for measurement dates in which a preferred transaction was not applicable. Additionally, the expected initial public offering value was considered in the determination of the equity value. The fair value of the warrants was impacted by the model selected as well as assumptions surrounding unobservable inputs including the underlying equity value, risk-free interest rate, expected dividend yield, expected term and expected volatility.

This liability is subject to re-measurement at each reporting period until exercised, and any change in fair value is recognized in our consolidated statements of operations and comprehensive loss.

#### **Business Combinations**

Under the acquisition method of accounting, we allocate the fair value of the total consideration transferred to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values on the date of acquisition. The fair values assigned, defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between willing market participants, are based on estimates and assumptions determined by management. We record the excess consideration over the aggregate fair value of tangible and intangible assets, net of liabilities assumed, as goodwill. These valuations require us to make significant estimates and assumptions, especially with respect to intangible assets.

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

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

Management typically uses the discounted cash flow method to value our acquired intangible assets. This method requires significant management judgment to forecast future operating results and establish residual growth rates and discount factors. The estimates we use to value and amortize intangible assets are consistent with the plans and estimates that we use to manage our business and are based on available historical information and industry estimates and averages. If the subsequent actual results and updated projections of the underlying business activity change compared with the assumptions and projections used to develop these values, we could experience impairment charges. In addition, we have estimated the economic lives of certain acquired assets and these lives are used to calculate depreciation and amortization expense. If our estimates of the economic lives change, depreciation or amortization expenses could be accelerated or slowed.

Goodwill is not amortized but is subject to periodic impairment testing. Goodwill is assigned to a reporting unit and the reporting unit's goodwill is tested for impairment at least on an annual basis and between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount. In the evaluation of goodwill for impairment, which we perform annually during the fourth quarter, we first assesses qualitative factors to determine whether the existence of events or circumstances led to a determination that it was more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, we determine that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, we perform the quantitative goodwill impairment test.

### **Recent Accounting Pronouncements**

See Note 2 to our consolidated financial statements included elsewhere in this prospectus for a description of recent accounting pronouncements applicable to our consolidated financial statements.

### **Emerging Growth Company and Smaller Reporting Company Status**

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 Operations" disclosure in this prospectus, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation, and an exemption from the requirements to obtain a non-binding advisory vote on executive compensation or golden parachute arrangements. We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to

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

We will remain an emerging growth company until the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering; (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 have total annual gross revenue of at least \$1.07 billion; (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

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

#### **Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily the result of fluctuations in interest rates and foreign currency exchange rates.

#### Interest Rate Risk

Our cash, cash equivalents and marketable securities as of March 31, 2020 and December 31, 2019 consisted of \$28.9 million and \$62.4 million, respectively, invested in commercial paper and short-term highly liquid, high credit quality corporate debt securities as well as \$21.0 million and \$9.5 million, respectively, invested in bank deposits and money market funds. Our historical interest income has not fluctuated significantly. We do not believe that a hypothetical 10% change in interest rates would have a material impact on our consolidated financial statements included elsewhere in this prospectus. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. As of March 31, 2020 and December 31, 2019, we had \$40.0 million in variable rate debt outstanding. Our 2019 Credit Agreement bears interest per annum at 7.75% plus LIBOR for such interest period. A hypothetical change in interest rates of 10% would have resulted in a change of \$4.0 million in interest expense in 2019.

#### Foreign Currency Exchange Risk

Our reporting currency is the U.S. dollar and our sales outside the United States are primarily denominated in Euros and GBP. For the three months ended March 31, 2020 and the years ended December 31, 2019 and 2018, approximately 51%, 74% and 79%, 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 are 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. We do not believe that a hypothetical 10% change in the relative value of the U.S. dollar to other currencies would have a material impact on our consolidated financial statements included elsewhere in this prospectus.

## **Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed by, or under the supervision of, that company's principal executive and principal financial officers, or persons performing similar functions, and influenced by that company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

In connection with the audits of our consolidated financial statements included elsewhere in this prospectus, we and our independent registered public accounting firm identified a material weakness related to our financial statement closing process, primarily related to a lack of appropriately designed and implemented controls over the review and approval of manual journal entries and the related supporting journal entry calculations. Under standards established by the Public Company Accounting Oversight Board, a material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected and corrected on a timely basis.

We are working to remediate the material weakness and are taking steps to strengthen our internal control over financial reporting. In order to do so, we have taken and plan to take the following actions: (i) the hiring of additional finance and accounting personnel over time to augment our accounting staff and to provide more resources for complex accounting matters and financial reporting; and (ii) further developing and implementing formal policies, processes and documentation procedures relating to our financial reporting. The actions that we are taking are subject to ongoing executive management review, and will also be subject to audit committee oversight. If we are unable to successfully remediate the material weaknesses, or if in the future, we identify further material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated.

## 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 frequencies 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, 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 2019 there were over 50 million individuals worldwide with arrhythmias and approximately 1.1 million ablation procedures globally, reflecting a \$5.7 billion global market that has grown 13% 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.

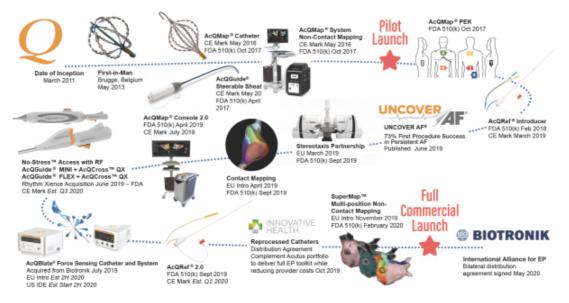
We have established a broad portfolio of electrophysiology products that complements our AcQMap System. In addition to our AcQMap System, our commercial product portfolio includes a suite of access devices, our transseptal crossing device and full product lines of diagnostic and, in our European markets, 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 gold-tip, irrigated, radiofrequency force sensing ablation catheters and control unit which we expect to commercialize once we obtain regulatory approval. We anticipate CE Mark approval and commercial launch of our AcQBlate force sensing ablation catheters and control unit in the same time frame. We currently anticipate FDA PMA approval, and the U.S. commercial launch, of our AcQBlate force sensing ablation catheters and control unit in late 2022. 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.

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 product line from Biotronik. Since our full launch, we have continued to enhance our product portfolio and global presence by entering into bi-lateral distribution agreements with Biotronik in May 2020, which added a full suite of diagnostic and ablation catheters to our product portfolio and significantly expanded our international distribution and market development capabilities. 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 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.

During the year ended December 31, 2019, we generated revenue of \$2.8 million and a net loss of \$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), compared to revenue of \$2.2 million and a net loss of \$47.9 million during the year ended December 31, 2018. During the quarter ended March 31, 2020, we generated revenue of \$1.6 million and a net loss of \$18.1 million, compared to revenue of \$0.8 million

and a net loss of \$14.7 million during the quarter ended March 31, 2019. As of March 31, 2020 and December 31, 2019, our installed base of AcQMap consoles and workstations placed into service at customer sites was 31 and 27 units, respectively. Since our full commercial launch through June 26, 2020, we have installed 20 AcQMap consoles and workstations. 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. The 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. See the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" 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 gold-tip, irrigated, radiofrequency force sensing ablation catheters and control unit, which we expect to initially commercialize in the United States and Europe upon regulatory approval. We currently anticipate that our AcQBlate force sensing ablation catheters will receive CE Mark in the second half of 2020, and we plan to commence an IDE trial for FDA PMA approval in the United States within the same time frame. 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 2019, there were over 50 million individuals worldwide with arrhythmias and approximately 1.1 million ablation procedures globally, reflecting a global market of \$5.7 billion that is less than 5% penetrated. While the global market has grown at 13% 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 400,000 cardiac ablation procedures performed in the United States in 2019 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 April 10, 2020, we solely owned or exclusively licensed more than 55 issued patents globally and more than 65 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 June 23, 2020, our commercial organization consisted of 60 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 gold-tip, irrigated, radiofrequency force sensing ablation catheters and control unit, which we expect to commence in the second half of 2020.

#### **Our Market and Industry**

## Cardiac Arrhythmias

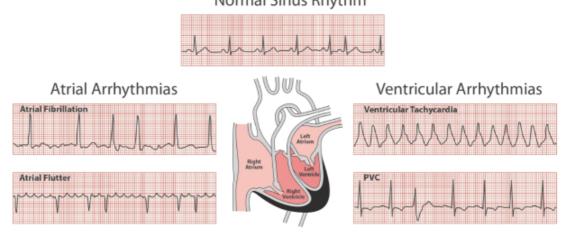
Cardiac arrhythmias, or heart rhythm disorders, are common and can occur when the heart beats too rapidly, too slowly or irregularly. Symptoms associated with arrhythmias include fatigue, reduced exercise tolerance, palpitations, lightheadedness, shortness of breath and significant quality of life impairment. 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 2019, 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 life style." 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.

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.
Normal Sinus Rhythm



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 2019. 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.



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 475,000 cardiac ablation procedures globally for atrial fibrillation in 2019, representing a current market size of approximately \$3.4 billion in disposable product revenue. We believe this market is significantly underpenetrated. For example, while 475,000 cardiac ablation procedures were performed globally in 2019, 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 2019. 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 516,000 ablation procedures worldwide for SVTs in 2019, reflecting a market size of approximately \$1.7 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 heart beat. 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 2019 there were 5.5 million individuals worldwide with ventricular arrhythmias who may have benefitted from ablation therapy. However, we estimate that approximately 90,000 global ablation procedures for ventricular arrhythmias were performed in 2019, reflecting a market size of approximately \$620 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	2019 Global Prevalence	2019 Global Procedures	2019 Market Size (Disposables)
Atrial fibrillation (AF)	30.0 million	475,000	\$ 3.4 billion
Supraventricular tachycardias (SVTs)	17.1 million	516,000	\$ 1.7 billion
Ventricular arrhythmias (VTs and PVCs)	5.5 million	90,000	\$ 0.6 billion
Total	52.6 million	1,081,000	\$ 5.7 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 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.

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.

# 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.

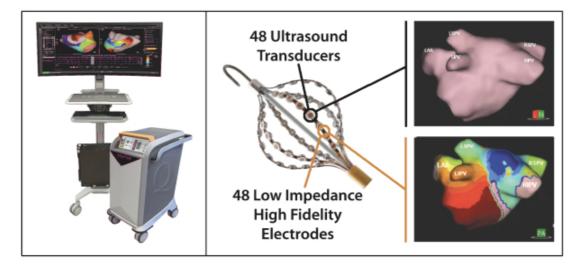
We have established a broad portfolio of electrophysiology products that complements our AcQMap System. We believe that our ability to offer a broad and differentiated product portfolio will support the adoption and utilization of our AcQMap System and drive an efficient business model with a growing 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.

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 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.

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	<ul> <li>Ultrasound is used to create the anatomy</li> <li>Non-contact data is collected from a single, central position within the chamber of interest</li> <li>Selected segments of the data are processed through the charge density algorithm</li> <li>Charge density maps display activation patterns and pathways</li> </ul>	<ul> <li>Ultrasound is used to create the anatomy</li> <li>Non-contact data is collected from multiple positions throughout the chamber of interest</li> <li>Data is automatically binned based on signal morphology</li> <li>The data in each unique bin is sequenced to a stable, timing reference</li> <li>Charge density maps display the activation pathway</li> </ul>
Mappable rhythms	<ul> <li>Simple, stable tachycardias (Atrial Tachycardia, Typical Atrial Flutter, Ventricular Tachycardia)</li> <li>Complex, stable tachycardias (Atypical Atrial Flutter, Atrial and ventricular tachycardias with small cycle length variations)</li> <li>Complex, unstable tachyarrhythmias (Atrial fibrillation)</li> </ul>	<ul> <li>Simple, stable tachycardias (Atrial Tachycardia, Typical Atrial Flutter, Ventricular Tachycardia)</li> <li>Complex, stable tachycardias (Atypical Atrial Flutter, Atrial and ventricular tachycardias with small cycle length variations)</li> </ul>
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 <sup>3</sup> 60 mm and UNCOVER AF excluded subjects with left atrial size <sup>3</sup> 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

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.

Two 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.

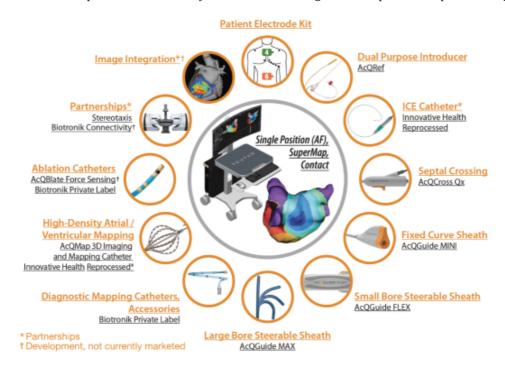
The PRECEPT IDE Study sponsored by Biosense Webster Inc. (a Johnson & Johnson Company) was a non-randomized study of persistent AF subjects that enrolled 381 subjects. Inclusion/exclusion criteria for PRECEPT and UNCOVER AF were very similar, however there were two key differences in the study designs; 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%.

## **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 gold-tip, irrigated, radiofrequency force sensing ablation catheters and control unit which we expect to commercialize once we obtain regulatory approval. We anticipate CE Mark approval and commercial launch of our AcQBlate force sensing ablation catheters and control unit in the second half of 2020. Biotronik had previously performed the BioConcept Study which was used as the base data for CE Mark submission, and we believe that no additional clinical data will be required for CE Mark approval. We also plan to commence two IDE trials for FDA PMA approval in the United States within the same time frame. We currently anticipate FDA PMA approval, and the U.S. commercial launch, of our AcQBlate force sensing ablation catheters and control unit in late 2022. The two IDE trials are expected to commence in late 2020, with one trial seeking a right atrial typical flutter indication and the second trial seeking a paroxysmal and persistent atrial fibrillation indication.

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. 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.			

Pr	oduct 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 in 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. 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.	
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 device. We currently anticipate that our AcQBlate force sensing ablation catheters and Qubic Force control unit will receive CE Mark in the second half of 2020, and we plan to commence an IDE trial for FDA clearance within the same time frame.	
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 2022 and in certain markets in Western Europe and the United Kingdom (where CE Mark is currently in place).	

Pr	roduct 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 device is used in conjunction with our AcQBlate force sensing catheters to allow the electrophysiologist to monitor and adjust the contact force of the ablation catheter tip on the cardiac wall during ablation. We currently anticipate that the Qubic Force device will receive CE Mark in the second half of 2020 and FDA clearance in the first half of 2022.
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 first 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 devices.
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 first 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 devices.

\* 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 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'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, 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.

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 June 23, 2020, our commercial organization consisted of 60 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 gold-tip, irrigated, radiofrequency force sensing ablation catheters and Qubic Force device. 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 (<u>U</u>tilizing <u>N</u>ovel dipole density <u>C</u>apabilities to <u>O</u>bjectively <u>V</u>isualize the <u>E</u>tiology of <u>R</u>hythms in <u>A</u>trial <u>F</u>ibrillation) 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.

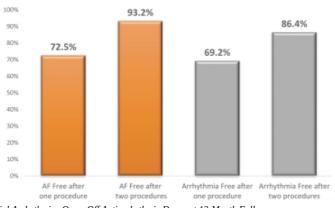
## Key Primary and Secondary Effectiveness Outcomes

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 100 treated patients in Europe and Canada. We expect to complete follow-up for the RECOVER AF trial in the second half of 2020.

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 patients in October 2019 and expect to enroll up to 500 patients. As of March 31, 2020, we had enrolled 62 patients.

Our PLASZMA (<u>PVI + Left Atrial Slow Zone Mapping and Ablation</u>) 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 2020 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 gold-tip, irrigated, radiofrequency force sensing ablation catheters. These two trials are expected to commence in late 2020 with one trial seeking a right atrial typical flutter indication and the second trial seeking a paroxysmal and persistent atrial fibrillation indication. The clinical trial for right atrial typical flutter will have 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 PMA approval. The paroxysmal and persistent atrial fibrillation trial has a primary effectiveness endpoint of freedom from atrial arrhythmia-freedom at 12-months and is expected to take three years to complete and obtain PMA approval.

#### **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.

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 2019, our research and development team released five new disposable products, two hardware products, including a major generational update to our AcQMap System, and 15 software updates. 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 in the United States.

C-APC	APC Description	National Medicare Rate	
<u>С-АРС</u> 5211	Level 1 EP procedures	\$ 988	
5212	Level 2 EP Procedures	\$ 5,885	
5213	Level 3 EP Procedures	\$ 20,433	

# **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.

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 2020.

MS-DRG	Description	2020 National Average Reimbursement	
273	Percutaneous intracardiac procedures with major complications	\$ 23,240	
274	Percutaneous intracardiac procedures without major complications	\$ 19,792	

### **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 \$1,178 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 \$447 in 2020. 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 \$446 according to the 2020 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.

#### **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 ablation catheters, which upon regulatory approval we will 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 device, which is designed for the visualization of contact force measured by our AcQBlate Force ablation catheters. Upon regulatory approvals, Biotronik will

initially manufacture our Qubic Force device 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 device 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 ablation catheters and Qubic Force device, 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 ablation catheters and our Qubic Force device 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. The Biotronik License Agreement also requires that we pay the Biotronik Parties certain milestone payments as follows: (i) \$2.0 million upon receipt of marketing approval for the sale of our AcQBlate Force ablation catheters in Europe; (ii) \$5.0 million upon the receipt of marketing approval for the sale of our AcQBlate Force ablation catheters; and (iii) \$3.0 million upon the first commercial sale of our AcQBlate Force ablation catheters in the United States; we make of our AcQBlate Force 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 licenses to our AcQBlate Force ablation catheters and Qubic Force device 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 ending on the Biotronik Parties, neither party nor their affiliates are allowed to commercialize competitive ablation catheters in the field of the license.

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 ablation catheters and Qubic Force device, 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 device and our disposable products (including our AcQBlate Force 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 such countries 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 device 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 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."

### 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.

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 specific intellectual property claims are directed at 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 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 April 10, 2020, our patent portfolio included 24 solely owned or exclusively licensed U.S. patents and 26 solely owned or exclusively licensed pending U.S. patent applications (including three solely owned Patent Cooperation Treaty, or PCT, applications and four solely owned provisional U.S. patent applications). In addition, we solely owned or exclusively licensed 32 issued patents and 42 pending patent applications in jurisdictions outside the United States. Of our 68 pending patent applications, eight have been allowed. Of our 24 owned and exclusively licensed U.S. patents, 20 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 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 applications.

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.

# **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 approval 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 Approval 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 approval 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 approval 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.

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 California Consumer Privacy Act, or CCPA, which creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA went into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA has been amended from time to time, and it remains unclear what, if any, further modifications will be made to this legislation or how it 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." 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.

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

#### 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 changes the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The Affordable Care Act imposed, among other things, a 2.3% federal excise tax, with limited exceptions, on any entity that manufactures or imports Class I, II and III medical devices offered for sale in the United States that began on January 1, 2013. Although this excise tax was in effect during the years 2013–2015, there was in effect a moratorium on the medical device excise tax through the end of 2019. The excise tax was repealed effective January 1, 2020. The Affordable Care Act also provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. We do not yet know the full impact that the Affordable Care Act will have on our business. There have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in the future. Moreover, the Trump administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the Tax Cuts and Jobs Act was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance, effective as of January 1, 2019.

On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall.

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

among other things, reduced CMS payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

# **Coverage and Reimbursement**

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

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

As of June 23, 2020, we had 223 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.

#### 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, 2022, 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.

## MANAGEMENT

# **Executive Officers and Directors**

The following table sets forth information, as of March 31, 2020, regarding our executive officers and directors.

Name	Age	Title
Executive Officers		—
Vince Burgess	55	President, Chief Executive Officer and Director
Gary W. Doherty	54	Chief Financial Officer
John Barnickel	52	Chief Commercial Officer
Non-Employee Directors		
R. Scott Huennekens	55	Executive Director and Chairman
David Bonita, M.D.(3)	44	Director
Andrew ElBardissi, M.D.(2)	38	Director
Jim Hinrichs(1)(2)(5)	52	Director
Shahzad Malik, MB BChir <sup>(1)(2)</sup>	53	Director
Aditya Puri <sup>(4)</sup>	49	Director
Christoph Scharf, M.D.(6)	53	Director
Significant Employees		
Graydon Beatty, Ph.D.	63	Chief Technology Officer
Tim Corvi	52	Vice President, Research & Development
Peter Elia	49	Chief Strategy & Business Development Officer
Rick Kimes	58	Senior Vice President, Operations
Steven McQuillan	57	Senior Vice President, Regulatory and Clinical Affairs
Charlie Piscitello	57	Chief People Officer
Tom Sohn	45	Senior Vice President, General Counsel & Secretary
(1) Member of the audit committee.		

Aember of the audit committee

(1) (2) (3) (4) Member of the compensation committee.

Member of the corporate governance and nominating committee.

Mr. Puri will resign from our board of directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as Mr. Puri is an Investment Partner at Xeraya Capital, whose policy prohibits Mr. Puri from serving on the board of directors of one of the firm's public portfolio companies. Lead independent director upon completion of this offering.

(5) (6) Dr. Scharf resigned from our board of directors on June 10, 2020.

#### **Executive Officers**

Vince Burgess. Mr. Burgess has served as our President and Chief Executive Officer since October 2017 and a member of our board of directors since June 2013. From September 2010 to June 2020, Mr. Burgess also served as a Venture Partner at OrbiMed Advisors, an investment company focused on the healthcare industry. From 2002 to 2010, Mr. Burgess held various leadership positions at Volcano Corporation, where he was part of the founding team. He also serves on the boards of a number of private medical technology companies. Mr. Burgess received a B.S. in Business Administration and Entrepreneurship from the University of Southern California and an M.B.A. from University of California, Los Angeles.

We believe Mr. Burgess' management experience in the medical device industry, his extensive experience as a venture capital investor and as a member of the boards of directors of multiple private medical technology companies and his extensive understanding of our business, operations, and strategy qualify him to serve on our board of directors.

**Gary W. Doherty**. Mr. Doherty has served as our Chief Financial Officer since November 2017 and has been with Acutus since October 2015. Mr. Doherty previously held various leadership positions at Volcano Corporation from August 2003 to October 2015, where he most recently served as Group Plant Controller from October 2010 to October 2015. Prior to this, he served as the Director of Financial Management with Digirad, Inc. from August 2001 to August 2003, and served as Corporate Controller for Palomar Technologies, Inc., from May 2000 to August 2001. Mr. Doherty received a B.S. in Business Administration, Finance from San Diego State University.

John Barnickel. Mr. Barnickel has served as our Chief Commercial Officer since March 2020. Prior to joining Acutus, Mr. Barnickel served as Vice President, Pacific Region for Medtronic plc's Cardiac and Vascular Group from July 2006 to March 2020. Mr. Barnickel has also held various commercial roles in the medical device industry, including serving as Regional Manager for Guidant Corporation, which was acquired by Boston Scientific Corporation in 2006, from 1998 to 2006 and Division Manager, Western Region for C.R. Bard, Inc., which was acquired by Boston, Dickinson and Company in 2017, from 1993 to 1998. Mr. Barnickel received a B.S. in Business Administration, Finance from California State University, East Bay and an M.B.A. from the University of California, Davis, Graduate School of Management.

# Non-Employee Directors

**R. Scott Huennekens**. Mr. Huennekens has served as our Executive Chairman of our board of directors since July 2019. Mr. Huennekens also serves as member of the board of directors of Envista Holdings Corporation, NuVasive, Inc. and ViewRay, Inc., and was previously on the board of REVA Medical, Inc. Mr. Huennekens was the President, Chief Executive Officer and Chairman of the Board for Verb Surgical, an independent start-up company formed by Google and Johnson & Johnson to develop surgical platforms including advanced surgical robotics, from August 2015 to December 2018. Prior to joining Verb Surgical in 2015, Mr. Huennekens was President, Chief Executive Officer and Board Member of Volcano Corporation for 13 years. Mr. Huennekens was President and Chief Executive Officer at Digirad Corporation from 1997 to 2002 and held various management roles at Baxter Healthcare from 1993 to 1997. Mr. Huennekens received a Bachelor of Science degree in Business Administration from the University of Southern California, and a Master of Business Administration degree from Harvard Graduate School of Business.

We believe Mr. Huennekens is qualified to serve as the Executive Chairman of our board of directors due to his background as a public company Chief Executive Officer, his extensive experience as an investor in medical technology companies and as a member of the boards of directors of multiple public and private companies.

**David P. Bonita, M.D.** Dr. Bonita has served as a member of our board of directors since March 2016. Dr. Bonita has also served as a member of the board of directors of IMARA Inc. since March 2019 and Tricida, Inc. since January 2014 and has previously served on the boards of ViewRay Inc. and SI-BONE, Inc. As of February 2020, Dr. Bonita is a member of OrbiMed Advisors. From June 2004 to February 2020, Dr. Bonita held other positions at OrbiMed Advisors. Dr. Bonita has also worked as a corporate finance analyst in the healthcare investment banking groups of Morgan Stanley and UBS. He has published scientific articles in peer-reviewed journals based on signal transduction research performed at Harvard Medical School. He received his B.A. in biology from Harvard University and his joint M.D./M.B.A. from Columbia University.

We believe Dr. Bonita is qualified to serve on our board of directors due to his background as a physician and his extensive experience as an investor in medical technology companies.

Andrew ElBardissi, M.D. Dr. ElBardissi has served as a member of our board of directors since July 2017. Dr. ElBardissi is a Partner at Deerfield Management. Previously, he served as a Principal at Longitude Capital Management Co., LLC, a private investment firm that focuses on venture growth investments in drug development and medical technology, from January 2014 to January 2017. Prior to that, Dr. ElBardissi served as an Associate in J.P. Morgan's Healthcare Investment Banking practice from June 2011 to July 2013.

Dr. ElBardissi received a B.S. in biology, (Phi Beta Kappa) from the Schreyer Honors College at the Pennsylvania State University, an M.P.H. in quantitative methods from Harvard University, an M.B.A. from Harvard Business School and an M.D. from the Mayo Clinic College of Medicine.

We believe Dr. ElBardissi is qualified to serve on our board of directors due to his background as a practicing physician, his extensive experience as an investor in medical technology companies and as a member of the boards of directors of multiple private companies.

**Jim Hinrichs**. Mr. Hinrichs has served as a member of our board of directors and chair of our Audit Committee, since October 2019. Mr. Hinrichs is also a member of the board of directors of Integer Holdings Corporation and Orthofix Medical, Inc., two leading medical device companies. Mr. Hinrichs has over 25 years of corporate finance experience and previously served as Executive Vice President and Chief Financial Officer of Alere, Inc., a publicly traded, global diagnostics company, from April 2015 until its sale to Abbott Labs for approximately \$8 billion in October 2017. Prior to joining Alere, Inc., Mr. Hinrichs served as Chief Financial Officer of CareFusion Corp., a publicly traded medical device company, from December 2010 until its sale to Becton Dickenson for \$12 billion in March of 2015. Before that, Mr. Hinrichs held various financial leadership positions at CareFusion, Cardinal Health and Merck & Co. He holds graduate and undergraduate degrees in business from Carnegie-Mellon University.

We believe Mr. Hinrichs is qualified to serve on our board of directors due to his background as a public company Chief Financial Officer, his extensive experience as an investor in medical technology companies and as a member of the boards of directors of multiple public and private companies.

**Shahzad Malik, MB BChir**. Dr. Malik has served as a member of our board of directors since December 2011. Dr. Malik is also a member of the board of directors of Iterum Therapeutics plc. Since April 1999, Dr. Malik has served as a General Partner at Advent Life Sciences, a venture capital firm that focuses on life sciences investments. Prior to that, Dr. Malik served as an Associate at McKinsey & Company and previously was a practicing interventional cardiologist in Britain's NHS. Dr. Malik received a MA in Physiological Sciences from the University of Oxford and an MB BChir in medicine from the University of Cambridge.

We believe Dr. Malik is qualified to serve on our board of directors due to his background as a practicing physician and his extensive experience as an investor in life sciences and medical device companies.

Aditya Puri. Mr. Puri has served as a member of our board of directors since March 2016. Mr. Puri previously served on the board of directors of medical device companies ConforMIS Inc. and ViewRay, Inc. Since October 2012, Mr. Puri has served as an Investment Partner at Xeraya Capital, which, among other mandates, is the exclusive life sciences investments platform for Khazanah Nasional Berhad, the Malaysian government's strategic investment fund. Mr. Puri has almost 25 years of experience in life science and technology industries, encompassing business unit leadership, international expansion, and corporate and venture capital investing roles in organizations that include Yankee Group, a global technology research and consulting company, and Boston Scientific. Mr. Puri received a B.S. from the University of Southern Maine, and an M.B.A from the MIT Sloan School of Management. He has also passed all parts of the U.S. Uniform CPA Examination.

Mr. Puri will resign from our board of directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as Mr. Puri is an Investment Partner at Xeraya Capital, whose policy prohibits Mr. Puri from serving on the board of directors of one of the firm's public portfolio companies.

# Significant Employees

**Graydon Beatty, Ph.D.** Dr. Beatty has served as our Chief Technology Officer since September 2011. Prior to joining Acutus, Dr. Beatty served as co-Founder, Director, and Chief Technical Officer at Endocardial Solutions, Inc., a cardiac mapping and navigation company which was acquired by St. Jude Medical, Inc. in

2004, from May 1992 to July 2010. Dr. Beatty also served as Senior Principle Engineer at Cardiac Pacemakers, Inc., an implantable device company, now Guidant Corporation, from September 1989 to October 1991 and Senior Engineer at Medical Devices, Inc., an electronic pain-control company, from July 1987 to September 1989. Dr. Beatty earned his B.S. degree in Electrical Engineering from the University of Minnesota, M.S. degree in Biomedical Engineering from the University of Minnesota.

**Tim Corvi**. Mr. Corvi has served as our Vice President, Research & Development since July 2011. Prior to joining Acutus, Mr. Corvi served as Director of Engineering at Ablation Frontiers LLC, which was acquired by Medtronic plc in 2009, from January 2008 to July 2011 and Sr. Program Manager of R&D at ALARIS Medical Systems, Inc., which was acquired by Cardinal Health, Inc. in 2004, from September 2002 to December 2007. Mr. Corvi holds a B.S. in Mechanical Engineering from the University of California, San Diego.

**Peter Elia**. Mr. Elia has served as our Chief Strategy & Business Development Officer since September 2019 and has been with Acutus since September 2018. Prior to joining Acutus, Mr. Elia served as Vice President Business and Market Development at Biotronik, Inc. from May 2008 to September 2018. Prior to joining Biotronik, Inc, Mr. Elia served as Vice President of Sales at Boston Scientific Corporation from September 1997 to May 2008. Mr. Elia received a B.S. in Kinesiology from San Diego State University.

**Rick Kimes**. Mr. Kimes has served as our Senior Vice President of Operations since October 2019. Prior to joining Acutus, Mr. Kimes served as Operations Consultant for Tandem Diabetes Care, Inc. from November 2018 to October 2019. Mr. Kimes was SVP of Operations for REVA Medical, Inc., a medical device company, from January 2016 to November 2018, and held consulting roles with various medical device companies, including Breg, Inc., from May 2013 to January 2016. Mr. Kimes also served as SVP of Operations at Volcano Corporation from June 2009 to May 2013. Mr. Kimes received a B.S., Mechanical Engineering from the University of Utah.

**Steven McQuillan**. Mr. McQuillan has served as our Senior Vice President, Regulatory and Clinical Affairs since September 2015. Prior to joining Acutus, Mr. McQuillan served as Senior Vice President, Regulatory and Clinical Affairs of St. Jude Medical, Inc., a medical device company, from January 2014 to September 2015 and as Vice President, Clinical Operations and Regulatory Affairs of Spinal Modulation, Inc., a medical device company, from March 2012 to January 2014. Mr. McQuillan received a B.A. in Engineering Statistics and a B.A. in Biostatistics from the University of Minnesota.

**Charlie Piscitello.** Mr. Piscitello has served as our Chief People Officer since July 2019. Prior to joining Acutus, Mr. Piscitello served as Chief People Officer for PETCO, a pet specialty retailer, from March 2007 to March 2018. Prior to this, he served as Vice President, Human Resources for Boston Scientific Corporation, from August 2004 to March 2007. Mr. Piscitello earned a bachelor's degree in communication from Marquette University.

**Tom Sohn**. Mr. Sohn has served as our Senior Vice President, General Counsel & Secretary since March 2020. Prior to joining Acutus, Mr. Sohn served as Vice President, General Counsel and Secretary of Breg, Inc., an orthopedic solutions provider, from June 2013 to October 2019. Prior to this, Mr. Sohn previously served as Sr. Director, Legal Affairs of NuVasive, Inc., from August 2011 to May 2013 and as Sr. Legal Counsel, Securities and Corporate Development for Websense, Inc. from October 2006 to August 2011. From 2004 to 2006, Mr. Sohn practiced corporate law at DLA Piper, LLP, specializing in public and private financings, mergers and acquisitions and corporate governance matters. Mr. Sohn received a B.A. in organizational leadership from the University of Michigan, Ann Arbor and a Juris Doctorate from the University of San Diego School of Law.

# **Family Relationships**

There are no family relationships among any of our directors or executive officers.

## **Executive Officers**

Each of our executive officers serves at the discretion of our board of directors and holds office until his or her successor is duly elected and qualified or until his or her earlier resignation or removal.

# **Board of Directors**

Our board of directors currently consists of seven sitting members. The current members of our board of directors were elected pursuant to our current amended and restated certificate of incorporation and under the provisions of our amended and restated voting agreement, which requires the stockholders who are party to the agreement to vote their respective shares of our capital stock to elect directors.

The provisions of our amended and restated voting agreement relating to the election of our directors will terminate and the provisions of our current certificate of incorporation by which our directors were elected will be amended and restated in connection with this offering. After the completion of this offering, the number of directors will be fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws. Each of our current directors will continue to serve as a director until the election and qualification of his or her successor, or until his or her earlier death, resignation or removal.

Our amended and restated certificate of incorporation will provide that our board of directors will be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our current directors will be divided among the three classes as follows:

- the Class I directors will be Mr. Burgess and Dr. Malik, and their terms will expire at the annual meeting of stockholders to be held in 2021;
- the Class II directors will be Mr. Huennekens, Dr. Bonita and to be held in 2022; and , and their terms will expire at the annual meeting of stockholders
- the Class III directors will be Mr. Hinrichs and Dr. ElBardissi, and their terms will expire at the annual meeting of stockholders to be held in 2023.

At each annual meeting of stockholders, upon the expiration of the term of a class of directors, the successor to each such director in the class will be elected to serve from the time of election and qualification until the third annual meeting following his or her election and until his or her successor is duly elected and qualified, in accordance with our amended and restated certificate of incorporation. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of our directors.

This classification of our board of directors may have the effect of delaying or preventing changes in control of our company.

#### **Director Independence**

Upon the completion of this offering, we anticipate that our common stock will be listed on The Nasdaq Global Market. Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of this offering. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and corporate governance and nominating committees be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered to be independent for purposes of Rule 10A-3 and under the rules of Nasdaq, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries.

To be considered independent for purposes of Rule 10C-1 and under the rules of Nasdaq, the board of directors must affirmatively determine that each member of the compensation committee is independent, including a consideration of all factors specifically relevant to determining whether the director has a relationship to the company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (i) the source of compensation of such director, including any consulting, advisory or other compensatory fee paid by the company to such director; and (ii) whether such director is affiliated with the company, a subsidiary of the company or an affiliate of a subsidiary of the company.

Our board of directors undertook a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that , representing of our seven directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of Nasdaq.

In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Party Transactions."

#### **Corporate Governance**

Our board of directors is currently chaired by Mr. Huennekens. As a general policy, our board of directors believes that separation of the positions of Chair of our board of directors and Chief Executive Officer reinforces the independence of our board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of our board of directors as a whole. As such, Mr. Burgess serves as our President and Chief Executive Officer while Mr. Huennekens serves as the Executive Chair of our board of directors but is not an officer. We currently expect and intend the positions of Chair of our board of directors and President and Chief Executive Officer to continue to be held by two individuals in the future. In addition, upon completion of this offering, Mr. Hinrichs will become our lead independent director.

## **Board Committees**

Our board of directors has an audit committee, a compensation committee and a corporate governance and nominating committee, each of which has the composition and the responsibilities described below.

#### Audit Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our audit committee will be Mr. Hinrichs, Dr. Malik and . Mr. Hinrichs will be the chair of our audit committee and will be our audit committee financial expert, as that term is defined under the SEC rules

implementing Section 407 of the Sarbanes-Oxley Act, and possesses financial sophistication, as defined under the rules of Nasdaq. Our audit committee will oversee our corporate accounting and financial reporting process and assist our board of directors in monitoring our financial systems. Our audit committee will also:

- select and hire the independent registered public accounting firm to audit our consolidated financial statements;
- help to ensure the independence and performance of the independent registered public accounting firm;
- approve audit and non-audit services and fees;
- review our consolidated financial statements and discuss with management and the independent registered public accounting firm our annual audited and quarterly consolidated financial statements, the results of the independent audit and the quarterly reviews and the reports and certifications regarding internal control over financial reporting and disclosure controls;
- prepare the audit committee report that the SEC requires to be included in our annual proxy statement;
- review reports and communications from the independent registered public accounting firm;
- review the adequacy and effectiveness of our internal controls and disclosure controls and procedure;
- review our policies on risk assessment and risk management;
- review and monitor conflicts of interest situations, and approve or prohibit any involvement in matters that may involve a conflict of interest or taking of a corporate opportunity;
- review related party transactions; and
- establish and oversee procedures for the receipt, retention and treatment of accounting related complaints and the confidential submission by our employees of concerns regarding questionable accounting or auditing matters.

Our audit committee will operate under a written charter, to be effective prior to the completion of this offering, which will satisfy the applicable rules of the SEC and the listing standards of

## **Compensation Committee**

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our compensation committee will be Dr. Malik, Dr. ElBardissi and Mr. Hinrichs. Dr. Malik will be the chair of our compensation committee. Our compensation committee will oversee our compensation policies, plans and benefits programs. The compensation committee will also:

- oversee our overall compensation philosophy and compensation policies, plans and benefit programs;
- review and approve or recommend to the board of directors for approval compensation for our executive officers and directors;
- prepare the compensation committee report that the SEC will require to be included in our annual proxy statement; and
- administer our equity compensation plans.

Our compensation committee will operate under a written charter, to be effective prior to the completion of this offering, which will satisfy the applicable rules of the SEC and the listing standards of Nasdaq.

# Corporate Governance and Nominating Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our corporate governance and nominating committee will be Dr. Bonita, and . Dr. Bonita will

be the chair of our corporate governance and nominating committee. Our corporate governance and nominating committee will oversee and assist our board of directors in reviewing and recommending nominees for election as directors. Specifically, the corporate governance and nominating committee will:

- identify, evaluate and make recommendations to our board of directors regarding nominees for election to our board of directors and its committees;
- consider and make recommendations to our board of directors regarding the composition of our board of directors and its committees;
- review developments in corporate governance practices;
- evaluate the adequacy of our corporate governance practices and reporting; and
- evaluate the performance of our board of directors and of individual directors.

Our corporate governance and nominating committee will operate under a written charter, to be effective prior to the completion of this offering, which will satisfy the applicable rules of the SEC and the listing standards of Nasdaq.

# **Code of Business Conduct and Ethics**

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Following the completion of this offering, our code of business conduct and ethics will be available on our website at www.acutusmedical.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements. 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.

# Limitation on Liability and Indemnification Matters

Our board of directors expects to adopt an amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, and will contain provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

Our board of directors expects to adopt an amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the completion of this offering, and will provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws also will provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permits us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We have entered, and expect to continue to enter, into agreements to indemnify our directors, executive officers and

other employees as determined by our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. 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. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damages.

## **Compensation Committee Interlocks and Insider Participation**

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or its compensation committee. None of the current members of the compensation committee of our board of directors has been one of our employees within the past five years.

#### **Director Compensation**

Prior to this offering, we have not implemented a formal policy with respect to compensation payable to our non-employee directors. Other than as set forth in the table and described more fully below, we did not pay any compensation, including equity awards, to any of our non-employee directors in 2019. We reimburse our directors for expenses associated with attending meetings of our board of directors and its committees. Following the completion of this offering, we expect to implement an annual cash and equity compensation program for our non-employee directors. In addition, from time to time we have granted equity awards to some of our directors.

The following table presents the total compensation each of our non-employee directors received during the year ended December 31, 2019.

	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)(1)	All Other Compensation (\$)	Total (\$)
R. Scott Huennekens <sup>(2)</sup>	132,750	7,587,887	153,250	7,873,887
David Bonita, M.D.		—	—	
Andrew ElBardissi, M.D.		_	—	
Jim Hinrichs <sup>(3)</sup>	10,500	—	1,750	12,250
Shahzad Malik, MB BChir		_	—	
Aditya Puri		—	—	—
Christoph Scharf, M.D.(4)		—	—	—

(1) These figures reflect the aggregate grant date fair value of restricted stock units granted in the fiscal year. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. The figure included here for Mr. Huennekens represents the grant date value of a performance-based restricted stock unit with respect to 5,518,463 shares of our common stock granted on June 30, 2019, subject to his continued service through designated vesting dates and occurrence of an initial public offering or change in control within ten years of the date of grant. As attainment of the performance conditions for this award were not considered probable, no compensation expense related to these awards has been recorded for the year ended December 31, 2019. While SEC rules generally require disclosure of stock awards subject to performance conditions being met as of December 31, 2019, we are reporting the value that would have been recorded if an initial public offering had been considered probable at the time of grant, considering the fact that this offering will satisfy that condition. As of December 31, 2019, stock awards outstanding to our directors included only the aforementioned performance-based restricted stock unit award with respect to 5,518,463 shares of our common stock for Mr. Huennekens.

- Mr. Huennekens joined our board of directors in July 2019 as an independent director and our Executive Chairman. The figure in the "All Other Compensation" column for (2)Mr. Huennekens represents the amount paid to Mr. Huennekens for consulting services from March through June 2019, prior to joining our board of directors. Pursuant to his Executive Chairman Agreement, described below under "—Executive Chairman Compensation," Mr. Huennekens was paid at a rate of \$500 an hour for service in 2019 as Chairman of our board.
- Mr. Hinrichs joined our board of directors in October 2019 as an independent director, Mr. Hinrichs was paid a cash retainer of \$3,500 per month for service in 2019 as a member of the board and chair of the audit committee. In addition, Mr. Hinrichs was paid \$1,750 for services provided as a consultant in advance of his appointment to the board. (3)

(4) Dr. Scharf resigned as a director on June 10, 2020.

Directors who are also our employees receive no additional compensation for their service as directors. During 2019, Mr. Burgess, who is one of our directors, was also an employee of our company. See the section titled "Executive Compensation—Summary Compensation Table" for additional information about the compensation for Mr. Burgess.

Upon the completion of this offering, directors who are also full-time officers or employees of our company will receive no additional compensation for serving as directors, and directors who are not full-time officers or employees of our company, or non-employee directors, will be compensated as discussed under "---Non-Employee Director Compensation Policy."

#### **Executive Chairman Compensation**

We have entered into an Executive Chairman Agreement with Mr. Huennekens under which we have agreed to pay him at a rate of \$500 per hour for his service as Executive Chairman of our Board. Pursuant to this agreement, we granted Mr. Huennekens a restricted stock unit award on June 30, 2019 with respect to 5,518,463 shares of our common stock. This award is subject to Mr. Huennekens' continued service through designated vesting dates over a period ending on March 1, 2022 and occurrence of an initial public offering or change in control with respect to the Company within ten years of the date of grant.

Mr. Huennekens' Executive Chairman Agreement provides that in the event that Mr. Huennekens' service is terminated by us without cause or by Mr. Huennekens without good reason, then, subject to Mr. Huennekens' waiver and release in a form reasonably satisfactory to the Company, his equity compensation awards will become vested and exercisable to the extent they would have become vested and exercisable if he had continued service to the Company for the 12-month period following the date of termination. The agreement also provides that in the event of a change in control (as defined in our 2011 Equity Incentive Plan), Mr. Huennekens' equity compensation awards will become fully vested and exercisable.

## **Non-Employee Director Compensation Policy**

Each non-employee director other than Mr. Huennekens will receive an annual cash retainer in recognition of his or her service to the board, along with an additional annual cash retainer for service as a chairperson or a member of each standing committee of our board on which the director serves.

Position		Annual Cash Retainer	
Lead Independent Director		50,000	
Board Member		40,000	
Committee Chair			
Audit	\$	20,000	
Compensation	\$	14,000	
Corporate Governance and Nominating	\$	10,000	
Committee Member			
Audit	\$	10,000	
Compensation	\$	7,000	
Corporate Governance and Nominating	\$	5,000	

Each non-employee director other than Mr. Huennekens will receive an annual equity award with a grant date value of \$100,000 in recognition of his or her continuing service to the board, in each case effective on the date of our annual shareholder meeting. Each annual equity award will vest in full after one year. In addition, each new non-employee director will receive an initial equity award with a grant date value of \$200,000 at the commencement of their service on our board of directors. Each initial equity award will vest over a three-year period, with 1/3 vesting after one year, and the remainder vesting monthly. Each of these grants will be made up of 70% options and 30% restricted stock units, by value.

# **EXECUTIVE COMPENSATION**

# **Summary Compensation Table**

This discussion contains forward looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

The following table provides information regarding the total compensation for services rendered in all capacities that was earned by our principal executive officer and our two other most highly compensated executive officers who were serving as executive officers as of December 31, 2019. These individuals are considered our named executive officers for 2019.

Name and Principal Position	Year	Salary (\$)(1)	Bonus (\$)(2)	Option Awards (\$)(3)	Non-Equity Incentive Plan Compensation (\$)	All Other Compensation (\$)	Total (\$)
Vince Burgess	2019	382,243	150,000			73	532,316
President and Chief Executive Officer							
Gary W. Doherty	2019	305,462	60,000	691,982		435	1,057,879
Chief Financial Officer							
Steven McQuillan	2019	309,000	92,700	314,780		435	716,915
Senior Vice President. Reaulatory and Clinical Affairs							

/ice President, Regulatory and Clinical Affairs

Mr. Burgess converted from a contractor to an employee of Acutus in October 2019. The figure for Mr. Burgess for 2019 reflects fees of \$312,500 for services as a contractor and a salary of \$69,743 for services as an employee. (1)

The figures for 2019 represent bonuses payable to them under our short-term cash incentive bonus program for executives, as described under "-Short-Term Cash Incentive (2) (3)

Program," below. These figures reflect the aggregate grant date fair value of stock options granted in the fiscal year, computed in accordance with the provisions of FASB ASC 718. Assumptions used in the calculation of these amounts are included in the notes to our consolidated financial statements included elsewhere in this registration statement. As required by SEC rules, the

## Short-Term Cash Incentive Program

We generally provide each of our executive officers an opportunity to receive annual cash incentive payments under our short-term cash incentive program. The amount of any cash incentive payable under this program is based on a target incentive amount for each named executive officer.

For 2019, the target incentive amount and actual year-end payments for Mr. Burgess, Mr. Doherty and Mr. McQuillan under our 2019 short-term cash incentive program were as follows:

	Target Award	Actual Award
Named Executive Officer	(\$)	(\$)
Vince Burgess	200,000	150,000
Gary W. Doherty	80,000	60,000
Steven McQuillan	92,700	92,700

#### Pension Benefits and Nonqualified Deferred Compensation

We do not provide a pension plan for our employees, and none of our named executive officers participated in a nonqualified deferred compensation plan in 2019.

# **Outstanding Equity Awards at 2019 Year-End**

The following table sets forth information regarding outstanding stock options and stock awards held by our named executive officers as of December 31, 2019:

	Option Awards(1)					
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price(2) (\$)	Option Expiration Date
Vince Burgess	9/19/2013	7/1/2013	350,000		\$ 0.42	9/19/2023
	9/22/2017	9/19/2017	158,327	123,144(3)	\$ 0.83	9/22/2027
	10/17/2018	1/1/2018	1,544,186	1,985,383(4)	\$ 1.06	10/17/2028
Gary W. Doherty	4/11/2016	10/19/2015	130,000	—	\$ 0.79	4/8/2026
	2/14/2018	2/14/2018	229,840	271,631(3)	\$ 1.06	2/14/2028
	9/19/2018	9/19/2018	127,746	281,043(3)	\$ 1.06	9/19/2028
	9/10/2019	9/10/2019		691,982(3)	\$ 1.375	9/10/2029
Steven McQuillan	4/11/2016	9/22/2015	539,288	—	\$ 0.79	4/8/2026
	4/11/2016	4/8/2016	301,240	27,385(3)	\$ 0.79	4/8/2026
	9/19/2017	9/14/2017	251,804	195,848(3)	\$ 1.06	9/19/2027
	9/10/2019	9/10/2019	—	314,780(3)	\$ 1.375	9/10/2029

(1)

Each of the outstanding equity awards was granted pursuant to our 2011 Plan. The exercise price for each option is the fair market value of our common stock on the date of grant, as determined by our board of directors.

(2) (3) This option vests over four years from the vesting commencement date, with 1/4 vesting on the first anniversary of the vesting commencement date, and the remainder vesting in 36 equal monthly installments, subject to continued service through each such vesting date. This option vests over four years from the vesting commencement date, with 1/16 vesting on each quarterly anniversary of the vesting commencement date, subject to continued

(4) service through each such vesting date.

## **Employment Agreements with Our Named Executive Officers**

#### Vince Burgess

We are party to an employment agreement dated as of October 14, 2019 with Mr. Burgess, our President and Chief Executive Officer. This agreement does not have a specific term and provides that Mr. Burgess is an at-will employee.

Mr. Burgess' current base salary is \$400,000 and his current annual target under our annual cash incentive program is 50% of his annual base salary. Mr. Burgess is eligible for severance benefits under his current employment agreement, subject to his execution of a general release in our favor, as more fully described in "-Potential Payments upon Termination or Change of Control."

# Gary W. Doherty

Prior to the completion of this offering, we intend to enter into a continuing employment agreement with Mr. Doherty, our Chief Financial Officer. The employment agreement is not expected to have a specific term and will provide that Mr. Doherty is an at-will employee.

Mr. Doherty's current base salary is \$320,000 and his current annual target under our annual cash incentive program is 25% of his annual base salary. We expect that Mr. Doherty will be eligible for severance benefits, subject to his execution of a general release in our favor, as more fully described in "-Potential Payments upon Termination or Change of Control."

#### Steven McQuillan

We are party to an employment agreement dated as of September 6, 2016 with Mr. McQuillan, our Senior Vice President, Regulatory and Clinical Affairs. This agreement does not have a specific term and provides that Mr. McQuillan is an at-will employee.

Mr. McQuillan's current base salary is \$309,000 and his current annual target under our annual cash incentive program is 30% of his annual base salary. Mr. McQuillan is eligible for severance benefits under his current employment agreement, subject to his execution of a general release in our favor, as more fully described in "—Potential Payments upon Termination or Change of Control."

# Potential Payments upon Termination or Change of Control

We provide the following severance benefits to our named executive officers in the event of a qualifying termination of employment under the terms of their employment agreements.

## Vince Burgess

In the event of a qualifying termination in the absence of a change in control, Mr. Burgess has the right to receive 12 months of base salary severance and paid COBRA continuation premiums, along with a pro-rated bonus at the target opportunity for the year of termination, all subject to Mr. Burgess' general release of the Company and its affiliates and agreement not to disparage the Company or solicit its employees.

In the event of a qualifying termination in connection with a change in control, Mr. Burgess has the right to receive 18 months of base salary severance, target bonus and paid COBRA continuation premiums, along with a pro-rated bonus at the target opportunity for the year of termination and accelerated vesting of any outstanding equity awards, all subject to Mr. Burgess' general release of the Company and its affiliates and agreement not to disparage the Company or solicit its employees.

In the event that Mr. Burgess remains employed with a successor employer through the six-month anniversary of a change in control, his Company equity awards will all become wholly vested, with any performance conditions deemed satisfied at the 100% level.

## Gary W. Doherty

We expect to provide Mr. Doherty with nine months of base salary severance in the event of a termination without cause in the absence of a change in control, or 12 months of base salary and pro-rated bonus for the year of termination in the event of a termination without cause in connection with a change in control.

## Steven McQuillan

In the event of a qualifying termination in the absence of a change in control, Mr. McQuillan has the right to receive six months of base salary severance and paid COBRA continuation premiums, along with a pro-rated bonus at the target opportunity for the year of termination, all subject to Mr. McQuillan's general release of the Company and its affiliates and agreement not to disparage the Company or solicit its employees.

In the event of a qualifying termination in connection with a change in control, Mr. McQuillan has the right to receive 12 months of base salary severance, target bonus and COBRA continuation premium reimbursements, along with a pro-rated bonus at the target opportunity for the year of termination and accelerated vesting of any outstanding equity awards, all subject to Mr. McQuillan's general release of the Company and its affiliates and agreement not to disparage the Company or solicit its employees.

#### **Equity Awards**

In the event of a merger or change in control in which the successor does not assume or substitute for an option or other award outstanding under our 2011 Plan (as defined below), then each option or other award outstanding under our 2011 Plan, will become fully vested. In addition, as described in more detail under "Employee Benefit and Stock Plans—2011 Equity Incentive Plan," our board of directors has broad discretion under the 2011 Plan with respect to treatment of awards outstanding under that plan in connection with a merger or change in control.

# **Employee Benefit and Stock Plans**

# 2020 Equity Incentive Plan

Prior to the effectiveness of this offering, we expect that our board of directors will adopt, and our stockholders will approve, our 2020 Equity Incentive Plan, or our 2020 Plan. The 2020 Plan will be effective on the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. Our 2020 Plan will provide for the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees and any of our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to our employees, directors and consultants and our subsidiary corporation's employees and consultants.

Authorized Shares. We expect that a total of shares of our common stock will be reserved for issuance pursuant to our 2020 Plan. In addition, the shares reserved for issuance under our 2020 Plan will also include: (i) those shares reserved but unissued under our 2011 Plan as of the effective date of the 2020 Plan; and (ii) shares of our common stock subject to awards granted under our 2011 Plan that, after the date of stockholder approval of the 2020 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2020 Plan pursuant to (i) and (ii) is shares). The number of shares available for issuance under our 2020 Plan will also include an annual increase on the first day of each fiscal year during the term of the plan, beginning with our 2020 fiscal year, equal to the least of:

- shares;
- 4% of the outstanding shares of common stock as of the last day of our immediately preceding fiscal year; or
- such other amount as our board of directors may determine.

If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, or, with respect to restricted stock, restricted stock units, performance units or performance shares, is forfeited or repurchased due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under our 2020 Plan.

With respect to stock appreciation rights, the net shares issued will cease to be available under the 2020 Plan and all remaining shares will remain available for future grant or sale under the 2020 Plan. Shares used to pay the exercise price of an award or satisfy the tax withholding obligations related to an award will become available for future grant or sale under our 2020 Plan. To the extent an award is paid out in cash rather than shares, such cash payment will not result in reducing the number of shares available for issuance under our 2020 Plan.

*Plan Administration*. Our board of directors or one or more committees appointed by our board of directors will administer our 2020 Plan. In addition, if we determine it is desirable to qualify transactions under the 2020 Plan as exempt under Rule 16b-3 of the Exchange Act, or Rule 16b-3, such transactions will be structured to

satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of our 2020 Plan, the administrator will have the power to administer our 2020 Plan and make all determinations deemed necessary or advisable for administering the 2020 Plan, such as the power to determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2020 Plan, determine the terms and conditions of awards (such as the exercise price, the times or times at which the awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions, and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of our 2020 Plan and awards granted under it, to prescribe, amend, and rescind rules relating to our 2020 Plan, including creating sub-plans, and to modify or amend each award, such as the discretionary authority to extent the post-termination exercisability period of awards (provided that no option or stock appreciation right will be extended past its original maximum term, and to allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also will have the authority to institute an exchange program by which: (i) outstanding awards may be surrendered or cancelled in exchange for awards of the same type which may have a higher or lower exercise price and/or different terms, awards of a different type and/or cash; (ii) participants have the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator; or (iii) the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations, and other actions will be final and binding on all participants.

*Stock Options*. Stock options may be granted under our 2020 Plan. The exercise price of options granted under our 2020 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option may not exceed 10 years, except that with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for 12 months. In all other cases, the option will generally remain exercisable for three months following the termination of service. However, in no event may an option be exercised later than the expiration of its term. Subject to the provisions of our 2020 Plan, the administrator determines the other terms of options.

*Stock Appreciation Rights.* Stock appreciation rights may be granted under our 2020 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding 10 years. After the termination of service of an employee, director or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her option agreement. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2020 Plan, the administrator determines the other terms of stock appreciation rights, including when such rights become exerciseable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

*Restricted Stock.* Restricted stock may be granted under our 2020 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of our 2020 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever conditions for lapse of the restriction on the shares it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the administrator, in its sole discretion,

may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting and dividend rights with respect to such shares upon grant without regard to the restriction, unless the administrator provides otherwise. Shares of restricted stock as to which the restrictions have not lapsed are subject to our right of repurchase or forfeiture.

*Restricted Stock Units.* Restricted stock units may be granted under our 2020 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2020 Plan, the administrator will determine the terms and conditions of restricted stock units, including the vesting criteria (which may include accomplishing specified performance criteria or continued service to us) and the form and timing of payment. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restricted stock units will vest.

Performance Units and Performance Shares. Performance units and performance shares may be granted under our 2020 Plan. Performance units and performance shares are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will establish organizational or individual performance goals or other vesting criteria in its discretion, which, depending on the extent to which they are met, will determine the number and/or the value of performance units and performance shares to be paid out to participants. After the grant of a performance unit or performance share, the administrator, in its sole discretion, may reduce or waive any performance criteria or other vesting provisions for such performance units or performance shares.

Performance units shall have an initial dollar value established by the administrator prior to the grant date. Performance shares shall have an initial value equal to the fair market value of our common stock on the grant date. The administrator, in its sole discretion, may pay earned performance units or performance shares in the form of cash, in shares or in some combination

*Outside Directors.* Our 2020 Plan will provide that all outside (non-employee) directors will be eligible to receive all types of awards (except for incentive stock options) under our 2020 Plan. Prior to the completion of this offering, we intend to implement a formal policy pursuant to which our outside directors will be eligible to receive equity awards under our 2020 Plan. Our 2020 Plan includes a maximum annual limit of \$500,000 of cash compensation and equity awards that may be paid, issued or granted to an outside director (other than the chair of our board of directors) in any fiscal year. For purposes of this limitation, the value of equity awards is based on the grant date fair value (determined in accordance with GAAP). Any cash compensation paid or equity awards granted to a person for his or her services as an employee, or for his or her services as a consultant (other than as an outside director), will not count for purposes of the limitation. The maximum limit does not reflect the intended size of any potential compensation or equity awards to our outside directors.

*Non-Transferability of Awards.* Unless the administrator provides otherwise, our 2020 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime. If the administrator makes an award transferable, such award will contain such additional terms and conditions as the administrator deems appropriate.

*Certain Adjustments.* In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under our 2020 Plan, the administrator will adjust the number and class of shares that may be delivered under our 2020 Plan and/or the number, class and price of shares covered by each outstanding award and the numerical share limits set forth in our 2020 Plan. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and all awards will terminate immediately prior to the consummation of such proposed transaction.

*Merger or Change in Control.* Our 2020 Plan provides that in the event of a merger or change in control, as defined under our 2020 Plan, each outstanding award will be treated as the administrator determines, without a participant's consent. The administrator is not required to treat all awards, all awards held by a participant, or all awards of the same type, similarly.

In the event that a successor corporation or its parent or subsidiary does not assume or substitute an equivalent award for any outstanding award, then such award will fully vest, all restrictions on such award will lapse, all performance goals or other vesting criteria applicable to such award will be deemed achieved at 100% of target levels and such award will become fully exercisable, if applicable, for a specified period prior to the transaction, unless specifically provided for otherwise under the applicable award agreement or other written agreement with the participant. The award will then terminate upon the expiration of the specified period of time. If an option or stock appreciation right is not assumed or substituted, the administrator will notify the participant in writing or electronically that such option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

In addition, in the event of a change in control, each outside director's options and stock appreciation rights, if any, will vest fully and become immediately exercisable, all restrictions on his or her restricted stock and restricted stock units will lapse and all performance goals or other vesting requirements for his or her performance shares and units will be deemed achieved at 100% of target levels, and all other terms and conditions met.

*Forfeiture and Clawback.* All awards granted under our 2020 Plan will be subject to recoupment under any clawback policy that we are required to adopt under applicable law. In addition, the administrator will be able to provide in an award agreement that the recipient's rights, payments and benefits with respect to such award will be subject to reduction, cancellation, forfeiture or recoupment upon the occurrence of specified events. In the event of any accounting restatement, the recipient of an award will be required to repay a portion of the proceeds received in connection with the settlement of an award earned or accrued under certain circumstances.

Amendment, Termination. The administrator will have the authority to amend, suspend or terminate the 2020 Plan provided such action will not impair the existing rights of any participant. Our 2020 Plan will automatically terminate in 2029, unless we terminate it sooner.

#### 2020 Employee Stock Purchase Plan

Prior to the effectiveness of this offering, we expect that our board of directors will adopt, and our stockholders will approve, our 2020 ESPP. Our 2020 ESPP will be effective on the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. We believe that allowing our employees to participate in our 2020 ESPP will provide them with a further incentive towards promoting our success and accomplishing our corporate goals.

Authorized Shares. A total of shares of our common stock will be available for sale under our 2020 ESPP. The number of shares of our common stock that will be available for sale under our 2020 ESPP also includes an annual increase on the first day of each fiscal year beginning with our 2021 fiscal year, equal to the least of:

- 1% of the outstanding shares of our common stock on the last day of the previous fiscal year;
  - shares; or
- such other amount as may be determined by our board of directors.

*Plan Administration.* Our board of directors, or a committee appointed by our board of directors will administer our 2020 ESPP and have full but non-exclusive authority to interpret the terms of our 2020 ESPP and determine eligibility to participate, subject to the conditions of our 2020 ESPP, as described below. We expect our compensation committee to administer our 2020 ESPP. The administrator will have full and exclusive discretionary authority to construe, interpret and apply the terms of the 2020 ESPP, to delegate ministerial duties to any of our employees, to designate separate offerings under the 2020 ESPP, to designate our subsidiaries and

affiliates as participating in the 2020 ESPP, to determine eligibility, to adjudicate all disputed claims filed under the 2020 ESPP and to establish procedures that it deems necessary or advisable for the administration of the 2020 ESPP, such as adopting such procedures, sub-plans and appendices to the enrollment agreement as are necessary or appropriate to permit participation in the 2020 ESPP by employees who are foreign nationals or employed outside the U.S. The administrator's findings, decisions and determinations will be final and binding on all participants to the full extent permitted by law.

*Eligibility.* Generally, all of our employees will be eligible to participate if they are customarily employed by us, or any participating subsidiary, for at least 20 hours per week and more than five months in any calendar year. The administrator will have the discretion prior to an enrollment date for all options granted on such enrollment date in an offering, to determine that an employee who: (i) has not completed at least two years of service (or a lesser period of time determined by the administrator) since his or her last hire date; (ii) customarily works not more than 20 hours per week (or a lesser period of time determined by the administrator); (iii) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator); (iii) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator); (iii) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator); (iii) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator); and (iv) is a highly compensated employee within the meaning of Section 414(v) of the Code or is an officer or subject to disclosure requirements under Section 16(a) of the Exchange Act, is or is not eligible to participate in such offering period.

However, an employee may not be granted rights to purchase shares of our common stock under our 2020 ESPP if such employee:

- immediately after the grant would own capital stock possessing 5% or more of the total combined voting power or value of all classes of our capital stock; or
- holds rights to purchase shares of our common stock under our 2020 ESPP or any other employee stock purchase plans that exceed \$25,000 worth of shares of our common stock in a calendar year.

*Offering Periods.* Our ESPP will include a component that allows us to make offerings intended to qualify under Section 423 of the Code and a component that allows us to make offerings not intended to qualify under Section 423 of the Code to designated companies, as described in our ESPP. Our ESPP will provide for six-month offering periods. The offering periods will be scheduled to start on the first trading day on or after January 1st and July 1st of each year, beginning on January 1, 2021. Each offering period will consist of one six-month purchase period, which will commence with one exercise date and end on the date immediately prior to the next exercise date.

*Contributions*. Our ESPP will permit participants to purchase shares of our common stock through payroll deductions of up to % of their eligible compensation. Notwithstanding the foregoing, a participant will be able to purchase a maximum of shares of our common stock during a purchase period.

*Exercise of Purchase Right.* Amounts deducted and accumulated by the participant will be used to purchase shares of our common stock at the end of each six-month purchase period. The purchase price of the shares will be 85% of the lower of the fair market value of our common stock on the first trading day of each offering period or on the exercise date. Participants will be able to end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of our common stock. Participation will end automatically upon termination of employment with us.

*Non-Transferability.* A participant will not be able to transfer rights granted under our ESPP. If our compensation committee permits the transfer of rights, it may only be done by will, the laws of descent and distribution or as otherwise provided under our ESPP.

*Merger or Change in Control.* Our ESPP will provide that in the event of a merger or change in control, as defined under our ESPP, a successor corporation may assume or substitute each outstanding purchase right. If the successor corporation refuses to assume or substitute for the outstanding purchase right, the offering period then in progress will be shortened, and a new exercise date will be set that will be before the date of the proposed

merger or change in control. The administrator will notify each participant that the exercise date has been changed and that the participant's option will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

Amendment; Termination. The administrator will have the authority to amend, suspend or terminate our ESPP, except that, subject to certain exceptions described in our ESPP, no such action may adversely affect any outstanding rights to purchase shares of our common stock under our ESPP. Our ESPP automatically will terminate in fiscal year 2029 unless we terminate it sooner.

## 2011 Equity Incentive Plan, as Amended

Our 2011 Plan was originally adopted by our board of directors and approved by our stockholders in March 2011. Our 2011 Plan was most recently amended in September 2019.

Our 2011 Plan allows us to provide incentive stock options, within the meaning of Section 422 of the Code, nonstatutory stock options, stock appreciation rights, restricted stock awards and restricted stock units (each, an award, and the recipient of such award, a participant) to eligible employees, directors, officers and consultants of ours and any parent or subsidiary of ours. It is expected that as of one business day prior to the effectiveness of the registration statement of which this prospectus forms a part, our 2011 Plan will be terminated and we will not grant any additional awards under our 2011 Plan thereafter. However, our 2011 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under our 2011 Plan.

Authorized Shares. Our 2011 Plan will be terminated in connection with this offering, and accordingly, no further awards will be available for issuance under the 2011 Plan following the completion of this offering. Our 2011 Plan will continue to govern outstanding awards granted thereunder. As of March 31, 2020, options to purchase 26,704,989 shares of our common stock and 5,518,463 restricted stock units remained outstanding under our 2011 Plan. In the event that an outstanding option or other right for any reason expires or is canceled, the shares allocable to the unexercised portion of such option or other right shall be added to the number of shares then available for issuance under the 2020 Plan once adopted by our board of directors and our stockholders.

*Plan Administration*. Our board of directors or a committee of our board (the administrator) administers our 2011 Plan. Subject to the provisions of the 2011 Plan, the administrator has the full authority and discretion to take any actions it deems necessary or advisable for the administration of the 2011 Plan. All decisions, interpretations and other actions of the administrator are final and binding on all participants in the 2011 Plan.

*Options*. Stock options have been granted under our 2011 Plan. Subject to the provisions of our 2011 Plan, the administrator determines the term of an option, the number of shares subject to an option, and the time period in which an option may be exercised.

The term of an option is stated in the applicable award agreement, but the term of an option may not exceed 10 years from the grant date. The administrator determines the exercise price of options, which generally may not be less than 100% of the fair market value of our common stock on the grant date, unless expressly determined in writing by the administrator on the option's grant date. However, an incentive stock option granted to an individual who directly or by attribution owns more than 10% of the total combined voting power of all of our classes of stock or of any our parent or subsidiary may have a term of no longer than five years from the grant date and will have an exercise price of at least 110% of the fair market value of our common stock on the grant date. In addition, to the extent that the aggregate fair market value of the shares with respect to which incentive stock options are exercisable for the first time by an employee during any calendar year (under all our plans and any parent or subsidiary) exceeds \$100,000, such options will be treated as nonstatutory stock options.

The administrator determines how a participant may pay the exercise price of an option, and the permissible methods are generally set forth in the applicable award agreement. If a participant's status as a "service provider"

(as defined in our 2011 Plan) terminates, that participant may exercise the vested portion of his or her option for the period of time stated in the applicable award agreement. Vested options generally will remain exercisable for 30 days or such longer period of time as set forth in the applicable award agreement if a participant's status as a service provider terminates for a reason other than death or disability. If a participant's status as a service provider terminates for a reason other than death or disability. If a participant's status as a service provider terminates for a reason other than death or disability. If a participant's status as a service provider terminates due to death or disability, vested options generally will remain exercisable for six months from the date of termination (or such other longer period as set forth in the applicable award agreement). In no event will an option remain exercisable beyond its original term. If a participant does not exercise his or her option within the time specified in the award agreement, the option will terminate. Except as described above, the administrator has the discretion to determine the post-termination exercisability periods for an option.

*Transferability of Awards*. Unless our administrator provides otherwise, our 2011 Plan generally does not allow for the transfer or assignment of options or stock purchase rights, except by will or by the laws of descent and distribution. Shares issued upon exercise of an option will be subject to such terms and conditions as the administrator may determine, including rights of first refusal and other transfer restrictions.

*Certain Adjustments.* In the event of a subdivision of our outstanding stock, a declaration of a dividend payable in shares, a combination or consolidation of our outstanding stock into a lesser number of shares, a reclassification, or any other increase or decrease in the number of issued shares of stock effected without receipt of consideration by us, the 2011 Plan will be appropriately adjusted by the administrator as to the class and maximum number of securities subject to the 2011 Plan and the class, number of securities and price per share of common stock subject to outstanding awards under the 2011 Plan, provided that our administrator will make any adjustments as may be required by Section 25102(o) of the California Corporations Code.

*Merger or Change in Control.* Our 2011 Plan provides that, in the event that we are a party to a merger or change in control, outstanding options and stock purchase rights may be assumed or substituted by the successor corporation or a parent or subsidiary thereof. In the event the successor corporation refuses to assume or substitute for the option or stock purchase right, then the vesting of such awards will be fully accelerated and the administrator will notify the holder in writing or electronically that such awards will be fully exercisable and vested for a period as determined by the administrator, and such awards will terminate upon expiration of such period.

In the event of a merger or change in control, our 2011 Plan provides that each outstanding award will be treated as the administrator determines without a participant's consent, including, without limitation, that: (i) upon written notice to the participant, awards will terminate upon or immediately prior to the consummation of such merger or change in control; (ii) outstanding awards will vest and become exercisable, realizable or payable, or restrictions applicable to an award will lapse, in whole or in part prior to or upon consummation of such merger or change in control, and, to the extent the administrator determines, terminate upon or immediately prior to the effectiveness of such merger or change in control; or (iii)(1) the termination of an award in exchange for an amount of cash and/or property, if any, equal to the amount that would have been attained upon the exercise of such award or realization of the participant's rights as of the date of the occurrence of the transaction (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction the administrator determines in good faith that no amount would have been attained upon the exercise of such award or realization of the participant's rights, then such award may be terminated by the Company without payment), or (2) the replacement of such award with other rights or property selected by the administrator in its sole discretion. In taking any of these actions, the administrator will not be obligated to treat all awards, all awards held by a participant, or all awards of the same type, similarly.

Amendment; Termination. Our board of directors may amend, suspend or terminate our 2011 Plan at any time, provided that such action does not impair a participant's rights under outstanding awards without such participant's written consent. As noted above, upon completion of this offering, our 2011 Plan will be terminated and no further awards will be granted thereunder. All outstanding awards will continue to be governed by their existing terms.

#### 401(k) Plan

We maintain a 401(k) retirement savings plan, or the 401(k) Plan, for the benefit of our employees, including our named executive officers, who satisfy certain eligibility requirements. Under the 401(k) Plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code, on a pre-tax or after-tax (Roth) basis, through contributions to the 401(k) Plan. The 401(k) Plan authorizes employer safe harbor contributions. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, pre-tax contributions to the 401(k) Pan and earnings on those pre-tax contributions are not taxable to the employees until distributed from the 401(k) Plan, and earnings on Roth contributions are not taxable when distributed from the 401(k) Plan. We do not match contributions made by our employees or make discretionary contributions under this plan.

## Limitation of Liability and Indemnification

Our amended and restated certificate of incorporation and amended and restated bylaws, each to be effective immediately prior to the completion of this offering, will provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by Delaware law. Delaware law prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated bylaws that will be in effect on the completion of this offering will also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors and executive officers. With certain exceptions, these agreements provide for indemnification for related expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in connection with any action, proceeding or investigation. We believe that these amended and restated certificate of incorporation and amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

# CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation arrangements, including employment, termination of employment and change in control arrangements, with our directors and executive officers, including those discussed in the sections titled "Management" and "Executive Compensation" and the registration rights described in the section titled "Description of Capital Stock—Registration Rights," the following is a description of each transaction since January 1, 2017 and each currently proposed transaction in which:

- the amounts involved exceeded or will exceed \$120,000; and
- any of our directors, executive officers or holders of more than 5% of our common stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Compensation arrangements for our directors and named executive officers are described elsewhere in this prospectus.

# **Sales of Securities**

#### 2018 Convertible Notes and Warrants

On June 7, 2018, we sold and issued \$22.8 million principal amount of convertible promissory notes, or the 2018 Convertible Notes. Purchasers of the 2018 Convertible Notes included venture capital funds that beneficially own more than 5% of our outstanding capital stock and/or are represented on our board of directors, and one of our other directors. The 2018 Convertible Notes accrued interest at a rate of 10% per annum. The 2018 Convertible Notes were subsequently automatically converted into an aggregate of 18,325,558 shares of our Series D convertible preferred stock at a price of \$1.3712 per share.

In connection with the issuance of the 2018 Convertible Notes, we also issued warrants to purchase up to 4,880,943 shares of our common stock at a price of \$0.01 per share, or the 2018 Warrants. Recipients of the 2018 Warrants included venture capital funds that beneficially own more than 5% of our outstanding capital stock and/or are represented on our board of directors.

The following table presents the principal amount of 2018 Convertible Notes purchased and the number of shares of our Series D convertible preferred stock received on conversion of the 2018 Convertible Notes by related parties, as well as the number of 2018 Warrants issued to each of these entities.

Investor	Principal Amount of 2018 Convertible Notes	Shares of Series D Convertible Preferred Stock	2018 Warrants
Deerfield Private Design Fund III, L.P. <sup>(1)</sup>	\$ 4,750,000	3,815,276	1,574,183
OrbiMed Private Investments IV, LP(2)	\$ 4,710,775	3,783,770	586,741
AMXeraya Ltd.(3)	\$ 4,000,000	3,212,864	1,246,004
Entities affiliated with Advent Life Sciences <sup>(4)</sup>	\$ 1,802,461	1,447,765	
Christoph Scharf, M.D. <sup>(5)</sup>	\$ 120,163	96,516	

(1) Dr. ElBardissi, a member of our board of directors, is a member of the private transaction team of Deerfield Management.

Mr. Burgess was a venture partner at OrbiMed Advisors until his resignation in June 2020, and Dr. Bonita is a member of OrbiMed Advisors. Mr. Burgess is our President and Chief Executive officer and is a member of our board of directors. Dr. Bonita is a member of our board of directors, is an investment partner at Xeraya Capital. Mr. Puri will resign from our board of directors effective immediately prior to the

Mr. Puri, a member of our board of directors, is an investment partner at Xeraya Capital. Mr. Puri will resign from our board of directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as Mr. Puri is an Investment Partner at Xeraya Capital, whose policy prohibits Mr. Puri from serving on the board of directors of one of the firm's public portfolio companies.
 Dr. Malik, a member of our board of directors, is a general partner of Advent Life Sciences.

(4) Dr. Mark, a member of our board of directors, is a general partier of Advent Ene otherces.
 (5) Dr. Scharf was a member of our board of directors until his resignation on June 10, 2020, and is one of our co-founders.

### 2019 Convertible Notes

On May 20, 2019, we sold and issued \$37.0 million in aggregate principal amount of convertible promissory notes, or the 2019 Convertible Notes. Purchasers of the 2019 Convertible Notes included venture capital funds that beneficially own more than 5% of our outstanding capital stock and/or are represented on our board of directors. The 2019 Convertible Notes accrued interest at a rate of 13% per annum. The 2019 Convertible Notes were subsequently automatically converted into an aggregate of 21,625,369 shares of our Series D convertible preferred stock at a price of \$1.714 per share.

The following table presents the principal amount of 2019 Convertible Notes purchased and the number of shares of our Series D convertible preferred stock received on conversion of the 2019 Convertible Notes by related parties.

Investor	Principal Amount of 2019 Convertible Notes	Shares of Series D Convertible Preferred Stock
OrbiMed Private Investments IV, LP(1)	\$ 20,000,000	11,689,391
Deerfield Private Design Fund III, L.P. <sup>(2)</sup>	\$ 7,000,000	4,091,286
AMXeraya Ltd. <sup>(3)</sup>	\$ 4,000,000	2,337,878
Entities affiliated with Advent Life Sciences(4)	\$ 500,000	292,233

Mr. Burgess was a venture partner at OrbiMed Advisors until his resignation in June 2020, and Dr. Bonita is a member of OrbiMed Advisors. Mr. Burgess is our President and Chief (1)Executive officer and is a member of our board of directors. Dr. Bonita is a member of our board of directors.

Dr. ElBardissi, a member of our board of directors, is a member of the private transaction team of Deerfield Management. Mr. Puri, a member of our board of directors, is an investment partner at Xeraya Capital. Mr. Puri will resign from our board of directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as Mr. Puri is an Investment Partner at Xeraya Capital, whose policy prohibits Mr. Puri from serving on the board of directors of one of the firm's public portfolio companies

Dr. Malik, a member of our board of directors, is a general partner of Advent Life Sciences. (4)

## 2019 Warrants to Purchase Preferred Stock

In connection with our entry into the 2019 Credit Agreement (as defined below), each of OrbiMed Royalty Opportunities II, LP, or ORO II, and Deerfield Private Design Fund III, L.P. received a warrant to purchase up to 2,042,007 shares of our Series C convertible preferred stock at a price of \$1.714 per share. Each of ORO II and Deerfield Private Design Fund III, L.P., together with their respective affiliates, are holders of 5% or more of our capital stock. These warrants were subsequently automatically converted into warrants to purchase an equal number of shares of our Series D convertible preferred stock at a price of \$1.714 per share.

#### 2019 Credit Agreement

On May 20, 2019, we entered into a credit agreement, or the 2019 Credit Agreement, between us, the lenders party thereto from time to time, ORO II as origination agent and Wilmington Trust, National Association as administrative agent. As of December 31, 2019, we had \$40.0 million in aggregate principal amount of long-term debt outstanding under the 2019 Credit Agreement, and the lenders under the 2019 Credit Agreement were ORO II and Deerfield Private Design Fund III, L.P. Each of ORO II and Deerfield Private Design Fund III, L.P., together with their respective affiliates, are holders of 5% or more of our capital stock. Mr. Burgess was a venture partner at OrbiMed Advisors until his resignation in June 2020, and Dr. Bonita is a member of OrbiMed Advisors. Mr. Burgess is our President and Chief Executive officer and is a member of our board of directors. Dr. Bonita is a member of our board of directors. Dr. ElBardissi, a member of our board of directors, is a member of the private transaction team of Deerfield Management.

# **Consulting Arrangements**

# Vince Burgess

Prior to his appointment as our President and Chief Executive Officer, Mr. Burgess provided services to us as the active chairman of our board of directors pursuant to a consulting arrangement, which provided that Mr. Burgess would receive a cash consulting fee equal to approximately \$0.4 million per year. For the years ended December 31, 2019, 2018 and 2017, we paid Mr. Burgess \$0.4 million, \$0.4 million and less than \$0.1 million, respectively, for such services.

# Peter Elia

We are party to a consulting agreement with Elia Health Sciences, Inc., or the Elia Consulting Agreement. Mr. Elia, our Chief Strategy & Business Development Officer, is the Chief Executive Officer of Elia Health Sciences, Inc. Under the Elia Consulting Agreement, Elia Health Sciences, Inc. provides services as a market development consultant, including by engaging in peer-to-peer physician engagement, establishing national accounts and contracts, and providing guidance, strategic planning and implementation for site selection and planning. For the years ended December 31, 2019 and 2018, we paid Elia Health Sciences, Inc. a total of \$0.3 million and \$0.1 million, respectively, for services performed under the Elia Consulting Agreement.

#### **Right of First Refusal**

Pursuant to certain of our equity compensation plans and certain agreements with our stockholders, including an amended and restated first refusal and co-sale agreement dated June 12, 2019, we have a right to purchase shares of our capital stock that stockholders propose to sell to other parties. Since January 1, 2017, we have waived our right of first refusal in connection with the sale of certain shares of our capital stock by certain holders of more than 5% of our capital stock, resulting in the purchase of such shares by certain holders of more than 5% of our capital stock in a series of transactions. Our right of first refusal will terminate upon the completion of this offering.

#### **Investors' Rights Agreement**

In June 2019, in connection with our Series D convertible preferred stock financing, we entered into an amended and restated investors' rights agreement with certain holders of our convertible preferred stock, including entities with which certain of our directors are affiliated. Under our amended and restated investors' rights agreement, certain holders of our capital stock have the right to demand that we file a registration statement or request that their shares of our capital stock be covered by a registration statement that we are otherwise filing. See the section titled "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights. The agreement also provides these holders pro rata participation rights and information rights, which will terminate upon completion of this offering.

## **Voting Agreement**

We are party to an amended and restated voting agreement under which certain holders of our capital stock, including the holders of more than 5% of our outstanding capital stock, have agreed as to the manner in which they will vote their shares of our capital stock on certain matters, including with respect to the election of directors. Upon the completion of this offering, the amended and restated voting agreement will terminate, and none of our stockholders will have any special rights regarding the election or designation of members of our board of directors.

## **Indemnification Agreements**

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent

permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, penalties, fines and settlement amounts incurred by the director or officer in any action or proceedings, including any action or proceeding by or in right of us, arising out of the person's service as a director or officer. 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.

# Equity Grants to Executive Officers and Directors

We have granted options and restricted stock units to our named executive officers and certain of our non-employee directors as more fully described in the sections titled "Director Compensation" and "Executive Compensation."

## **Policies and Procedures for Related Party Transactions**

Our board of directors has approved a policy, effective immediately prior to the completion of this offering, that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the prior consent of our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock or any member of the immediate family of any of the foregoing persons in which the amount involved exceeds \$120,000 and such person would have a direct or indirect interest must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction. We did not have a formal review and approval policy for related party transactions at the time of any of the transactions described above. However, all of the transactions described above were entered into after presentation, consideration and approval by our board of directors.

# PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of March 31, 2020 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of the named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Exchange Act.

We have based our calculation of the percentage of beneficial ownership prior to this offering on 168,068,784 shares of our common stock outstanding as of March 31, 2020, which includes 161,155,827 shares of our common stock resulting from the automatic conversion of all outstanding shares of our convertible preferred stock into our common stock immediately prior to the completion of this offering, as if this conversion had occurred as of March 31, 2020. We have based our calculation of the percentage of beneficial ownership after this offering on shares of our common stock outstanding immediately after the completion of this offering, assuming no exercise by the underwriters of their option to purchase additional shares. We have deemed shares of our common stock subject to stock options or warrants that are currently exercisable or exercisable within 60 days of March 31, 2020, to be outstanding and to be beneficially owned by the person holding the stock option for the purpose of computing the percentage ownership of that person.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Acutus Medical, Inc., 2210 Faraday Ave., Suite 100, Carlsbad, CA 92008.

	Shares Be Owned I this Of	Shares Beneficially Owned After this Offering		
Name of Beneficial Owner	Shares	Percentage	Shares	Percentage
5% and Greater Stockholders:				
Entities affiliated with OrbiMed Advisors LLC <sup>(1)</sup>	52,466,129	30.6%		%
Entities affiliated with Deerfield Management Company <sup>(2)</sup>	31,855,040	18.5%		%
Advent Life Sciences Fund I LP(3)	15,725,229	9.4%		%
AMXeraya Ltd.(4)	14,089,628	8.3%		%
Revelation Alpine, LLC <sup>(5)</sup>	10,291,476	6.1%		%
CVF 2018, LLC(6)	9,918,319	5.9%		%
Named Executive Officers and Directors:				
Vince Burgess <sup>(7)</sup>	3,105,005	1.8%		%
Gary W. Doherty(8)	582,406	*		%
Steven McQuillan(9)	1,166,348	*		%
R. Scott Huennekens	_	*		%
David Bonita, M.D.(1)	52,466,129	30.6%		%
Andrew ElBardissi, M.D.(2)	_	*		%
Jim Hinrichs(10)	145,857	*		%
Shahzad Malik, MB BChir(3)	15,725,229	9.4%		%
Aditya Puri(4)	14,089,628	8.3%		%
Dr. Christoph Scharf <sup>(11)</sup>	3,586,130	2.1%		%
All executive officers and directors as a group (11 persons) <sup>(12)</sup>	90,866,732	51.6%		%

\* Represents ownership of less than 1%

Consists of: (i) 36,797,976 shares held by OrbiMed Private Investments IV, LP, or OPI IV; (ii) 12,434,260 shares held by OrbiMed Royalty Opportunities II, LP, or ORO II; (iii) 586,741 shares issuable to OPI IV pursuant to a warrant exercisable within 60 days of March 31, 2020; and (iv) 2,647,152 shares issuable to ORO II pursuant to a warrant exercisable within 60 days of March 31, 2020; and (iv) 2,647,152 shares issuable to ORO II pursuant to a warrant exercisable within 60 days of March 31, 2020; and (iv) 2,647,152 shares issuable to ORO II pursuant to a warrant exercisable within 60 days of March 31, 2020. OrbiMed Advisors, is the managing member of GP IV. OrbiMed Advisors may be deemed to have voting and investment power with respect to the shares held by OPI IV and ORO II and as a result may be deemed to have beneficial ownership of such shares. David Bonita, a member of OrbiMed Advisors, is a member of the Company's board of directors. OrbiMed Advisors, Carl L. Gordon, Sven H. Borho, Jonathan T. Silverstein and David Bonita disclaims beneficial ownership of the shares held by OeI IV and ORO II, except to the extent of its or his pecuniary interest therein if any. The address for OrbiMed Advisors is 601 Lexington Avenue, 54th floor, New York, New York 10022.
 Consists of: (i) 21,416,574 shares held by Deerfield Private Design Fund III, L.P.; (ii) 6,217,131 shares held by Deerfield Partners, L.P.; (iii) 3,918,761 shares issuable to Deerfield

Consists of: (i) 21,416,574 shares held by Deerfield Private Design Fund III, L.P.; (ii) 6,217,131 shares held by Deerfield Partners, L.P.; (iii) 3,918,761 shares issuable to Deerfield Private Design Fund III, L.P. pursuant to warrants exercisable within 60 days of March 31, 2020; and (iv) 302,574 shares issuable to Deerfield Partners, L.P. pursuant to warrants exercisable within 60 days of March 31, 2020. Deerfield Mgmt, L.P. is the general partner of Deerfield Management Company, L.P. is the investment manager of each of the Deerfield Funds. Mr. James E. Flynn is the sole member of the general partner of Deerfield Mgmt, L.P. may be deemed to beneficially own the shares held by Deerfield Partners, L.P. Deerfield Mgmt III, L.P. and Deerfield Management Company, L.P. Deerfield Mgmt, L.P. may be deemed to beneficially own the shares held by Deerfield Partners, L.P. Deerfield Mgmt III, L.P. may be deemed to beneficially own the shares held by Deerfield Partners, L.P. Deerfield Mgmt III, L.P. may be deemed to beneficially own the shares held by Deerfield Partners, L.P. Deerfield Mgmt III, L.P. may be deemed to beneficially own the shares held by Deerfield Partners, L.P. Deerfield Mgmt III, L.P. may be deemed to beneficially own the shares held by Deerfield Partners, L.P. Deerfield Mgmt III, L.P. may be deemed to beneficially own the shares held by Deerfield Partners, L.P. Deerfield Mgmt III, L.P. may be deemed to beneficially own the shares held by Deerfield Partners, L.P. The address of the Deerfield Funds is 780 Third Avenue, 37th Floor, New York, NY 10017.
 Consists of: (i) 15,088,894 shares held by Advent Life Sciences Fund I LP; and (ii) 636,335 shares held by Advent Life Sciences LLP. Advent Life Sciences LLP is the manager of the Deerfield Partners held by Advent Life Sciences Fund I LP; and (ii) 636,335 shares held by Advent Life Sciences LLP.

(3) Consists of: (i) 15,088,894 shares held by Advent Life Sciences Fund I LP; and (ii) 636,335 shares held by Advent Life Sciences LLP. Advent Life Sciences LLP at has voting and dispositive power over the shares held by Advent Life Sciences Fund I LP. Dr. Malik, who is a member of our board of directors, is a general partner of Advent Life Sciences LLP, and may be deemed to have voting and dispositive power over the shares held by Advent Life Sciences LLP. The mailing address of Advent Life Sciences LLP and Advent Life Sciences Fund I LP is 158-160 North Gower Street, London, United Kingdom NW1 2ND.

(4) Consists of: (i) 12,843,624 shares held by AMXeraya Ltd., or Xeraya; and (ii) 1,246,004 shares issuable to Xeraya pursuant to a warrant exercisable within 60 days of March 31, 2020. Pulau Manukan Ventures Labuan Ltd. is the holding company of Xeraya and may therefore be deemed to share beneficial ownership of the shares held by Xeraya. Aditya Puri, an Investment Partner at Xeraya Capital, is a member of the Company's board of directors. Fares Zahir, a director of Xeraya, has the voting and dispositive power with respect to

the shares held by Xeraya. Each of Mr. Puri and Mr. Zahir disclaim beneficial ownership of the shares held by Xeraya. The principal address of Xeraya is Lot 26.03-26.08, Level 26, GTower, No. 199, Jalan Tun Razak, 50400, Kuala Lumpur, Malaysia. Mr. Puri will resign from our board of directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as Mr. Puri is an Investment Partner at Xeraya Capital, whose policy prohibits Mr. Puri from serving on the board of directors of one of the firm's public portfolio companies.

- the firm's public portfolio companies. Consists of: (i) 10,027,751 shares held by Revelation Alpine, LLC and (ii) 263,725 shares issuable to Revelation Alpine, LLC pursuant to a warrant exercisable within 60 days of March 31, 2020. Revelation Alpine GP, LLC is the manager of Revelation Alpine, LLC. Revelation Alpine, LLC, through three managing members, composed of Scott Halsted, Zachary Scott, and Michael Boggs, has voting and dispositive authority over the shares held. Revelation Alpine, LLC, Revelation Alpine GP, LLC and each of the managing members disclaim beneficial ownership of the shares, except, in each case, to the extent of such person or entity's pecuniary interest therein. The address for each of these entities is 255 California Street, 12th Floor, San Francisco, CA 94111. Richard H. Robb, manager of CVF 2018, LLC, exercises voting and investment power with respect to the shares held by CVF 2018, LLC. The address of CVF 2018, LLC is 222 N. LaSalle Street, Suite 2000, Chicago, IL 60601. Consists of 3,105,005 shares underlying options exercisable within 60 days of March 31, 2020. (5)
- (6)

- Consists of 582,406 shares underlying options exercisable within 60 days of March 31, 2020. Consists of 1,166,348 shares underlying options exercisable within 60 days of March 31, 2020. Consists of shares held of record by Hinrichs Joint Revocable Trust DTD 9/20/2013.
- (7) (8) (9) (10) (11) (12) Dr. Schaft resigned from our board of directors on June 10, 2020. Includes: (i) 3,687,411 shares underlying options exercisable within 60 days of March 31, 2020 and (ii) 4,479,897 shares issuable pursuant to warrants exercisable within 60 days of March 31, 2020.

# 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, which will become effective immediately prior to the completion of this offering, 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

Upon the filing of our amended and restated certificate of incorporation to be effective immediately prior to the completion of this offering, our authorized capital stock will consist of shares of common stock, par value \$0.001 per share, and shares of convertible preferred stock, par value \$0.001 per share.

Immediately prior to the completion of this offering, all the outstanding shares of our convertible preferred stock will automatically convert into an aggregate of shares of our common stock.

Based on shares of common stock outstanding as of March 31, 2020, and after giving effect to the automatic conversion of all of our outstanding convertible preferred stock into an aggregate of shares of common stock immediately prior to the completion of this offering and the issuance of shares of common stock in this offering, there will be shares of common stock outstanding upon the closing of this offering. As of March 31, 2020, we had 128 stockholders of record. As of March 31, 2020, there were 26,704,989 shares of common stock subject to outstanding options.

#### **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.

## **Preferred Stock**

Immediately prior to the completion of this offering, all outstanding shares of our convertible preferred stock will be automatically converted into shares of our common stock. Upon the completion of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preferences, sinking fund provisions and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after completion of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

## Options

As of March 31, 2020, we had outstanding options to purchase an aggregate of 26,704.989 shares of our common stock, with a weighted-average exercise price of \$1.13 per share.

#### Warrants

The following table sets forth information about outstanding warrants to purchase shares of our stock as of March 31, 2020.

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
Series D convertible preferred stock, par value \$0.001 per share	4,346,557	4,346,557	\$ 1.714	\$ 1.714
Common stock, par value \$0.001 per share	4,955,017	4,955,017	\$ 0.018	\$ 0.018
Total	9,301,574	9,301,574		

The warrants to purchase shares of our Series D convertible preferred stock (which will be automatically converted into warrants to purchase shares of our common stock immediately prior to the completion of this offering) will expire upon the earlier of the expiration date set forth in each warrant, which are various dates between July 2028 and May 2029, our acquisition or a sale of all or substantially all our assets.

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 June 2028, our acquisition, or a sale of all or substantially all our assets.

# **Restricted Stock Units**

As of March 31, 2020, we had 5,518,463 outstanding restricted stock units, which were subject to performance and time-based vesting conditions, of which units will vest upon the effectiveness of the registration statement of which this prospectus forms a part.

# **Registration Rights**

After the completion of this offering, under our amended and restated investors' agreement, as amended, the holders of 146,775,825 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**

After the completion of this offering, the holders of up to 146,775,825 shares of our common stock will be entitled to certain demand registration rights. At any time beginning six months after the consummation of this offering, the holders of at least 50% of the shares having registration rights then outstanding can request that we file a registration statement to register the offer and sale of their shares. We are only obligated to effect up to two such registrations. Each such request for registration must cover securities the anticipated aggregate gross proceeds of which, before deducting underwriting discounts and expenses, is at least \$20.0 million. These demand registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. If we determine that it would be materially detrimental to us and our stockholders to effect such a demand registration, we have the right to defer such registration, not more than twice in any twelve-month period, for a period of up to 90 days.

#### Form S-3 Registration Rights

After the completion of this offering, the holders of up to 146,775,825 shares of our common stock will be entitled to certain 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

After the completion of this offering, the holders of up to 146,775,825 shares of our common stock will be entitled to certain "piggyback" registration rights. If we propose to register the offer and sale of shares of our common stock under the Securities Act, all holders of these shares then outstanding can request that we include their shares in such registration, subject to certain marketing and other limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to: (i) a registration related to any employee benefit plan or a corporate reorganization or other transaction covered by Rule 145 promulgated under the Securities Act; (ii) a registration relating to the offer and sale of debt

securities; (iii) a registration on any registration form that does not permit secondary sales; or (iv) a registration pursuant to the demand or Form S-3 registration rights described in the preceding two paragraphs above, the holders of these shares are entitled to notice of the registration and have the right, subject to certain limitations, to include their shares in the registration.

## **Expenses of Registration**

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

# Termination

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

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

Some provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws that will be in effect immediately prior to the completion of this offering 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 will contain 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 will provide that our board of directors is divided into three classes, designated Class I, Class II and Class III. Each class will be an equal number of directors, as nearly as possible, consisting of one third of the total number of directors constituting the entire board of directors. The term of initial Class I directors 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 will provide 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 will authorize only our board of directors to fill vacant directorships.

#### No Cumulative Voting

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

#### Advance Notice Procedures for Director Nominations

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

#### Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws will 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 will provide 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 will 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 will 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 will 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.

## **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, when 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 will 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.

# Limitations on Liability and Indemnification Matters

For a discussion of liability and indemnification, see the section titled "Management—Limitation on Liability and Indemnification Matters."

# **Exchange Listing**

We intend to apply to list our common stock on The Nasdaq Global Market under the symbol "AFIB."

# **Transfer Agent and Registrar**

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

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to the completion of this offering, there has been no public market for our common stock, and we cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock 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, 2020, we will have a total of shares of common stock outstanding (including all shares of our convertible preferred stock on an as-converted basis). 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 purchased by our affiliates.

The remaining outstanding shares of our common stock will be deemed "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. In addition, holders of all or substantially all of our equity securities have entered into or will enter into lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for at least 180 days following the date of this prospectus, as described below. As a result of these agreements, based on the number of shares of our capital stock outstanding as of December 31, 2019, subject to the provisions of Rule 144 or Rule 701, these restricted securities will be available for sale in the public market as follows:

- beginning on the date of this prospectus, all shares of common stock sold in this offering will be immediately available for sale in the public market; and
- beginning 181 days after the date of this prospectus, additional shares of common stock will become eligible for sale in the public market, of which shares will be held by affiliates and will be subject to the volume and other restrictions of Rule 144, as described below.

## Lock-Up Agreements

Our officers, directors and the holders of substantially all of our capital stock, options, warrants and restricted stock units have entered into or will enter into lock-up agreements with the underwriters, subject to certain exceptions, not to dispose of or hedge any of 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 180 days after the date of this prospectus, except with the prior consent of J.P. Morgan Securities LLC and BofA Securities, Inc. See the section titled "Underwriting" for additional information.

## Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, 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.

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,

provided, in each case, that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the 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. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares pursuant to Rule 701.

#### **Registration Rights**

After the completion of this offering, the holders of up to 146,775,825 shares of our common stock will be 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.

#### **Stock and Option Plans**

Following the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register shares of our common stock issued or reserved for issuance under our 2020 Plan and 2020 ESPP. The registration statement on Form S-8 will become effective immediately upon filing, and shares covered by such registration statement will thereupon be eligible for sale in the public markets, subject to vesting restrictions, the lock-up agreements described above and Rule 144 limitations applicable to affiliates. See the section titled "Executive Compensation— Employee Benefit and Stock Plans" for additional information.

# 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 Internal Revenue Code of 1986, as amended to the date hereof (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(1)(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.

# 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.

# UNDERWRITING

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC and BofA Securities, Inc. are acting as joint book-running managers of the offering and as representatives of the underwriters. We will enter into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we will agree to sell to the underwriters, and each underwriter will severally agree to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of Shares
J.P. Morgan Securities LLC	
BofA Securities, Inc.	
William Blair & Company, L.L.C.	
Canaccord Genuity LLC	
BTIG, LLC	
Total	

The underwriters will be committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement will also provide that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ per share. After the initial offering of the shares to the public, if all of the shares of common stock are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is \$ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without	With Full
	Exercise of	Exercise of
	Option to	Option to
	Purchase	Purchase
	Additional	Additional
	Shares	Shares
Per Share	\$	\$
Total	\$	\$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$ . We have agreed to reimburse the underwriters for expenses relating to the clearance of this offering with the Financial Industry Regulatory Authority, Inc. in an amount up to \$35,000.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not, subject to certain exceptions, for a period of 180 days after the date of this prospectus: (i) offer, pledge, 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, hedge, lend, or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock, or publicly disclose the intention to undertake any of the foregoing; or (ii) enter into any swap, hedging, or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock or any such other securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of common stock or such other securities, in cash or otherwise, in each case without the prior written consent of J.P. Morgan Securities LLC and BofA Securities, Inc.

Our directors and executive officers, and substantially all of our securityholders have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 180 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities LLC and BofA Securities, Inc.: (i) offer, pledge, 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, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including without limitation, common stock or such other securities which may be deemed to be beneficially owned by the securityholder in accordance with the rules and regulations of the Securities and Exchange Commission and securities which may be issued upon exercise of a stock option or warrant); or (ii) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of our common stock or such other securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of common stock or such other securities, whether any demand for or exercise any right with respect to the registration of any shares of our common stock or any security convertible into or exercisable or exchangeable for our common stock; or (iv) publicly disclose the intention to do any of the foregoing.

The restrictions described in the immediately preceding paragraph do not apply to, among other items:

- (i) transfer shares of our common stock or any security convertible into or exercisable or exchangeable for our common stock:
  - (1) as a bona fide gift or gifts, or for bona fide estate planning purposes,
  - (2) by will, other testamentary document or intestacy,
  - (3) to any trust for the direct or indirect benefit of the signatory or the immediate family of the signatory, or if the signatory is a trust, to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust
  - (4) to a partnership, limited liability company or other entity of which the signatory and/or the signatory's immediate family are the legal and beneficial owner of all of the outstanding equity securities or similar interests,
  - (5) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (1) through (4) above,

- (6) if the signatory is a corporation, partnership, limited liability company, trust or other business entity, to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of the signatory, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the signatory or affiliates of the signatory or as part of a distribution to members or shareholders of the signatory,
- (7) by operation of law, such as pursuant to a qualified domestic order, divorce settlement, divorce decree, separation agreement or other similar court order, provided no public filing or announcement shall be made voluntarily during the 180-day lockup period in connection with such transfer or disposition,
- (8) to the Company from an employee of the Company upon death, disability or termination of employment, in each case, of such employee, provided that such contractual arrangement is either pursuant to a stock incentive plan or other equity award plan described herein, and provided further that no public filing, report or announcement reporting a change in beneficial ownership shall be required or shall be voluntarily made within 60 days after the date the signatory ceases to provide services to the Company,
- (9) as part of a sale of the signatory's common stock acquired in this offering (other than any Company-directed securities acquired in this offering by an officer or director of the Company or in open market transactions after the closing date for this offering,
- (10) to the Company in connection with the vesting, settlement, or exercise of restricted stock units, options, warrants or other rights to purchase shares of our common stock (including, in each case, by way of "net" or "cashless" exercise), including for the payment of exercise price and tax and remittance payments due as a result of the vesting, settlement, or exercise of such restricted stock units, options, warrants or rights, provided that any such shares of common stock received upon such exercise, vesting or settlement shall be subject to the terms of a lock-up agreement, and provided further that any such restricted stock units, options, warrants or rights are held pursuant to an agreement or equity awards granted under any stock incentive plan or other equity award plan described herein, and provided further that no public filing, report or announcement reporting a change in beneficial ownership of shares of common stock shall be required or shall be voluntarily made during the 45 days after the date hereof, or
- (11) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction that is approved by the board of directors of the Company and made to all holders of the Company's capital stock involving a transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons, of shares of capital stock of the Company if, after such transfer, such person or group of affiliated persons would hold more than 50% of the outstanding voting securities of the Company (or the surviving entity); provided that in the event that such tender offer, merger, consolidation or other similar transaction is not completed, the signatory's shares of common stock or any security convertible into or exercisable or exchangeable for our common stock shall remain subject to the lock-up agreement;

provided that (A) in the case of any transfer or distribution pursuant to clauses (i)(1), (2), (3), (4), (5), (6) and (7), such transfer shall not involve a disposition for value and each donee, devisee, transferee or distributee shall execute and deliver to the representatives a lock-up agreement substantially in the form of the above-described lock-up agreement and (B) in the case of any transfer or distribution pursuant to clauses (i)(1), (2), (3), (4), (5), (6) and (7), no filing by any party (donor, donee, devisee, transferor, transferee, distributer or distributee) under the Exchange Act, or other public announcement shall be required or shall be made voluntarily in connection with such transfer or distribution (other than a filing on a Form 5 made after the expiration of the 180-day lock-up period);

- (ii) exercise (a) options to purchase shares of our common stock granted under any stock incentive plan or other equity award plan described herein or (b) warrants to acquire shares of our common stock or preferred stock described herein; provided the exercise is made on a cash basis (or in accordance with clause (i)(9)), and provided further that any shares of our common stock or securities convertible into or exercisable or exchangeable for our common stock received pursuant to clauses (ii)(a) and (b) shall be subject to the terms of the lock-up agreement;
- (iii) receive shares of our common stock upon the vesting or settlement of restricted stock units described herein pursuant to any stock incentive plan or other equity award plan described herein; provided that the payment of any tax and remittance payments due as a result of the vesting or settlement thereof is made on a cash basis or in accordance with clause (i)(9), and provided further that the underlying shares of common stock shall continue to be subject to the terms of the lock-up agreement;
- (iv) convert outstanding convertible preferred stock, warrants to acquire convertible preferred stock or convertible securities into shares of our common stock or warrants to acquire shares of our common stock; provided that any such shares of common stock or warrants received upon such conversion shall be subject to the terms of the lock-up agreement; and
- (v) establish trading plans pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of our common stock; provided that
   (1) such plans do not provide for the transfer of common stock during the 180-day lock-up period and (2) no filing by any party under the Exchange Act or other public announcement shall be required or made voluntarily in connection with such trading plan.

The representatives, in their sole discretion, may release shares of our common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release shares of our common stock and other securities from lock-up agreements, the representatives will consider, among other factors, the holder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time of the request. In the event of such a release or waiver for one of our directors or officers, the representatives shall provide us with notice of the impending release or waiver at least three business days before the effective date of such release or waiver and we will announce the impending release or waiver by issuing a press release at least two business days before the effective date of the release or waiver.

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

We intend to apply to list our shares of common stock on the The Nasdaq Global Market under the trading symbol "AFIB."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of the common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market compared to the price at which the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. 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 that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the , in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for shares of our common stock, or that the shares will trade in the public market at or above the initial public offering price.

# **Other Relationships**

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

## **Selling Restrictions**

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such

securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

## Notice to Prospective Investors in the European Economic Area and the United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (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 offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

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

provided that no such offer of shares shall require the Company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and the Company that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to 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.

## Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Regulation): (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order; and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

#### Notice to Prospective Investors in Canada

The shares may be sold 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 shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

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 for particulars 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.

#### Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

#### Notice to Prospective Investors in the Dubai International Financial Centre

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority, or DFSA. This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 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 supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this 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 document you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

#### Notice to Prospective Investors in the United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

#### Notice to Prospective Investors in Australia

This prospectus:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth), or the Corporations Act;
- has not been, and will not be, lodged with the Australian Securities and Investments Commission, or ASIC, as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act, or Exempt Investors.

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

#### Notice to Prospective Investors in Japan

The shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

#### Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than: (i) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571

of the Laws of Hong Kong), or the SFO, of Hong Kong and any rules made thereunder; or (ii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, or the CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the pupposes of issue, 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 of 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" as defined in the SFO and any rules made thereunder.

### Notice to Prospective Investors in Singapore

Each representative has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each representative has represented and agreed that it has not offered or sold any shares or caused the shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares or cause the shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, whether directly or indirectly, to any person in Singapore other than:

- (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA;
- (ii) 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
- (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (i) 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; or
- (ii) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- (1) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)
   (B) of the SFA;
- (2) where no consideration is or will be given for the transfer;
- (3) where the transfer is by operation of law;
- (4) as specified in Section 276(7) of the SFA; or
- (5) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Singapore SFA Product Classification—In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of the shares, the Company has determined, and



hereby notifies all relevant persons (as defined in Section 309A(1) of the SFA), 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).

#### Notice to Prospective Investors in Bermuda

Shares may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

#### Notice to Prospective Investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority, or CMA, pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended. The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

#### Notice to Prospective Investors in the British Virgin Islands

The shares are not being and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of the Company. The shares may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), or BVI Companies, but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

#### Notice to Prospective Investors in China

This prospectus will not be circulated or distributed in the PRC and the shares will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

#### Notice to Prospective Investors in Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder, or the FSCMA, and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder, or the FETL. The shares have not been listed on any of the securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

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### Notice to Prospective Investors in Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares has been or will be registered with the Securities Commission of Malaysia, or Commission, for the Commission's approval pursuant to the Capital Markets and Services Act 2007. 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 Malaysia other than: (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services License; (iii) a person who acquires the shares, as principal, if the offer is on terms that the shares may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the shares is made by a holder of a Capital Markets Services License who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

#### Notice to Prospective Investors in Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

### Notice to Prospective Investors in South Africa

Due to restrictions under the securities laws of South Africa, no "offer to the public" (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted), or the South African Companies Act) is being made in connection with the issue of the shares in South Africa. Accordingly, this document does not, nor is it intended to, constitute a "registered prospectus" (as that term is defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. The shares are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions stipulated in section 96 (1) applies:

Section 96 the offer, transfer, sale, renunciation or delivery is to:

(1)(a)

(i) persons whose ordinary business, or part of whose ordinary business, is to deal in securities, as principal or agent;

- (ii) the South African Public Investment Corporation;
- (iii) persons or entities regulated by the Reserve Bank of South Africa;
- (iv) authorised financial service providers under South African law;
- (v) financial institutions recognised as such under South African law;

(vi) a wholly-owned subsidiary of any person or entity contemplated in (iii), (iv) or (v), acting as agent in the capacity of an authorized portfolio manager for a pension fund, or as manager for a collective investment scheme (in each case duly registered as such under South African law); or

- (vii) any combination of the person in (i) to (vi); or
- Section 96 the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than (1)(b) ZAR1,000,000 or such higher amount as may be promulgated by notice in the Government Gazette of South Africa pursuant to section 96(2)(a) of the South African Companies Act.

Information made available in this prospectus should not be considered as "advice" as defined in the South African Financial Advisory and Intermediary Services Act, 2002.

#### 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, 2019 and 2018, and for each of the years in the two-year period ended December 31, 2019, 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. The audit report covering the December 31, 2019 and 2018 consolidated financial statements contains an explanatory paragraph that states that the Company has incurred operating losses since inception and expects to continue to incur significant operating losses for at least the next several years that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty. The audit report covering the December 31, 2019 consolidated financial statements also refers to a change to the method of accounting for leases.

The consolidated financial statements of Rhythm Xience, Inc. as of December 31, 2018 and for the year then ended included in this prospectus have been so included in reliance on the report of Meuwissen, Flygare, Kadrlik & Associates, P.A., independent auditors, given upon the authority of said firm as experts in auditing and accounting.

### 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.

When we complete this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file annual, quarterly and special reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be 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.

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#### **Report of Independent Registered Public Accounting Firm**

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

#### Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Acutus Medical, Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

#### Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred operating losses since inception and expects to continue to incur significant operating losses for at least the next several years that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Codification 842, *Leases*.

#### Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

#### /s/ KPMG LLP

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

San Diego, California May 14, 2020

### ACUTUS MEDICAL, INC. AND SUBSIDIARIES Consolidated Balance Sheets (in thousands, except share and per share amounts)

(in thousands, except share and per share amounts)	Ma	rch 31,	Decem	ber 31,	Pro Forma March 31,
	-	2020	2019	2018	2020
ASSETS:	(una	udited)			(unaudited)
Current assets:					
Cash and cash equivalents	\$	21,000	\$ 9,452	\$ 9,625	
Marketable securities		28,880	62,351	8,120	
Restricted cash		150	150	150	
Accounts receivable		971	263	164	
Inventory		10,459	8,424	3,003	
Prepaid expenses and other current assets		1,651	1,816	877	
Total current assets		63,111	82,456	21,939	
Property and equipment, net		5,435	4,427	3,922	
Operating lease right-of-use asset, net		2,172 4.000	2,341 4,110		
Intangible assets, net Goodwill		4,000	4,110		
Goodwin Goodwi		362	95	87	
Total assets	¢	87,106	\$ 105,455	\$ 25,948	
	φ	07,100	φ 100,400	φ 23,940	
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT					
Current liabilities:	¢	7.464	¢ 2,002	¢ 1.507	
Accounts payable	\$	7,464	\$ 3,882	\$ 1,597	
Accrued liabilities		4,993	10,076	5,149	
Contingent consideration, short-term Operating lease liabilities, short-term		3,100 853	8,200 833	_	
Common and preferred stock warrant liability		8,338	8,919	6,842	
Short-term debt		0,550	0,515	11,274	
Total current liabilities		24,748	31,910	24,862	
		1,827	2,054	24,002	
Operating lease liabilities, long-term Long-term debt		38,398	38,244	14,591	
Contingent consideration, long-term		3,800	5,700	14,591	
Total liabilities		68,773	77,908	39,453	
Commitments and contingencies (Note 11)		00,775	//,500		
Convertible preferred stock					
Series A convertible preferred stock, \$0.001 par value; 3,848,696, 3,848,696 and 6,490,577 shares authorized as of March 31, 2020, December 31, 2019 and 2018, respectively; 3,804,152, 3,804,152 and 3,778,356 shares issued and outstanding as of March 31, 2020, December 31, 2019 and 2018, respectively; liquidation preference of \$3,245, \$3,245 and \$3,223 as of March 31, 2020, December 31, 2019 and 2018, respectively; no shares issued and outstanding as of March 31, 2020, December 31, 2018, respectively; no shares issued and outstanding as of March 31, 2020, proforma (unaudited)		3,059	3,059	3,059	
Series B convertible preferred stock, \$0.001 par value; 30,032,100, 30,032,100 and 35,343,594 shares authorized as of March 31, 2020, December 31, 2019 and 2018, respectively; 30,032,100 shares issued and outstanding as of each of March 31, 2020, December 31, 2019 and 2018; liquidation preference of \$41,294 as of each of March 31, 2020, December 31, 2019 and 2018; no shares issued and outstanding as of March 31, 2020, pro forma (unaudited)		40,685	40,685	40,685	
Series C convertible preferred stock, \$0.001 par value; 48,184,000, 48,184,000 and 43,800,000 shares authorized as of March 31, 2020, December 31, 2019 and 2018, respectively; 43,757,292 shares issued and outstanding as of each of March 31, 2020, December 31, 2019 and 2018; liquidation preference of \$75,000 as of each of March 31, 2020, December 31, 2019 and 2018; no shares issued and outstanding as of March 31, 2020, pro forma (unaudited)		74,575	74,575	74,575	
Series D convertible preferred stock, \$0.001 par value; 90,000,000 shares authorized as of each of March 31, 2020 and December 31, 2019; 83,562,283 and 79,740,085 issued and outstanding as of March 31, 2020 and December 31, 2019; none authorized, issued or outstanding as of December 31, 2018; liquidation preference of \$157,348 and \$136,675 as of March 31, 2020 and December 31, 2019, no liquidation preference as of December 31, 2018; no shares issued and outstanding as of March 31, 2020, and December 31, 2019, no liquidation preference as of December 31, 2018; no shares issued and outstanding as of March 31, 2020, and December 31, 2019, no liquidation preference as of December 31, 2018; no shares issued and outstanding as of March 31, 2020, and December 31, 2019, no liquidation preference as of December 31, 2018; no shares issued and outstanding as of March 31, 2020, and December 31, 2019, no liquidation preference as of December 31, 2018; no shares issued and outstanding as of March 31, 2020, and December 31, 2019; no shares issued and outstanding as of March 31, 2020, and December 31, 2019; no shares issued and outstanding as of March 31, 2020, and December 31, 2019; no shares issued and outstanding as of March 31, 2020, and December 31, 2019; no shares issued and outstanding as of March 31, 2020, and December 31, 2019; no shares issued and outstanding as of March 31, 2020, and December 31, 2019; no shares issued and outstanding as of March 31, 2020, and December 31, 2019; no shares issued and outstanding as of March 31, 2020; no shares issued and outstanding as of March 31, 2020; no shares issued and outstanding as of March 31, 2020; no shares issued and outstanding as of March 31, 2020; no shares issued as other 31, 2019; no shares issued 31, 310; no shares issued				, 0	
pro forma (unaudited) Stockholders' deficit Commerce track 60 (201 per value) 220 000 000 and 111 500 000 shares authorized as of March 21, 2020. December		142,236	135,039	—	
Common stock, \$0.001 par value; 220,000,000, 220,000,000 and 111,508,000 shares authorized as of March 31, 2020, December 31, 2019 and 2018, respectively; 6,912,957, 6,767,457 and 6,385,612 shares issued and outstanding as of March 31, 2020, December 31, 2019 and 2018, respectively; shares issued and outstanding as of March 31, 2020, pro forma (unaudited) Additional paid-in capital		7 34,987	7 33,246	6 30,145	
Accumulated deficit	(	277,132)	(259,034)	(161,995)	
Accumulated other comprehensive (loss) income	(	(84)	(30)	20	
Total stockholders' deficit	(	242,222)	(225,811)	(131,824)	
Total liabilities, convertible preferred stock and stockholders' deficit	\$	87,106	\$ 105,455	\$ 25,948	
The account of a net of the council is the second state of the council is the second state of the second s	•	07,100	\$ 100, <del>1</del> 00	φ <u>2</u> 3,3 <del>4</del> 0	

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

### ACUTUS MEDICAL, INC. AND SUBSIDIARIES Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share amounts)

		e Months Ended March 31,		ır Ended ember 31,
	2020	2019	2019	2018
Revenue	\$ 1,58	(unaudited) 3 \$ 787	\$ 2.836	\$ 2,166
Costs and operating expenses:	φ 1,50	υ ψ /0/	φ 2,050	ψ 2,100
Cost of products sold	3,19	4 2,176	9,243	7,510
Research and development	7,97		23,029	19,077
Research and development—license acquired	_		15,000	_
Selling, general and administrative	10,23	5 4,093	26,847	13,330
Impairment of property and equipment	_		786	
Change in fair value of contingent consideration	(2,21	9) —	500	
Total costs and operating expenses	19,18	3 10,646	75,405	39,917
Loss from operations	(17,60	0) (9,859)	(72,569)	(37,751)
Other income (expense):		-		
Change in fair value of warrant liability and embedded derivative	58	1 841	(1,919)	(4,298)
Loss on issuance of convertible notes and warrants	_		_	(924)
Loss on debt extinguishment	_		(1,447)	_
Interest income	27	5 65	1,164	297
Interest expense	(1,35	4) (5,742)	(22,268)	(5,231)
Total other income (expense), net	(49)	8) (4,836)	(24,470)	(10,156)
Loss before income taxes	(18,09	8) (14,695)	(97,039)	(47,907)
Income tax benefit	_		_	
Net loss	\$ (18,09	B) \$ (14,695)	\$ (97,039)	\$ (47,907)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	(2	7) 1	46	(1)
Foreign currency translation adjustment	(2)	7) (14)	(96)	(43)
Comprehensive loss	\$ (18,15)	2) \$ (14,708)	\$ (97,089)	\$ (47,951)
Net loss per common share, basic and diluted	\$ (2.6	6) \$ (2.30)	\$ (14.85)	\$ (9.03)
Weighted-average shares outstanding, basic and diluted	6,812,22	6 6,385,612	6,534,469	5,307,392
Pro forma net loss per common share, basic and diluted (unaudited)	\$		\$	
Pro forma weighted-average shares outstanding, basic and diluted (unaudited)		=		

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

# ACUTUS MEDICAL, INC. AND SUBSIDIARIES Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit (in thousands, except share amounts)

Current allow         Current allow         Current allow         Current allow         Additional         Additional         Current allow         Current allow<		Serie	s A	Series	5 B	Series	s C	Serie	s D		1				Accumulated		
Name         Name <th< th=""><th></th><th>Conver</th><th>rtible</th><th>Conver</th><th>tible</th><th>Conver</th><th>tible</th><th>Conver</th><th>rtible</th><th></th><th></th><th></th><th>Additional</th><th></th><th></th><th>Te</th><th>otal</th></th<>		Conver	rtible	Conver	tible	Conver	tible	Conver	rtible				Additional			Te	otal
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Decomposition         Decomposition         Aut2230 S         4.5         4.40 S         0.102.00 S         0.14 S         0.100 S           ender department relet subjection         -	Balance as of	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amo	unt	Shares	Amount	Capital	Deficit	Income (Loss)	De	ficit
Constantion         - <td< td=""><td>December 31,</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td<>	December 31,																
effect ASJ 2016 0		6,420,238	\$ 5,270	35,343,594	\$ 47,804	43,757,292	\$ 74,575	_	\$	—	3,872,569	\$ 4	\$ 4,691	\$ (113,876)	\$ 64	\$ (1	109,117
Asiz 210409       -       -       -       -       -       10       -       100       -         securities       -       -       -       -       -       -       0       -       00       -       00       -       00       <																	
on analysiski       -       <		-	-	-	-	-	-	-		—	-	-	212	(212)			_
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Conversible breeficient compensation		(2,641,882)	(2,211)	(5,311,494)	(7,119)	_		_		_	1,590,668	2	9,328	_	_		9,330
Note- conversion         Image: second s	2018																
beneficial (secure (secure secures)       -       -       -       -       13.45       -       -       13.45         (secure size)       -       -       -       -       2.071       -       -       2.071       -       -       2.071       -       -       2.071       -       -       2.071       -       -       2.071       -       -       2.071       -       -       2.071       -       -       2.071       -       -       2.071       -       -       2.071       -       -       2.071       -       -       2.071       -       -       2.071       -       -       2.071       -       -       -       -       -       -       -       2.071       -																	
conversion																	
index-based	conversion																
compensation         -         -         -         -         -         -         2.071         -         -         2.071           exercise         -         -         -         -         -         348         -		_	—	_	—	_	—	_		—	_	_	13,495	_	_		13,495
side cigning in environmental		_	_	_	_	_	_	_			_	_	2 071	_			2,071
Ver loss																	2,071
Balance and December 31, 2018         3,778,256         8         3,0032,100         \$ 40,685         43,777,292         \$ 7,4,575         \$         -         6,385,612         \$         8         30,145         \$         (161,995)         \$         20         \$         (131,14)           2018         - </td <td></td> <td>_</td> <td>_</td> <td>-</td> <td>_</td> <td>-</td> <td>_</td> <td>-</td> <td></td> <td>—</td> <td>922,375</td> <td>_</td> <td>348</td> <td>(45.005)</td> <td></td> <td></td> <td>348</td>		_	_	-	_	-	_	-		—	922,375	_	348	(45.005)			348
December 31, Damail 24018       778,250       8       30,032,100       8 40,685       43,757,292       5 74,575       5       6,385,50.2       6       8       30,145       8       (161,995)       5       20       5       (151,095)         Damail 2400       -														(47,907)			(47,907
2018       3778.35       5       30.92       30.032.100       5 40.85       43,757.292       5 74.575       - 5       - 6       5385.612       5       6       5       30.145       5       (161.995)       5       20       5       (131.47)         100 marketable       -       -       -       -       -       -       -       -       -       -       -       46       -<																	
an markeable	2018	3,778,356	\$ 3,059	30,032,100	\$ 40,685	43,757,292	\$ 74,575	_	\$	—	6,385,612	\$6	\$ 30,145	\$ (161,995)	\$ 20	\$ (1	131,824
security in a field of																	
Toreign Corrency		_	_	_	_	_	_	_			_	_	_	_	46		46
adjustment	Foreign currency														10		
sseamere of series A preferred stock for cash preferred stock for cash preferred stock for cash red (25,796 – – – – – – – – – – – – – – – – – – –															(2.0)		(0.0
Series A       sock for cashes       25,796			_	_						_				_	(96)		(96)
stock for convertible prefered Series D convertible prefered Series D convertible Series D Series D Seri																	
cashles       varrat																	
warati sexercise         25,796																	
ssance of Series D convertible prefered stock for cash, pet of issuance costs of \$1,636																	
Series D       convertible       preferred       sock for cash, net of       sock for cash,		25,796	—	—	—	—		—		—	—	—	—	—	—		_
convertible       stock for cash, ner of       stor       stock for cash, ner of																	
stock for cash, per of issuance costs of \$1,636 39,789,158 66,563																	
net of issuance of Series D. convertible prefered stock for 2018 Convertible Notes and 2019       - <td></td>																	
issuance costs series D convertible refered sock for 2018 Convertible Notes and 2019 2019 Convertible Notes — — — — — — — 39,550,927 68,476 Convertible Notes — — — — — — — — — — — — — — — — — — —																	
ssuarc of Series D convertible prefered stock for 2018 Convertible Notes and 2019 Convertible Notes — — — — — — — 39,950,927 68,476 — — — — — — — — — — — — — — — — — — —																	
Series D       convertible       preferred       stock for 2018       convertible       stock for 2018       stoc		-	_	-	_	-	_	39,789,158	66,	563	-	-	-	_	_		-
convertible       stock for 2018       stock for 2018       stock for 2018       stock for 2018       stock for 2019       stock for 2018       stock for 2019       stock for 2019       stock for 2018       stock for 2019       stock for 2018       stock for 2018       stock for 2018       stock for 2019       stock fo																	
stock for 2018       Convertible       Notes and 2019       -	convertible																
Convertible Notes and 2019       -       -       -       39,950,927       68,476       - <td></td>																	
Notes and 2019       2019																	
Convertible	Notes and																
Notes																	
Stock-based compensation		_	_	_	_	_	_	39 950 927	68	476	_	_	_	_			_
Stock option									,								
exercises		—	—	—	—	_	—	—		—	111,452	—	2,994	_	_		2,994
Net loss		_	_	_	_	_	_	_			270 393	1	107	_	_		108
December 31, 2019       3,804,152       \$       0.59       30,032,100       \$ 40,685       43,757,292       \$ 74,575       79,740,085       \$ 135,039       6,767,457       \$ 7       \$ 33,246       \$ (259,034)       \$ (30)       \$ (255,037)         Unrealized loss on marketable securities       - </td <td></td> <td></td> <td></td> <td>_</td> <td></td> <td>_</td> <td></td> <td></td> <td></td> <td>_</td> <td>270,333</td> <td>_</td> <td></td> <td>(97,039)</td> <td>_</td> <td></td> <td>(97,039)</td>				_		_				_	270,333	_		(97,039)	_		(97,039)
2019       3,804,152       \$ 3,059       30,032,100       \$ 40,685       43,757,292       \$ 74,575       79,740,085       \$135,039       6,767,457       \$ 7       \$ 33,246       \$ (259,034)       \$ (20)       \$ (225,100)         Unrealized loss on marketable	Balance as of																
Unrealized loss on marketable securities		2 004 152	¢ 2.050	20.022.100	¢ 40.005	40 757 000	¢	70 740 005	¢105	020	0 707 457	¢ 7	¢ 22.240	¢ (250.034)	¢ (30)		DDE 011
on marketable securities		3,004,132	\$ 3,039	30,032,100	\$ 40,005	43,/3/,292	\$ /4,3/3	/9,/40,005	\$135,	039	0,/0/,43/	<b>\$</b> /	\$ 33,240	\$ (259,054)	<b>р</b> (30)	» (4	223,011
Foreign currency translation adjustment <u>— — — — — — — — — — — — — — (27)</u> Issuance of Series D convertible preferred stock for the Biotronik Asset	on marketable																
translation adjustment (27) ssuance of Series D convertible preferred stock for the Biotronik Asset		—	—	—	—	_	—	—		—	—	—	_	_	(27)		(27
adjustment (27) ssuance of Series D convertible preferred stock for the Biotronik Asset	translation																
Issuance of Series D convertible preferred stock for the Biotronik Asset	adjustment	_		_	_		_	_		_	_	_		_	(27)		(27)
convertible preferred stock for the Biotronik Asset	ssuance of																
preferred stock for the Biotronik Asset																	
stock for the Biotronik Asset																	
Asset	stock for the																
Purchase — — — — — — — 2,655,337 5,000 — — — — — —		_	_	_	_	_		2,655 337	5	000	_	_	_	_	_		

Issuance of															
Series D															
convertible															
preferred															
stock for the															
contingent															
consideration															
related to the															
Rhythm															
Xience															
Acquisition	_		_	_	_		1,166,861	2,197					_		
Stock-based															
compensation	_		_	_	_		_	_	145,500		- 1,741		_		1,741
Net loss	_	_		_	_		_	_		_	- ´—	(18,098)	_	(18	8,098)
Balance as of									1					-	
March 31,															
2020															
(unaudited)	3,804,152	\$ 3,059	30,032,100	\$ 40,685	43,757,292 \$	74,575	83,562,283	\$142,236	6,912,957	\$ 2	7 \$ 34,987	\$ (277,132)	\$ (84)	\$ (242	2,222)
. ,		<u> </u>												<u>`</u>	
	Series	A	Series	B	Series (	2	Serie	s D	1						
	Conver		Conver	tible	Converti		Conver				Additional		Other	Tota	ıl
	Preferred	Stock	Preferred	Stock	Preferred S	tock	Preferrec	l Stock	Commo	n Stock	Paid-in	Accumulated	Comprehensive	Stockhol	ders'
	Shares	Amount	Shares	Amount	Shares A	Amount	Shares	Amount	Shares	Amoun	t Capital	Deficit	Income (Loss)	Defic	t
Balance as of															
December 31,															
2018	3,778,356	\$ 3,059	30,032,100	\$ 40,685	43,757,292 \$	74,575	_	\$ —	6,385,612	\$ (	5 \$ 30,145	\$ (161,995)	\$ 20	\$ (13)	1,824)
Unrealized gain															
on marketable															
securities	—	—	_	—	—	_	—	—	—	-		_	1		1
Foreign currency															
translation															
adjustment		_			—			—					(14)		(14)
Issuance of															
Series A															
preferred															
stock for															
cashless															
warrant															
exercise	25,796	_	_	_	_	-	_	_	-	-		_	_		-
Stock-based															
compensation	—	—	—	—	—		—	—	_	_	- 559		—		559
Net loss									!			(14,695)		(14	4,69 <u>5</u> )
Balance as of															
March 31,															
2019															
(unaudited)	3,804,152	\$ 3,059	30,032,100	\$ 40,685	43,757,292 \$	74,575		<u>\$                                    </u>	6,385,612	\$ (	5 \$ 30,704	\$ (176,690)	<u>\$7</u>	\$ (14)	5,97 <u>3</u> )
			The acces	moonvin	g notes are	on into	gral part o	f those or	ncolidator	finan	ial statem	onte			
			The accor	mpanying	g notes ale	an me	grai part 0	i mese ((	nsonualed	1 IIIallo	lai statem	CIII.5.			

### ACUTUS MEDICAL, INC. AND SUBSIDIARIES Consolidated Statements of Cash Flows (in thousands)

	Three I Ended M 2020	larch 31, 2019	Year E Deceml 2019	
Cash flows from operating activities	(unau	allea)		
Cash hows from operating activities	\$(18,098)	\$(14,695)	\$ (97,039)	\$(47,907)
Adjustments to reconcile net loss to net cash used in operating activities:	\$(10,050)	φ(14,000)	\$ (37,033)	\$(47,307)
Depreciation expense	429	567	2,280	2,121
Amortization of intangible assets	110	_	250	
Stock-based compensation expense	1,741	559	2,994	2,071
Accretion of discounts on marketable securities, net of amortization of premiums	(5)	(10)	(153)	(99)
Amortization of debt issuance costs	154	4,828	17,579	3,316
Amortization of right-of-use assets	169	158	637	
Research and development—license acquired	_	_	15,000	
Loss on issuance of convertible notes and warrants	—	—	1.447	924
Loss on debt extinguishment Change in fair value of warrant liability and embedded derivative	(581)	(841)	1,447	4,298
Impairment of property and equipment	(501)	(041)	786	4,296
Change in fair value of contingent consideration	(2,219)	_	500	_
Changes in operating assets and liabilities, net of effect from business combination:	(2,215)		500	
Accounts receivable	(708)	(273)	(96)	26
Inventory	(1,809)	(772)	(5,421)	523
Prepaid expenses and other current assets	214	(272)	(928)	(386)
Other assets	(267)	(75)	(8)	1
Accounts payable	3,602	1,214	2,111	18
Accrued liabilities	(83)	205	2,901	1,314
Lease liabilities	(207)	(177)	(745)	
Net cash used in operating activities	(17,558)	(9,584)	(55,986)	(33,780)
Cash flows from investing activities				
Purchases of available-for-sale marketable securities	—	_	(68,735)	(14,304)
Sales of available-for-sale marketable securities	8,100			
Maturities of available-for-sale marketable securities	25,300	8,100	14,700	11,600
Purchases of property and equipment	(1,683)	(23)	(3,395)	(2,038)
Purchase of research and development license Cash paid, net of cash acquired for the Rhythm Xience Acquisition			(10,000) (3,000)	_
	31,717	8,077		(4.742)
Net cash used in investing activities	51,717	0,077	(70,430)	(4,742)
Cash flows from financing activities			77.000	27.015
Proceeds from issuance of debt and warrants Repayment of debt	_		77,000 (15,000)	37,815 (600)
Payments of issuance and extinguishment costs related to debt	_	_	(2,332)	(149)
Payment of contingent consideration	(2,584)	_	(2,332)	(145)
Proceeds from issuance of convertible preferred stock, net of issuance costs	(2,004)	_	66,563	_
Proceeds from stock option exercises		—	108	348
Net cash provided by financing activities	(2,584)		126,339	37,414
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(27)	(14)	(96)	(43)
Net change in cash, cash equivalents and restricted cash	11.548	(1,521)	(173)	(1,151)
Cash, cash equivalents and restricted cash, at the beginning of the period	9,602	9,755	9,775	10,926
Cash, cash equivalents and restricted cash, at the end of the period	\$ 21,150	\$ 8,254	\$ 9,602	\$ 9,775
	\$ 21,150	<del>\$ 0,234</del>	<del>\$ 5,002</del>	<del>\$ 3,773</del>
Supplemental disclosure of cash flow information: Cash paid for income taxes	\$ —	\$ —	\$ —	\$ —
Cash paid for interest	\$ 1,188	\$ <u>342</u>	\$ 3,593	\$ 493
Supplemental disclosure of noncash investing and financing activities:	φ 1,100	J J4∠	φ 3,333	J 495
Issuance of Series D convertible preferred stock for 2018 Convertible Notes and 2019 Convertible Notes	\$ —	\$ —	\$ 68,476	\$ —
Issuance of Series D convertible preferred stock for Biotroniks asset purchase	\$ 5,000	š —	\$	\$ —
Issuance of Series D convertible preferred stock for Rhythm Xience Acquisition	\$ 2,197	\$ —	\$ —	\$ —
Accrued purchase of research and development—license	\$ —	\$ —	\$ 5,000	\$ —
Change in unrealized (gain) loss on marketable securities	\$ 27	\$ (1)	\$ (46)	\$ 1
2018 Convertible Notes—beneficial conversion feature	\$ —	\$ —	\$ —	\$ 13,495
Right-of-use assets exchanged for operating lease liabilities	\$	\$ 2,978	\$ 2,978	\$ —
Unpaid purchases of property, plant and equipment	\$ 119	\$ 44	\$ 174	\$ —

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

#### Note 1—Organization and Description of Business

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

#### Going Concern, Liquidity and Capital Resources

The Company has limited revenue, has incurred operating losses since inception and expects to continue to incur significant operating losses for at least the next several years and may never become profitable. As of March 31, 2020 and December 31, 2019 and 2018, the Company had an accumulated deficit of \$277.1 million, \$259.0 million and \$162.0 million, respectively, and working capital of \$38.4 million and \$50.5 million and working capital deficit of \$2.9 million, as of March 31, 2020 and December 31, 2019 and 2018, respectively. The Company has historically funded its operations primarily through the sale of debt and equity securities, as well as other indebtedness.

The Company evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern over the next twelve months through June 2021. The Company's cash requirements include, but are not limited to, investments in additional sales and marketing and product research and development resources, capital expenditures and working capital requirements. The Company has concluded that there is substantial doubt about its ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

Beginning in early March 2020, the COVID-19 pandemic and the measures imposed to contain this pandemic disrupted and are expected to continue to impact the Company's business, though in June 2020, the effects of the COVID-19 pandemic began to decrease. For example, 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. The Company's primary operations are located in Carlsbad, California. As a result of such order, the majority of the Company's employees have telecommuted, which may impact certain of its operations over the near term and long term. Moreover, beginning in March 2020, access to hospitals and other customer sites has been restricted to essential personnel, which has negatively impacted the Company's ability to install AcQMap consoles and workstations in new accounts and for the Company's sales representatives and mappers to promote the use of the Company's products with physicians. Moreover, hospitals and other therapeutic centers have suspended many elective procedures, resulting in a significantly reduced volume of procedures using the Company's products. In addition, all clinical trials in Europe have been suspended with follow-ups for clinical trials done via telecom, and the Company believes enrollment timing in the Company's planned clinical trials will be slowed due to COVID-19 driven delayed access to enrollment sites. As a result of the interruptions to the Company's business due to COVID-19, the Company has enacted a cash conservation program, which includes delaying certain non-critical capital expenditures and other projects and implementing a hiring freeze and temporary compensation and headcount reductions throughout its organization. The magnitude of the impact of the COVID-19 pandemic on the Company's productivity, results of operations and financial position, and its disruption to the Company's business and clinical programs and timelines, will depend, in part, on the length and severity of these restrictions and on the Company's ability to conduct business in the ordinary course. Quarantines, shelter-in-place and similar government orders have also impacted, and may continue to impact, the Company's third-party manufacturers and suppliers, and could in turn adversely impact the availability or cost of materials, which could disrupt the Company's supply chain.

The accompanying consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

In order to proceed with the Company's business plan, the Company will need to raise substantial additional funds through one or more of the following: issuance of additional debt, equity or both. Until such time, if ever, the Company can generate revenue sufficient to achieve profitability, the Company expects to finance its operations through equity or debt financings, which may not be available to the Company on the timing needed or on terms that the Company deems to be favorable. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interest of its stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting the Company is unable to maintain sufficient financial resources, its business, financial condition and results of operations will be materially and adversely affected. The Company may be required to delay, limit, reduce or terminate its product discovery and development activities or future commercialization efforts. There can be no assurance that the Company will be able to obtain the needed financing on acceptable terms or at all.

In June and July 2019, the Company completed an equity financing pursuant to which the Company issued 79,740,085 shares of its Series D convertible preferred stock in a private placement (the "Series D Preferred Stock Issuance"). The Series D Preferred Stock Issuance was comprised of: (i) 39,789,158 shares at \$1.714 per share for cash proceeds of \$66.6 million, net of issuance costs of \$1.6 million; and (ii) 39,950,927 shares at \$1.3712 per share (including a 20% discount) for the conversion of the Company's convertible notes issued in 2018 (the "2018 Convertible Notes") and related accrued interest and \$1.714 per share for the conversion of the Company's convertible notes issued in 2019 (the "2019 Convertible Notes") and related accrued interest, in an aggregate amount of \$68.5 million, including the fair value of the embedded derivative of \$6.3 million relating to the 20% discount for the conversion of the 2018 Notes.

### Note 2—Summary of Significant Accounting Policies

### Unaudited Pro Forma Financial Information

Immediately prior to the completion of an initial public offering ("IPO") of the Company's common stock, all outstanding shares of the Company's convertible preferred stock will automatically convert into shares of its common stock and all warrants to purchase shares of its convertible preferred stock will automatically convert into warrants to purchase shares of its common stock. Pro forma basic and diluted net loss per common share has been computed to give effect to the automatic conversion of all outstanding shares of the Company's convertible preferred stock and the automatic conversion of all of its outstanding warrants to purchase shares of its convertible preferred stock into warrants to purchase shares of its common stock. The unaudited pro forma net loss per common share for the three months ended March 31, 2020 and the year ended December 31, 2019 has been computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the automatic conversion of all outstanding shares of its common stock and the automatic conversion of all outstanding shares of its common stock into shares of its common stock and the automatic conversion of all outstanding shares of the Company's convertible preferred stock into shares of its common stock and the automatic conversion of all outstanding shares of the Company's convertible preferred stock into shares of its common stock and the automatic conversion of all outstanding warrants to purchase shares of its convertible preferred stock into warrants to purchase shares of its convertible preferred stock into warrants to purchase shares of its common stock, as if the IPO had occurred at the beginning of the period or their issuance dates, if later. The unaudited pro forma net loss per common share does not include the shares of common stock expected to be sold in, and related proceeds to be received from, the IPO.

#### **Basis of Presentation**

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

#### **Principles of Consolidation**

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

#### **Unaudited Interim Financial Information**

The accompanying consolidated balance sheet as of March 31, 2020, the consolidated statements of operations and comprehensive loss and the statements of cash flows for the three months ended March 31, 2020 and 2019, and the consolidated statement of convertible preferred stock and stockholders' deficit for the three months ended March 31, 2020 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the Company's opinion, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2020 and the results of its operations and its cash flows for the three months ended March 31, 2020 and 2019. The financial data and other information disclosed in these notes related to the three months ended March 31, 2020 and 2019 are unaudited. The results for the three months ended March 31, 2020, any other interim periods, or any future year or period.

### Use of Estimates and Assumptions

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and disclosures of contingent assets and liabilities. The most significant estimates and assumptions in the Company's consolidated financial statements include, but are not limited to, revenue recognition, useful lives of intangible assets, assessment of impairment of goodwill, provisions for income taxes, measurement of operating lease liabilities, and the fair value of common stock, stock options, warrants, embedded derivative in convertible notes, intangible assets, contingent consideration and goodwill. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results could differ from those estimates.

#### Segments

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

#### Cash and Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. All of the Company's cash equivalents have liquid markets and high credit ratings. The Company maintains its cash in bank deposits and other accounts, the balances of which, at times and as of March 31, 2020 and December 31, 2019 and 2018, exceeded federally insured limits.

Restricted cash serves as collateral for the Company's corporate credit card program. The following table reconciles cash and restricted cash in the consolidated balance sheets to the totals shown on the consolidated statements of cash flows (in thousands).

	March 31, 2020	Decem 2019	
	(unaudited)	2013	2018
Cash and cash equivalents	\$ 21,000	\$9,452	\$9,625
Restricted cash	150	150	150
Total cash, cash equivalents and restricted cash	\$ 21,150	\$9,602	\$9,775

#### Marketable Securities

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

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

Marketable securities are subject to a periodic impairment review. The Company may recognize an impairment charge when a decline in the fair value of investments below the cost basis is determined to be other-than-temporary. In determining whether a decline in market value is other-than-temporary, various factors are considered, including the cause, duration of time and severity of the impairment, any adverse changes in the investees' financial condition and the Company's intent and ability to hold the security for a period of time sufficient to allow for an anticipated recovery in market value. Declines in value judged to be other-than-temporary are included in the Company's consolidated statements of operations and comprehensive loss. There were no marketable securities deemed to be impaired as of March 31, 2020 or December 31, 2019 or 2018.

#### Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to credit risk consist principally of cash, cash equivalents, restricted cash, accounts receivable and marketable securities. Cash and restricted cash are

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### Acutus Medical, Inc. and Subsidiaries Notes to Consolidated Financial Statements (including data related to unaudited periods)

maintained in accounts with financial institutions, which, at times may exceed the Federal depository insurance coverage of \$0.25 million. The Company has not experienced losses on these accounts and management believes, based upon the quality of the financial institutions, that the credit risk with regard to these deposits is not significant. The Company's marketable securities portfolio consists primarily of investments in money market funds, commercial paper and short-term high credit quality corporate debt securities.

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

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

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

The Company places its medical diagnostic equipment, AcQMap System, at customer sites under loan agreements and generates revenue from disposable products used with the AcQMap System. Disposable products include AcQMap Catheters and AcQGuide Steerable Sheaths. The Company provides the disposable products in exchange for consideration, which occurs when a customer submits a purchase order and the Company provides disposables at the agreed upon prices in the invoice. Generally, customers purchase disposable products using separate purchase orders after the equipment has been provided to the customer for free with no binding agreement or requirement to purchase any disposable products. The Company also sells the AcQMap System to customers along with software updates on a when-and-if-available basis and equipment service. The Company has elected the practical expedient and accounting policy election to account for the shipping and handling as activities to fulfill the promise to transfer the disposable products and not as a separate performance obligation. The following table sets forth the Company's revenue for disposables and systems/service for the three months ended March 31, 2020 and 2019 and the years ended December 31, 2019 and 2018 (in thousands):

		onths Ended rch 31,		Ended ıber 31,
	<u>2020</u>	2019 audited)	2019	2018
Disposables	\$ 1,057	\$ 782	\$ 2,817	\$ 2,160
Systems/service	526	5	19	6
Total revenue	\$ 1,583	\$ 787	\$ 2,836	\$ 2,166

Systems/service revenue for 2019 and 2018 was comprised solely of revenue from service agreements with the Company's customers, as the AcQMap systems were loaned to customers in 2019 and 2018 without charge.

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

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

The installation and delivery of the AcQMap system is satisfied at a point in time when the installation is complete, which is when the customer can benefit and has control of the system. The Company's software updates and equipment service performance obligations are satisfied evenly over time as the customer simultaneously receives and consumes the benefits of the Company's performance for these services throughout the service period.

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

The Company's contracts with customers generally have an expected duration of one year or less, and therefore the Company has elected the practical expedient in ASC 606 to not disclose information about its remaining performance obligations. Any incremental costs to obtain contracts are recorded as selling, general and administrative expense as incurred due to the short duration of the Company's contracts. The Company's contract balances consisted solely of accounts receivable as of March 31, 2020 and December 31, 2019 and 2018.

The following table provides revenue by geographic location for the three months ended March 31, 2020 and 2019 and the years ended December 31, 2019 and 2018 (in thousands):

		e Months Ended March 31,		r Ended mber 31,
	2020	2019 (unaudited)	2019	2018
United States	\$ 76	9 \$ 235	\$ 738	\$ 461
Europe	81	4 552	2,098	1,705
Total revenue	\$ 1,58		\$ 2,836	\$ 2,166

#### Inventory

Inventory is comprised of raw materials, direct labor and manufacturing overhead and is stated at the lower of cost (first-in, first-out basis) or net realizable value. The Company recorded write-downs for excess and obsolete inventory based on management's review of inventories on hand, compared to estimated future usage and sales, shelf-life and assumptions about the likelihood of obsolescence of \$0.1 million in each of the three months ended March 31, 2020 and 2019 and \$0.7 million and \$0.1 million, for the years ended December 31, 2019 and 2018, respectively.

### Accounts Receivable

Trade accounts receivable are recorded net of allowances for uncollectible accounts. The Company evaluates the collectability of its accounts receivable based on various factors including historical experience, the

length of time the receivables are past due and the financial health of the customer. The Company reserves specific receivables if collectability is no longer reasonably assured. Based upon the assessment of these factors, the Company did not record an allowance for uncollectible accounts as of March 31, 2020 and December 31, 2019 or 2018.

#### Property and Equipment, Net

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

### **Intangible Assets**

Intangible assets consist of acquired developed technology, acquired in-process technology, trademarks and trade names and a customer-related intangible which were acquired as part of the acquisition of Rhythm Xience, Inc. ("Rhythm Xience") in June 2019. The Company determines the appropriate useful life of its finite-lived intangible assets by performing an analysis of expected cash flows of the acquired assets. Finite-lived intangible assets are amortized over their estimated useful lives using the straight-line method, which approximates the pattern in which the economic benefits are consumed. Acquired in-process technology was classified as an indefinite-lived intangible asset, until the receipt of FDA approval for the technology in January 2020. Once the FDA approval was received, the in-process technology was classified as a finite-lived intangible and amortization for in-process technology began. Indefinite-lived intangible assets are tested for impairment at least annually and are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Indefinite-lived intangible assets are impaired if their estimated fair values are less than their carrying value.

#### Goodwill

Goodwill represents the excess of the purchase price of an entity over the estimated fair value of the assets acquired and liabilities assumed, and it is presented as goodwill in the accompanying consolidated balance sheets. Under ASC 350, *Intangibles – Goodwill and Other* ("ASC 350"), goodwill is not amortized but is subject to periodic impairment testing. ASC 350 requires that an entity assign its goodwill to reporting units and test each reporting unit's goodwill for impairment at least on an annual basis and between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount. In the evaluation of goodwill for impairment, which is performed annually during the fourth quarter, the Company first assesses qualitative factors to determine whether the existence of events or circumstances led to a determination that it was more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, it is determined that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, the Company is required to perform the quantitative goodwill impairment test. The Company has one reporting unit. For the year ended December 31, 2019, the qualitative testing did not indicate any impairment for the carrying amount of goodwill.

#### Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment and finite-lived intangible assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss is recognized when the asset's carrying value exceeds the total undiscounted cash flows expected from its use and eventual disposition. The amount of the impairment loss is determined as the excess of the carrying value of the asset over its fair value. For the year

ended December 31, 2019, the Company recorded a \$0.8 million impairment of its property and equipment resulting from the release of a second generation of the Company's AcQMap System. For the three months ended March 31, 2020 and 2019 and the year ended December 31, 2018, the Company determined that there was no impairment of property and equipment. For the three months ended March 31, 2020 and the year ended December 31, 2019, the Company did not have an impairment of the intangible assets.

### Foreign Currency Translation and Transactions

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

#### Leases

Effective January 1, 2019, the Company accounts for its leases under ASC 842, *Leases* ("ASC 842"). Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases, and are recorded on the consolidated balance sheet as both a right-of-use asset and a lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset results in straight-line rent expense over the lease term. Variable lease expenses are recorded when incurred.

In calculating the right-of-use asset and lease liability, the Company elects to combine lease and non-lease components. The Company excludes short-term leases having initial terms of 12 months or less from the new guidance as an accounting policy election.

The Company accounted for leases prior to January 1, 2019 under ASC 840, *Leases*. For the year ended December 31, 2018, the Company recognized lease incentives and rent escalations included in the base price of the rent payments in the Company's operating leases on a straight-line basis over the lease term. Deferred rent is included in accrued liabilities in the accompanying consolidated balance sheet as of December 31, 2018.

### **Cost of Products Sold**

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

#### **Research and Development**

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

expenses also include payments for the asset acquisition from Biotronik SE & Co. KG and VascoMed GmbH (collectively, the "Biotronik Parties") for certain licenses of patents, technology, know-how rights and equipment (the "Biotronik Asset Acquisition").

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

### Selling, General and Administrative

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

#### Fair Value Measurements

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

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

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

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

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. Management's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed or initial amounts recorded may not be indicative of the amount that the Company or holders of the instruments could realize in a current market exchange. There were no transfers made among the three levels in the fair value hierarchy for the three months ended March 31, 2020 and 2019 and the years ended December 31, 2019 and 2018.

As of March 31, 2020 and December 31, 2019 and 2018, the Company's cash (excluding cash equivalents which are recorded at fair value on a recurring basis), restricted cash, accounts receivable, accounts payable and accrued expenses were carried at cost, which approximates the fair values due to the short-term nature of the instruments.

The carrying amount of the Company's long-term debt approximates fair value due to its variable market interest rate and management's opinion that current rates and terms that would be available to the Company with

the same maturity and security structure would be essentially equivalent to that of the Company's long-term debt. Certain features of the convertible notes were determined to be an embedded derivative requiring separate measurement from the loan host instrument.

The following tables classify the Company's financial assets and liabilities measured at fair value on a recurring basis into the fair value hierarchy as of March 31, 2020 and December 31, 2019 and 2018 (in thousands):

	Fa	Fair Value Measured as of March 31, 2020						
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value as of March 31, 2020				
Assets included in:		(una	udited)					
Cash and cash equivalents								
Money market securities	\$ 16,619	\$ —	\$ —	\$ 16,619				
Marketable securities at fair value								
Corporate debt securities		13,823		13,823				
Asset-backed securities		9,020	—	9,020				
U.S. treasury securities	_	5,037		5,037				
Commercial paper		1,000	—	1,000				
Total fair value	\$ 16,619	\$ 28,880	\$ —	\$ 45,500				
Liabilities included in:								
Contingent consideration	\$ —	\$ —	\$ 6,900	\$ 6,900				
Common and preferred stock warrant liability		—	8,338	8,338				
Total fair value	\$	\$	\$ 15,238	\$ 15,238				

	F Quoted	of		
	Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value as of December 31, 2019
Assets included in:				
Cash and cash equivalents				
Money market securities	\$ 8,901	\$ —	\$ —	\$ 8,901
Investments available-for-sale at fair value				
Corporate debt securities	_	28,224	—	28,224
Asset-backed securities		17,121	_	17,121
U.S. treasury securities	_	5,032	—	5,032
Commercial paper		11,974		11,974
Total fair value	\$ 8,901	\$ 62,351	\$	\$ 71,252

Corporate debt securities

Common and preferred stock warrant liability

Included in short-term debt on the consolidated balance sheet.

Embedded derivative in convertible notes(1)

Commercial paper

Liabilities included in:

Total fair value

Total fair value

(1)

### Acutus Medical, Inc. and Subsidiaries Notes to Consolidated Financial Statements (including data related to unaudited periods)

	Fa	of		
	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value as of December 31, 2019
Liabilities included in:				
Contingent consideration	\$ —	\$ —	\$ 13,900	\$ 13,900
Common and preferred stock warrant liability			8,919	8,919
Total fair value	<u>\$                                    </u>	<u>\$                                    </u>	\$ 22,819	\$ 22,819
	Quoted Prices in Active Markets for Identical Assets or Liabilities	Fair Value Measured a December 31, 2018 Significant Other Observable Inputs	3 Significant Unobservable Inputs	Fair Value as of December 31,
Assets included in:	Quoted Prices in Active Markets for Identical Assets or	December 31, 2018 Significant Other Observable	Significant Unobservable	as of
Assets included in: Cash and cash equivalents	Quoted Prices in Active Markets for Identical Assets or Liabilities	December 31, 2018 Significant Other Observable Inputs	3 Significant Unobservable Inputs	as of December 31,
Cash and cash equivalents	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	December 31, 2018 Significant Other Observable Inputs <u>(Level 2)</u>	3 Significant Unobservable Inputs (Level 3)	as of December 31, 2018
Cash and cash equivalents Money market securities	Quoted Prices in Active Markets for Identical Assets or Liabilities	December 31, 2018 Significant Other Observable Inputs (Level 2) \$ —	3 Significant Unobservable Inputs	as of December 31, 2018 \$ 5,529
Cash and cash equivalents	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	December 31, 2018 Significant Other Observable Inputs <u>(Level 2)</u>	3 Significant Unobservable Inputs (Level 3)	as of December 31, 2018

The Company's portfolio of marketable securities is comprised of commercial paper, asset-backed securities, U.S. treasury securities, and short-
term highly liquid, high credit quality corporate debt securities. The fair value for the available-for-sale marketable securities is determined based on
trade prices in active markets for identical assets (Level 1 inputs) or valuation models using inputs that are observable either directly or indirectly (Level
2 inputs), such as quoted prices for similar assets or liabilities, yield curve, volatility factors, credit spreads, default rates, loss severity, current market
and contractual prices for the underlying instruments or debt, broker and dealer quotes, as well as other relevant economic measures.

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

2,730

5,390

9,814

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\$

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2,730

5,390

15,343

6,842

5,568

12,410

\$

\$

\$

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6,842

5,568

12,410

\$

\$

\$

The following table presents changes in Level 3 liabilities measured at fair value for the three months ended March 31, 2020 and the years ended December 31, 2019 and 2018 (in thousands):

	Common and Preferred Stock Warrant Liability	Preferred Embedded		Total
Balance, January 1, 2018	\$ —	\$ —	<u>Consideration</u> \$	<u> </u>
Issuance of preferred stock warrants	347	—	—	347
Issuance of common stock warrants	5,357			5,357
Issuance of convertible notes	—	2,408	—	2,408
Change in fair value	1,138	3,160	—	4,298
Balance, December 31, 2018	6,842	5,568		12,410
Issuance of preferred stock warrants in conjunction with				
debt	872	—	—	872
Conversion of convertible notes	—	(6,282)	—	(6,282)
Fair value of contingent consideration – Rhythm Xience				
acquisition	—	—	13,400	13,400
Change in fair value	1,205	714	500	2,419
Balance, December 31, 2019	8,919	_	13,900	22,819
Payment of contingent consideration	—	—	(2,584)	(2,584)
Issuance of preferred stock for contingent consideration	—	—	(2,197)	(2,197)
Change in fair value	(581)		(2,219)	(2,800)
Balance, March 31, 2020 (unaudited)	\$ 8,338	\$	\$ 6,900	\$15,238

Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs. In June 2019, the convertible notes were converted into shares of the Company's Series D convertible preferred stock.

The fair value of the common stock and preferred stock warrants issued by the Company has been estimated using a Monte Carlo simulation in 2018 and in the first quarter of 2019 and as an output of the Hybrid Method for the remaining quarters of 2019 and the first quarter of 2020. The underlying equity included in the Monte Carlo simulation and the Hybrid Method was determined based on the equity value implied from the preferred stock transactions and from examination of income and market approaches for measurement dates in which a preferred transaction was not applicable. Additionally, the expected IPO value was considered in the determination of the equity value. The fair value of the warrants was impacted by the model selected as well as assumptions surrounding unobservable inputs including the underlying equity value, risk-free interest rate, expected dividend yield, contractual term and expected volatility. The weighted-average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the common and preferred stock warrant liabilities as of March 31, 2020 and December 31, 2019 and 2018 were as follows:

	March 31,	December	r 31,
	2020	2019	2018
	(unaudited)		
Risk-free interest rate	0.13% - 0.16%	1.59% - 1.60%	2.63%
Expected dividend yield			—
Contractual term in years	0.4 - 0.8	0.7 - 1.0	1.1
Expected volatility	80.0% - 132.0%	60.0% - 110.5%	75.0%

The fair value of the contingent consideration from the acquisition of Rhythm Xience represents the estimated fair value of future payments due to the sellers of Rhythm Xience based on the achievement of certain milestones and revenue-based targets in certain years. The initial fair value of the revenue-based contingent consideration was calculated through the use of a Monte Carlo simulation using revenue projections for the respective earn-out period, corresponding targets and approximate timing of payments as outlined in the purchase agreement. The analyses used the following assumptions: (i) expected term; (ii) risk-adjusted net sales or earnings; (iii) risk-free interest rate; and (iv) expected volatility of earnings. Estimated payments, as determined through the respective model, were further discounted by a credit spread assumption to account for credit risk. The fair value of the milestones-based contingent consideration was determined by probability weighting and discounting to the respective valuation date at the Company's cost of debt. The Company's cost of debt was determined by performing a synthetic credit rating for the Company and selecting yields based on companies with a similar credit rating. The contingent consideration is revalued to fair value each period, and any increase or decrease is recorded in operating loss. The fair value of the contingent consideration may be impacted by certain unobservable inputs, most significantly with regard to discount rates, expected volatility and historical and projected performance. Significant changes to these inputs in isolation could result in a significantly different fair value measurement. The weighted-average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the contingent consideration from the acquisition of Rhythm Xience as of March 31, 2020, December 31, 2019 and June 18, 2019 (acquisition date) were as follows:

	March 31, 2020 (unaudited)	December 31, 2019	June 18, 2019 (Acquisition Date)
Risk-free interest rate	0.30%	1.60%	1.80%
Expected term in years	1.0 - 2.0	1.0 - 2.0	1.0 - 2.0
Expected volatility	19.0%	11.8%	11.6%

For the year ended December 31, 2018, the fair value of the embedded derivative in the 2018 Convertible Notes has been estimated using the Black-Scholes option pricing model. The underlying equity included in the

Black-Scholes option pricing model was valued based on preferred stock transactions and from examination of income and market approaches for measurement dates in which a preferred transaction was not applicable. Additionally, the expected IPO value was considered in the determination of the equity value. The fair value of the embedded derivative was impacted by the model selected as well as assumptions surrounding unobservable inputs including the underlying equity value, risk free interest rate, expected dividend yield, the expected term and expected volatility. As of June 12, 2019 (conversion date), the fair value of the embedded derivative of \$6.3 million was based on the difference between the fair value of the Series D convertible preferred stock issued upon the conversion of the 2018 Convertible Notes of \$31.4 million, or \$1.714 per share, and the discounted conversion price of \$25.1 million, or \$1.3712 per share. A summary of the weighted-average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the embedded derivative in the 2018 Convertible Notes as of December 31, 2018 is as follows:

	December 31, 2018
Risk-free interest rate	2.51%
Expected dividend yield	
Expected term in years	0.3
Expected volatility	75.0%

#### Stock-Based Compensation

The Company accounts for all stock-based payments to employees and non-employees, including grants of stock options, restricted stock awards ("RSAs") and restricted stock units with non-market performance and service conditions ("PSUs") to be recognized in the consolidated financial statements, based on their respective grant date fair values. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. The RSAs and PSUs are valued based on the fair value of the Company's common stock on the date of grant. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The Company expenses stock-based compensation related to stock options and RSAs over the requisite service period. As the PSUs have a performance condition, compensation expense is recognized for each vesting tranche over the respective requisite service period of each tranche if and when the Company's management deems it probable that the performance conditions will be satisfied. The Company may recognize a cumulative true-up adjustment related to PSUs once a condition becomes probable of being satisfied if the related service period had commenced in a prior period. All stock-based compensation costs are recorded in cost of products sold, research and development expense or SG&A expense in the consolidated statements of operations and comprehensive loss based upon the respective employee's or non-employee's roles within the Company. Forfeitures are recorded as they occur. See also "Note 15—Stock-Based Compensation" below.

#### **Income Taxes**

Income taxes are recorded in accordance with ASC 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse, and net operating loss ("NOL") carryforwards and research and development ("R&D") tax credit carryforwards. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

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

#### Warrant Liability

The Company accounts for certain common stock warrants and convertible preferred stock warrants outstanding as a liability, in accordance with ASC 815, *Derivatives and Hedging* ("ASC 815"), at fair value. This liability is subject to re-measurement at each reporting period until exercised, and any change in fair value is recognized in the consolidated statements of operations and comprehensive loss.

#### Asset Acquisitions (Research and Development—License Acquired)

The Company accounts for asset acquisitions, where substantially all of the fair value of the assets acquired is concentrated in a group of similar assets (i.e., intellectual property) and therefore the acquisitions do not constitute a business, in accordance with ASC 805, *Business Combinations* ("ASC 805"), under the asset acquisition method. Under the asset acquisition method of accounting, the Company is required to fair value the assets transferred. The cost of the assets acquired, including transaction costs, is allocated to the individual assets acquired based on their relative fair values and does not give rise to goodwill.

#### **Business Combinations**

The Company accounts for business acquisitions using the acquisition method of accounting based on ASC 805, which requires recognition and measurement of all identifiable assets acquired and liabilities assumed at their fair value as of the date control is obtained. The Company determines the fair value of assets acquired and liabilities assumed based upon its best estimates of the acquisition-date fair value of assets acquired and liabilities assumed based upon its best estimates of the acquisition-date fair value of assets acquired and liabilities assumed in the acquisition. Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired. Subsequent adjustments to fair value of any contingent consideration are recorded to the Company's consolidated statements of operations and comprehensive loss.

#### **Recently Adopted Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASC 606. This guidance applies to any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards. The core principle of this guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance supersedes existing revenue recognition guidance, including most industry-specific guidance, as well as certain related guidance on accounting for contract costs. The Company early adopted ASC 606 on January 1, 2018 using the full retrospective method. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments—Overall*, that amends certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The new guidance

changes the current accounting guidance related to: (i) the classification and measurement of certain equity investments; (ii) the presentation of changes in the fair value of financial liabilities measured under the fair value option that are due to instrument-specific credit risk; and (iii) certain disclosures associated with the fair value of financial instruments. The Company adopted this ASU on January 1, 2018. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASC 842 in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous U.S. GAAP. For public companies, ASC 842 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous U.S. GAAP. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides entities an optional transition method to apply the guidance under ASC 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted ASC 842 on January 1, 2019, using the optional transition method by recording a right-of-use asset of approximately \$3.0 million, a lease liability of \$3.6 million and eliminated deferred rent of approximately \$0.6 million; there was no effect on opening accumulated deficit, and the Company continues to account for leases in the prior period consolidated financial statements under ASC 840. In adopting the new standard, the Company elected to apply the practical expedients regarding the identification of leases, lease classification, indirect costs and the combination of lease and non-lease components.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation-Stock Compensation (Topic 718)*, which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The Company adopted this ASU on January 1, 2018 and elected to account for forfeited awards as they occur. The adoption of this guidance had an impact of approximately \$0.2 million which was recorded in accumulated deficit as of January 1, 2018.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory*. ASU No. 2016-16 required an entity to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. The amendments eliminate the exception for an intra-entity transfer of an asset other than inventory. The amendments in ASU No. 2016-16 are effective for non-public business entities for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2018. The Company adopted ASU No. 2016-16 on January 1, 2019 and there was no impact from the adoption.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which clarifies the presentation of restricted cash in the statement of cash flows. Under ASU No. 2016-18, restricted cash is included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted ASU No. 2016-18 as of January 1, 2018. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other: Simplifying the Test for Goodwill Impairment*. ASU No. 2017-04 eliminated the second step in goodwill impairment testing, which

required that goodwill impairment losses be measured as the difference between the implied value of a reporting unit's goodwill and its carrying amount. Under the new guidance, goodwill impairment losses are measured as the excess of a reporting unit's carrying amount, including goodwill and related goodwill tax effects, over its fair value. The Company early adopted ASU No. 2017-04 as of January 1, 2019. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging* (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. This ASU simplifies the accounting for certain financial instruments with down round features, a provision in an equity-linked financial instrument (or embedded feature) that provides a downward adjustment of the current exercise price based on the price of future equity offerings. Down round features are common in warrants, preferred shares and convertible debt instruments issued by private companies and early-stage public companies. This update requires companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. This ASU is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, including adoption in any interim period. The amendments in Part I should be applied: (i) retrospectively to outstanding financial instruments with a down round feature by means of a cumulative-effect adjustment to the consolidated balance sheet as of the beginning of the first fiscal year and interim periods; and (ii) retrospectively to outstanding financial instruments with a down round feature by means of a cumulative-effect adjustment to the consolidated balance sheet as of the beginning of the first fiscal year and interim periods; and (ii) retrospectively to outstanding financial instruments with a down round feature for each prior reporting period presented. The Company's adoption of this ASU on January 1, 2019 did not have a material impact on the Company's consolidated financia

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance about such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The Company adopted ASU No. 2018-07 as of January 1, 2018. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. The amendments in this update clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill and consolidation. The guidance is effective for fiscal periods beginning after December 15, 2017, including interim periods within those periods. The Company adopted ASU No. 2017-01 on January 1, 2018. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,* which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. The Company adopted ASU No. 2018-13 as of January 1, 2019. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

### Accounting Pronouncements to Be Adopted

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

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects related to accounting for income taxes. ASU No. 2019-12 removes certain exceptions to the general principles in ASC 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, which provides temporary optional guidance to ease the potential burden in accounting for reference rate reform. The new guidance provides optional expedients and exceptions for applying U.S. GAAP to transactions affected by reference rate reform if certain criteria are met. These transactions include: contract modifications, hedging relationships and sale or transfer of debt securities classified as held-to-maturity. Entities may apply the provisions of the new standard as of the beginning of the reporting period when the election is made (i.e., as early as the first quarter 2020). Unlike other topics, the provisions of this update are only available until December 31, 2022, when the reference rate replacement activity is expected to have been completed. The Company is currently evaluating the impact of this standard on its consolidated financial statements and has yet to elect an adoption date.

#### Note 3—Asset Acquisition and Business Combination

#### **Biotronik Asset Acquisition**

In July 2019, the Company entered into a License and Distribution Agreement with the Biotronik Parties to obtain certain licenses to the Biotronik Parties' patents, whereby the Company acquired certain manufacturing equipment and obtained from the Biotronik Parties a license under certain patents and technology to develop, commercialize, distribute and manufacture the AcQBlate Force ablation catheters and Qubic Force device. In exchange for the rights granted to the Company, the Company made cash payments totaling \$10.0 million during the year ended December 31, 2019, and issued 2,655,337 shares of Series D convertible preferred stock with an implied value of \$5.0 million during the three months ended March 31, 2020. The implied value of \$5.0 million was recorded as an accrued liability as of December 31, 2019. In accordance with ASC 805, the Biotronik Asset Acquisition is accounted for as an asset acquisition as substantially all of the \$15.0 million value transferred to Biotronik was allocated to intellectual property. On the acquisition date, the products licensed had not yet received regulatory approval and the intellectual property did not have an alternative use. Accordingly, the \$15.0 million paid to Biotronik was immediately charged to research and development expense—licensed acquired in the consolidated statement of operations and comprehensive loss.

Additional contingent milestone payments of up to \$10.0 million are to be made to the Biotronik Parties contingent upon certain regulatory approvals and first commercial sale. In further consideration of the rights

granted, beginning with the Company's first commercial sale of the first force sensing ablation catheter within the licensed product line, the Company will also make per unit royalty payments. The Company has determined that as of the acquisition date and as of March 31, 2020 and December 31, 2019, the contingent milestone and royalty payments are not probable and estimable and therefore have not been recorded as a liability. Upon regulatory approval of the Company's force sensing ablation catheter in Europe, the milestone payments will be capitalized and amortized, and the royalty payments will be recorded as cost of products sold as sales of catheters are recognized.

#### **Rhythm Xience Business Combination**

On June 18, 2019 (the "Acquisition Date"), the Company acquired an integrated family of transseptal crossing and steerable introducer systems through its acquisition of Rhythm Xience for \$3.0 million in cash in exchange for all of the stock of Rhythm Xience (the "Rhythm Xience Acquisition"). The cash payment did not include the potential \$17.0 million in earn out consideration, of which \$2.0 million was paid with the issuance of Series D convertible preferred stock in February 2020 and the remainder is to be paid based on the achievement of certain regulatory milestones and revenue milestones. In accordance with ASC 805, the Rhythm Xience Acquisition is accounted for as a business combination.

#### Purchase Price Allocation

The following table summarizes the allocation of the purchase price to the assets acquired and liabilities assumed for the Rhythm Xience Acquisition (in thousands):

Accounts receivable, net	\$ 3
Prepaid expenses and other current assets	8
Property and equipment, net	3
Intangible assets	4,360
Goodwill	12,026
Contingent consideration	(13,400)
Cash consideration	\$ 3,000

The Company recorded \$12.0 million of goodwill that arose out of synergies from the Rhythm Xience Acquisition. The Company does not expect goodwill to be deductible for tax purposes.

As part of Rhythm Xience Acquisition, the Company recorded a contingent consideration liability for potential additional payments due to the sellers of Rhythm Xience if certain regulatory approval milestones and revenue milestones are achieved. The contingent consideration liability of \$13.4 million is based on the fair value of the contingent consideration liability at the acquisition date. During the three months ended March 31, 2020, the Company issued 1,166,861 shares of Series D convertible preferred stock and paid \$2.6 million of the contingent consideration for the achievement of certain regulatory milestones and revenue milestones. Additionally, the Company recorded a \$2.2 million decrease and a \$0.5 million increase to the fair value of the contingent consideration liability for the three months ended March 31, 2020 and from June 18, 2019 to December 31, 2019, respectively, which is included in change in fair value of contingent consideration in its consolidated statement of operations and comprehensive loss for the three months ended March 31, 2020 and for the year ended December 31, 2019 , respectively. As of March 31, 2020, the contingent consideration liability of \$6.9 million is the fair value of the remaining payments due to the sellers of Rhythm Xience if certain additional regulatory approval milestones and revenue milestones are achieved.

From the Acquisition Date to December 31, 2019, the Company recorded revenue and net loss for Rhythm Xience of \$0.1 million and \$1.0 million, respectively.

### Pro Forma (Unaudited)

The following unaudited pro forma financial information presents results of operations as if the Rhythm Xience Acquisition had occurred on January 1, 2018 (in thousands):

		Three Months Ended March 31,		Ended ber 31,
	2019(unaudited)		2019	2018
Revenue	\$	847	\$ 2,933	\$ 2,235
Net loss		(15,188)	\$(97,850)	\$(48,945)

For purposes of the pro forma disclosures above, the primary adjustments for the three months ended March 31, 2019 include the elimination of interest expense of \$0.1 million and the inclusion of amortization of the intangible assets of \$0.1 million.

For purposes of the pro forma disclosures above, the primary adjustments for the year ended December 31, 2019 include the elimination of transaction costs of \$0.2 million, the income tax benefit of Rhythm Xience of \$0.1 million and interest expense of \$0.1 million, and the inclusion of amortization of the intangible assets of \$0.2 million.

For purposes of the pro forma disclosures above, the primary adjustments for the year ended December 31, 2018 include the elimination of interest expense of \$0.1 million and the inclusion of amortization of the intangible assets of \$0.4 million.

For the year ended December 31, 2019, the Company recorded acquisition costs of \$0.2 million for the Rhythm Xience Acquisition, which are recorded in SG&A expense in the consolidated statement of operations and comprehensive loss.

# Note 4—Marketable Securities

Marketable securities consisted of the following as of March 31, 2020 and December 31, 2019 and 2018 (in thousands):

	March 31, 2020					
	Amortized Cost	Gross Unrealized Gains		Gross Unrealized Losses udited)		Fair Value
Available-for-sale securities—short-term:			(unau	uiteu)		
Corporate debt securities	\$ 13,831	\$	—	\$	(8)	\$ 13,823
Asset-backed securities	9,023		—		(3)	9,020
U.S. treasury securities	5,008		29		_	5,037
Commercial paper	1,000					1,000
Total available-for-sale securities	\$ 28,862	\$	29	\$	(11)	\$ 28,880

		December 31, 2019				
	Amortized Cost	Unre	ross ealized ains	Unr	ross ealized osses	Fair Value
Available-for-sale securities—short-term:						
Corporate debt securities	\$ 28,204	\$	20	\$	—	\$ 28,224
Asset-backed securities	17,108		13			17,121
U.S. treasury securities	5,020		12		_	5,032
Commercial paper	11,974					11,974
Total available-for-sale securities	\$ 62,306	\$	45	\$		\$ 62,351

	December 31, 2018					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value		
Available-for-sale securities—cash equivalents:						
Commercial paper	\$ 1,694	\$	\$ —	\$ 1,694		
Total available-for-sale securities—cash equivalents	1,694			1,694		
Available-for-sale securities—short-term:						
Corporate debt securities	2,731	—	(1)	2,730		
Commercial paper	5,390			5,390		
Total available-for-sale securities—short-term	8,121		(1)	8,120		
Total available-for-sale securities	\$ 9,815	\$ —	<u>\$ (1</u> )	\$ 9,814		

As of March 31, 2020 and December 31, 2019, all of the Company's available-for-sale securities mature in one year or less.

### Note 5—Inventory

Inventory as of March 31, 2020 and December 31, 2019 and 2018 consisted of the following (in thousands):

	March 31,	December 31,	
	2020	2019	2018
	(unaudited)		
Raw materials	\$ 6,244	\$5,492	\$1,032
Work in process	875	1,605	1,720
Finish goods	3,340	1,327	251
Total inventory	\$ 10,459	\$8,424	\$3,003

### Note 6—Property and Equipment, Net

The Company's property and equipment, net, consisted of the following as of March 31, 2020 and December 31, 2019 and 2018 (in thousands):

	March 31,	Decem	December 31,	
	2020	2019	2018	
Medical diagnostic equipment	(unaudited) \$  4,696	\$ 5,492	\$ 3,928	
Furniture and fixtures	388	159	146	
Office equipment	1,339	1,321	922	
Laboratory equipment and software	3,044	2,807	2,217	
Leasehold improvements	592	507	493	
Construction in process	265	306	101	
Total property and equipment	10,324	10,592	7,807	
Less: accumulated depreciation	(4,889)	(6,165)	(3,885)	
Property and equipment, net	\$ 5,435	\$ 4,427	\$ 3,922	

Property and equipment includes certain medical diagnostic equipment, AcQMap Systems, located at customer premises. The Company retains the ownership of the equipment and has the right to remove the equipment if it is not being used according to expectations.

Depreciation expense was \$0.4 million and \$0.6 million for the three months ended March 31, 2020 and 2019 and \$2.3 million and \$2.1 million for the years ended December 31, 2019 and 2018, respectively. For the year ended December 31, 2019, the Company recorded a \$0.8 million impairment of its property and equipment. For the three months ended March 31, 2020 and 2019 and the year ended December 31, 2018, the Company determined that there was no impairment of property and equipment.

# Note 7—Goodwill and Intangible Assets

The table below summarizes goodwill and intangible assets activities as of March 31, 2020 and December 31, 2019 and 2018 (in thousands):

	Goodwill	Intangible Assets
Balance as of December 31, 2018	\$ —	\$ —
Rhythm Xience Acquisition	12,026	4,360
Amortization expense		(250)
Balance as of December 31, 2019	12,026	4,110
Amortization expense		(110)
Balance as of March 31, 2020 (unaudited)	\$12,026	\$ 4,000

		Estimated Useful Life <u>(in years)</u>	Weighted- Average Remaining Life <u>(in years)</u>	Intangible Assets (unaudited)	Accumulated <u>Amortization</u> (unaudited	n <u>2020</u>
	Developed technology	10	9.25	\$ 3,600	\$ (270	) \$ 3,330
	In-process technology	10	9.75	600	(15	5) 585
	Trademarks and trade names	0.5	—	60	(60	D) —
	Customer-related intangible	5	4.25	100	(15	5) 85
To	otal			\$ 4,360	\$ (360	0) \$ 4,000

	Estimated Useful Life (in years)	Weighted- Average Remaining Life (in years)	Intangible Assets	Accumulated Amortization	December 31, 2019
Developed technology	10	9.5	\$ 3,600	\$ (180)	\$ 3,420
In-process technology	indefinite		600		600
Trademarks and trade names	0.5		60	(60)	
Customer-related intangible	5	4.5	100	(10)	90
Total			\$ 4,360	\$ (250)	\$ 4,110

Acquired in-process technology was classified as an indefinite-lived intangible asset until the receipt of FDA approval for the technology in January 2020. Once the FDA approval was received, the in-process technology was classified as a finite-lived intangible and amortization for in-process technology began. The Company recorded \$0.1 million and \$0.3 million of amortization expense related to the above intangible assets for the three months ended March 31, 2020 and the year ended December 31, 2019, respectively.

The following table shows the remaining amortization expense associated with amortizable intangible assets as of March 31, 2020 (in thousands):

	Developed Technology	In-process Technology	Customer- Related Intangible	Total Amortization
Nine months ending December 31, 2020	\$ 270	\$ 45	\$ 15	\$ 330
December 31, 2021	360	60	20	440
December 31, 2022	360	60	20	440
December 31, 2023	360	60	20	440
December 31, 2024	360	60	10	430
Thereafter	1,620	300		1,920
Total	\$ 3,330	\$ 585	\$85	\$ 4,000

The following table shows the remaining amortization expense associated with amortizable intangible assets as of December 31, 2019 (in thousands):

		Customer-	
	Developed	Related	Total
	Technology	<u>Intangible</u>	<u>Amortization</u>
December 31, 2020	\$ 360	\$ 20	\$ 380
December 31, 2021	360	20	380
December 31, 2022	360	20	380
December 31, 2023	360	20	380
December 31, 2024	360	10	370
Thereafter	1,620	—	1,620
Total	\$ 3,420	\$ 90	\$ 3,510

# Note 8—Accrued Liabilities

Accrued liabilities consisted of the following as of March 31, 2020 and December 31, 2019 and 2018 (in thousands):

	March 31,	Deceml	ber 31,
	2020 (unaudited)	2019	2018
Biotronik Asset Acquisition—accrued purchase price	\$ —	\$ 5,000	\$ —
Payroll and related expense	3,697	3,785	2,349
Interest			1,399
Deferred rent			652
Deferred revenue	36	311	318
Other	1,260	980	431
Total accrued liabilities	\$ 4,993	\$10,076	\$5,149

## Note 9—Debt

Outstanding debt as of March 31, 2020 and December 31, 2019 and 2018 consisted of the following (in thousands):

	March 31, 2020 (unaudited)	Decen 2019	nber 31, 2018
2019 Credit Agreement <sup>(1)</sup>	\$ 44,550	\$44,550	\$ —
2018 Convertible Notes <sup>(2)</sup>	—		28,383
2018 Term Loan <sup>(3)</sup>	—	—	15,638
Total debt, gross	44,550	44,550	44,021
Less: Unamortized debt discount and fees	(6,152)	(6,306)	(18,156)
Total debt, net	38,398	38,244	25,865
Less: Short-term debt			(11,274)
Long-term debt	\$ 38,398	\$38,244	\$ 14,591

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

The 2018 Convertible Notes includes the fair value of the embedded derivative liability of \$5.6 million. (2) (3)

The 2018 Term Loan includes a final payment fee of \$0.6 million.

### 2019 Credit Agreement

On May 20, 2019, the Company entered into a Credit Agreement (the "2019 Credit Agreement"). The 2019 Credit Agreement provided the Company with a senior term loan facility in aggregate principal amount of \$70.0 million, of which the Company borrowed \$40.0 million upon closing. Of the remaining amount of the facility, \$10.0 million is available for borrowing by the Company on or prior to June 30, 2020 and \$20.0 million is available for borrowing by the Company on or prior to December 31, 2020, in each case subject to the achievement of specified trailing revenue levels. The 2019 Credit Agreement bears interest per annum at 7.75% plus LIBOR for such interest period and the principal amount of term loans outstanding under the 2019 Credit Agreement is due on May 20, 2024. The 2019 Credit Agreement provides for final payment fees of an additional \$4.6 million that are due upon prepayment or on the maturity date or upon acceleration.

Upon the occurrence and during an event of default, which includes but is not limited to payment default, covenant default or the occurrence of a material adverse change, the lenders may declare all outstanding principal and accrued and unpaid interest immediately due and payable, all unfunded commitments would be terminated, there would be an increase in the applicable interest rate by 10.0% per annum, and the lenders would be entitled to exercise their other rights and remedies provided for under the 2019 Credit Agreement. Additionally, the lenders may request repayment of a portion of obligations outstanding under the 2019 Credit Agreement to the extent of the Company's receipt of any (i) net casualty proceeds or (ii) net asset sales proceeds, as defined. These acceleration and early payment features are an embedded derivative that is separately measured from the loan host instrument and classified with the loan host instrument.

In connection with the issuance of the 2019 Credit Agreement, the Company issued liability-classified warrants with a fair value of \$0.9 million to purchase 4,084,014 shares of Series C convertible preferred stock at \$1,714 per share. These warrants were subsequently automatically converted into warrants to purchase an equal number of shares of the Company's Series D convertible preferred stock at a price of \$1.714 per share.

The initial recognition of the warrant liability and direct fees of \$1.2 million and final payment fees of \$4.6 million for the 2019 Credit Agreement resulted in a discount of \$6.7 million, which is being amortized to interest expense over the term of the 2019 Credit Agreement using the effective interest method.

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

### 2019 Convertible Notes

On May 20, 2019, the Company sold and issued \$37.0 million in aggregate principal amount of convertible promissory notes (the "2019 Convertible Notes"). The 2019 Convertible Notes bore interest at 13% per annum and were due on December 31, 2019. The 2019 Convertible Notes, including accrued interest, automatically convert into preferred stock at the lowest price per share paid by a cash investor in a qualified equity financing of at least \$23.0 million (excluding the principal of any debt that is cancelled or converted into preferred stock in the equity financing), which occurred on June 12, 2019 (see "*—Conversion of Convertible Notes*" below). In accordance with ASC 480, *Distinguishing Liabilities from Equity*, the 2019 Convertible Notes were recorded as share-settled debt at fair value. As the 2019 Convertible Notes converted to Series D convertible preferred stock on June 12, 2019, the initial proceeds of \$37.0 million is the fair value and the settlement value of the 2019 Convertible Notes.

### 2018 Term Loan

On July 31, 2018, the Company entered into a loan and security agreement with investors for a \$15.0 million secured term loan credit facility, with an interest rate of the greater of: (i) 8.95% and (ii) 7.04% plus the 30-day month-end U.S. LIBOR rate maturing on July 1, 2023 (the "2018 Term Loan"). The 2018 Term Loan provided for a final payment fee of an additional \$0.6 million (the "Final Fee") due upon prepayment or on the maturity date, and prepayment penalties. Interest was payable on a monthly basis. The Company was obligated to make equal quarterly principal payments beginning on September 1, 2020 or September 1, 2021 in the event of certain financings, as defined in the 2018 Term Loan.

Upon the occurrence and during an event of default, which includes but is not limited to payment default, covenant default or the occurrence of a material adverse change, the lenders may declare all outstanding principal and accrued and unpaid interest immediately due and payable, all unfunded commitments would be terminated, there would be an increase in the applicable interest rate by 5.0% per annum, and the lenders would be entitled to exercise their other rights and remedies provided for under the 2018 Term Loan.

The Company's obligations under the 2018 Term Loan were secured by substantially all of its assets, excluding intellectual property, and subject to certain exceptions and limitations. The 2018 Term Loan contained customary covenants. For the years ended December 31, 2019 and 2018, the Company was in compliance with all such covenants.

In connection with the entry into the 2018 Term Loan, the Company issued liability-classified warrants with a fair value of \$0.3 million to purchase 262,543 shares of Series C convertible preferred stock at \$1.714 per

share. These warrants were subsequently automatically converted into warrants to purchase an equal number of shares of the Company's Series D convertible preferred stock at a price of \$1.714 per share.

The initial recognition of the warrant liability, the Final Fee and direct fees of \$0.1 million for the 2018 Term Loan resulted in a discount of \$1.1 million, which was being amortized to interest expense over the term of the 2018 Term Loan using the effective interest method.

In May 2019, in connection with the entry into the 2019 Credit Agreement, the Company paid \$16.2 million for the extinguishment of the 2018 Term Loan, including the principal and accrued interest, the Final Fee and a prepayment penalty. The Company recorded a loss on extinguishment of debt of \$1.4 million related to the write-off of deferred financing fees of \$0.9 million, the prepayment penalty of \$0.5 million and fees of approximately \$61,000.

### 2018 Convertible Notes

On June 7, 2018, the Company sold and issued convertible notes payable to certain of the Company's investors for total proceeds of \$22.8 million (the "2018 Convertible Notes"). The 2018 Convertible Notes bore interest at 10% per annum and were originally due on June 7, 2019, but were converted to Series D convertible preferred stock on June 12, 2019. In connection with issuance of the 2018 Convertible Notes, the Company issued liability-classified warrants with a fair value of \$5.4 million to purchase 4,880,943 shares of common stock.

In accordance with ASC 470-20, *Debt with Conversions and Other Options*, the beneficial conversion feature (the "BCF"), which provides the holder with the ability to convert the principal and interest of the 2018 Convertible Notes into Series C convertible preferred stock, or preferred stock issued in the Next Equity Financing, as defined in the 2018 Convertible Notes, at maturity or upon a change in control of the Company, is recorded as additional paid-in capital. The BCF of \$13.5 million was recorded at its issuance date intrinsic value, limited to the gross proceeds of the 2018 Convertible Notes less the initial warrant fair value by individual lender.

The 2018 Convertible Notes, including accrued interest, automatically convert into preferred stock at 80% of the lowest price per share paid by a cash investor in an equity financing of at least \$20 million (excluding the principal of any debt that is cancelled or converted into preferred stock in the equity financing) (the "Automatic Conversion Feature"). In accordance with ASC 815-15, *Embedded Derivatives*, the Automatic Conversion Feature, a bifurcated embedded derivative, was recorded at its fair value of \$2.4 million and classified with the 2018 Convertible Notes on the consolidated balance sheet. Changes in the fair value were recognized in change in fair value of warrant liability and embedded derivative in the consolidated statements of operations and comprehensive loss at the end of each reporting period.

The Company recorded a loss on the issuance of the 2018 Convertible Notes and warrants of \$0.9 million for the excess fair value of the Automatic Conversion Feature after allocating the gross proceeds of the 2018 Convertible Notes to the initial fair value of the warrants and the BCF by lender.

The initial recognition of the warrant liability, the BCF and the Automatic Conversion Feature (excluding the loss on the issuance of convertible notes and warrants) resulted in a discount of \$20.3 million on the 2018 Convertible Notes, which was amortized to interest expense over the term of the 2018 Convertible Notes using the effective interest method.

The following table summarizes the aggregate values recorded for the 2018 Convertible Notes at issuance and as of December 31, 2018 (in thousands):

	At Issuance	December 31, 2018
Liability component:		
Principal	\$ 22,815	\$ 22,815
Unamortized discounts and fees	(20,336)	(17,109)
Net carrying amount of the liability component	2,479	5,706
Embedded derivative liability	2,408	5,568
Total	\$ 4,887	\$ 11,274
Warrant liability	\$ 5,357	\$ 6,480
Equity component:		
BCF recorded in additional paid-in capital	\$ 13,495	\$ 13,495
r · · ·	4 - 7	

In June 2019, the 2018 Convertible Notes were converted to Series D convertible preferred stock in accordance with the Automatic Conversion Feature. See "—*Conversion of Convertible Notes*" below.

# 2015 Loan

On January 30, 2015, the Company entered into a Loan and Security Agreement to borrow up to \$10.0 million. During 2018, the Company repaid the remaining principal balance as of December 31, 2017 of \$0.6 million.

## **Conversion of Convertible Notes**

In June 2019, in conjunction with the Series D Preferred Stock Issuance, the 2019 Convertible Notes and the 2018 Convertible Notes, along with accrued interest thereon, were converted into shares of Series D convertible preferred stock. As such, the convertible noteholders received an aggregate of 39,950,927 shares of Series D convertible preferred stock for the conversion of all outstanding 2019 Convertible Notes and 2018 Convertible Notes at a conversion price of \$1.714 per share and \$1.3712 per share (including the 20% discount provided for in the 2018 Convertible Notes), respectively. The following table provides the shares issued upon conversion:

					Conversion on June 12, 2019						
	Stated Interest Rate	Conversion Price		Conversion Accrued Conver Price Per Face Value Interest Amou		Face Value Interest		Total onversion Amount thousands)	Shares Issued		
2019 Convertible Notes	13%	Lowest price paid by cash investor in 2019 Series D Preferred Stock Issuance	\$	1.714	\$	37,000	\$	66	\$	37,066	21,625,369
2018 Convertible Notes	10%	80% of lowest price paid by cash investor in 2019 Series D Preferred Stock Issuance	\$	1.371		22,815		2,313		25,128	18,325,558
Total					\$	59,815	\$	2,379	\$	62,194	39,950,927

Upon the conversion of the 2018 Convertible Notes, the embedded derivative included in the 2018 Convertible Notes with a fair value of \$6.3 million has been included in Series D convertible preferred stock in the accompanying consolidated balance sheet.

#### Note 10—Operating Leases

The Company leases approximately 50,800 square feet of office space for its corporate headquarters and manufacturing facility in Carlsbad, California under a noncancelable operating lease that expires on December 31, 2022. The lease is subject to variable charges for common area maintenance and other costs that are determined annually based on actual costs. The base rent is subject to an annual increase each year. The Company has a renewal option for an additional five-year term upon the expiration date of the lease, which has been excluded from the calculation of the right-of-use asset as it is not reasonably certain to be exercised.

The Company also leases approximately 3,900 square feet of office space in Zaventem, Belgium under a noncancelable operating lease that expires on December 31. 2021. The lease is subject to variable charges that are determined annually for common area maintenance and other costs based on actual costs, and base rent is subject to an annual increase each year based on an index rate. The Company has a renewal option for an additional three-year term upon the expiration date of the lease, which has been included in the calculation of the right-of-use asset as it is reasonably certain to be exercised.

The following table summarizes quantitative information about the Company's operating leases for the three months ended March 31, 2020 and the year ended December 31, 2019 (dollars in thousands):

		Three Months Ended March 31,				ear Ended cember 31,
	2	2020		2019		2019
		(unaudited)				
Operating cash flows from operating leases	\$	253	\$	235	\$	972
Right-of-use assets exchanged for operating lease liabilities	\$		\$	2,978	\$	2,978
Weighted-average remaining lease term—operating leases	2.9	2.9 years 3.9 year		.9 years	3.2 years	
Weighted-average discount rate—operating leases		7.0%		7.0%		7.0%

The following table provides the components of the Company's lease cost (in thousands):

	 Three Months Ended March 31, 2020 2019 (unaudited)			Year Ended December 31, 2019		
Operating leases						
Operating lease cost	\$ 216	\$	216	\$	864	
Variable lease cost	73		64		234	
Operating lease expense	 289		280		1,098	
Short-term lease rent expense	—		—			
Total lease cost	\$ 289	\$	280	\$	1,098	

For the year ended December 31, 2018, the Company recorded approximately \$0.8 million in rent expense under ASC 840.

As of March 31, 2020, future minimum payments under the non-cancelable operating leases under ASC 842 were as follows (in thousands):

Nine months ending December 31, 2020	\$ 760
Year ending December 31, 2021	1,044
Year ending December 31, 2022	1,074
Year ending December 31, 2023	51
Year ending December 31, 2024	51 2,980
Total	2,980
Less: present value discount	(300)
Operating lease liabilities	\$2,680

As of December 31, 2019, future minimum payments under the non-cancelable operating leases under ASC 842 were as follows (in thousands):

Year ending December 31, 2020	\$1,013
Year ending December 31, 2021	1,044
Year ending December 31, 2022	1,074
Year ending December 31, 2023	51
Year ending December 31, 2024	51
Total	<u>51</u> 3,233
Less: present value discount	(346)
Operating lease liabilities	\$2,887

As of December 31, 2018, future minimum payments under the non-cancelable operating leases under ASC 840 were as follows (in thousands):

Year ending December 31, 2019	\$ 986
Year ending December 31, 2020	1,013
Year ending December 31, 2021	1,044
Year ending December 31, 2022	1,024
Total	1,024 \$4,067

# Note 11—Commitments and Contingencies

The Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims. From time to time however, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

# Note 12—Warrants

As of March 31, 2020 and December 31, 2019 and 2018, the outstanding warrants to purchase the Company's common stock were comprised of the following:

	Equity Upon Exercise	Exercise Price	Expiration Date	March 31, 2020 (unaudited)	Deceml 2019	ber 31, 2018
Warrants issued in 2012	Series A					
	convertible preferred	\$ 0.85	3/16/19			70,340
Warrants issued in 2015	Common stock	\$ 0.54	1/30/25	74,074	74,074	74,074
Warrants issued with 2018 Convertible Notes	Common stock	\$ 0.01	6/7/28	4,880,943	4,880,943	4,880,943
Warrants issued with 2018 Term Loan	Series D					
	convertible preferred	\$ 1.71	7/31/28	262,543	262,543	262,543
Warrants issued with 2019 Credit Agreement	Series D					
	convertible preferred	\$ 1.71	5/20/29	4,084,014	4,084,014	—
Total warrants				9,301,574	9,301,574	5,287,900

The Company's warrant activity for the three months ended March 31, 2020 and the years ended December 31, 2019 and 2018 is as follows:

Warrants	Weighted- Average Exercise Price		Weighted- Average Remaining Contractual Life (in years)
144,414	\$	0.54	7.1
5,143,486		0.10	9.4
5,287,900	\$	0.11	9.3
4,084,014		1.71	8.5
(70,340)		0.85	5.1
9,301,574	\$	0.81	8.4
9,301,574	\$	0.81	8.2
	144,414 5,143,486 5,287,900 4,084,014 (70,340) 9,301,574	Ave           Warrants         P           144,414         \$           5,143,486         \$           5,287,900         \$           4,084,014         \$           (70,340)         \$           9,301,574         \$	Average Exercise           Warrants         Price           144,414         \$ 0.54           5,143,486         0.10           5,287,900         \$ 0.11           4,084,014         1.71           (70,340)         0.85           9,301,574         \$ 0.81

#### Warrants Classified as Liabilities

During 2019, in connection with the Company's entry into the 2019 Credit Agreement, the Company issued warrants to purchase 4,084,014 shares of its Series C convertible preferred stock with an exercise price of \$1.714 per share. These warrants were subsequently automatically converted into warrants to purchase an equal number of shares of the Company's Series D convertible preferred stock at a price of \$1.714 per share. During 2018, in connection with the issuance of the 2018 Convertible Notes and the 2018 Term Loan, the Company issued ten-year warrants to purchase 4,880,943 shares of common stock with an exercise price of \$0.01 per share and 262,543 shares of Series C convertible preferred stock with an exercise price of \$1.714 per share, respectively. The warrants for Class C convertible preferred stock were subsequently automatically converted into warrants to purchase an equal number of shares of the Company's Series D convertible preferred stock at a price of \$1.714 per share.

The Company's warrants provide the holder the option to purchase a specified number of shares for a specified price. The holder may exercise the warrant in cash or exercise pursuant to a cashless exercise whereby a calculated number of shares are withheld upon exercise to satisfy the exercise price. The warrants do not provide the holder any voting rights until the warrants are exercised. In the event of conversion of the Company's convertible preferred stock into common shares, the warrants become exercisable into common shares of the Company's stock, subject to certain adjustments.

In accordance with ASC 815, other than the warrants issued in 2012 and 2015, the warrants are recorded as liabilities at fair value at the issuance date. Changes in the fair value are recognized in change in fair value of warrant liability and embedded derivative in the consolidated statements of operations and comprehensive loss at the end of each reporting period.

## Warrants Classified as Equity

In accordance with ASC 815, the warrants issued in 2012 and 2015 do not meet the definition of a derivative and are classified in stockholders' deficit in the consolidated balance sheets.

### Note 13—Convertible Preferred Stock

In February 2020, the Company issued 1,166,861 shares of its Series D convertible preferred stock with an implied value of \$2.2 million in connection with a contingent consideration payment related to the Rhythm Xience Acquisition.

In February 2020, the Company issued 2,655,337 shares of its Series D convertible preferred stock with an implied value of \$5.0 million for the final purchase consideration of the Biotronik Asset Acquisition.

As of December 31, 2019 and 2018, the Company's Amended and Restated Certificate of Incorporation authorized the issuance of 172,064,796 and 85,634,171 shares of convertible preferred stock, par value \$0.001 per share, respectively, consisting of: (i) 3,848,696 and 6,490,577 shares of Series A convertible preferred stock, respectively; (ii) 30,032,100 and 35,343,594 shares of Series B convertible preferred stock, respectively; (iii) 48,184,000 and 43,800,000 shares of Series C convertible preferred stock, respectively; and (iv) 90,000,000 and no shares of Series D convertible preferred stock, respectively.

In June and July 2019, the Company completed an equity financing pursuant to which the Company issued 79,740,085 shares of Series D convertible preferred stock in a private placement. The Series D Preferred Stock Issuance was comprised of: (i) 39,789,158 shares at \$1.714 per share for net cash proceeds of \$68.2 million; (ii) 18,325,558 shares at \$1.3712 per share (including a 20% discount) for the conversion of the outstanding 2018 Convertible Notes (and related accrued interest) of \$25.1 million; and (iii) 21,625,369 shares at \$1.714 per share for the conversion of the outstanding 2019 Convertible Notes (and related accrued interest) of \$37.1 million. Upon the conversion of the 2018 Convertible Notes, the embedded derivative with a fair value of \$6.3 million immediately prior to the conversion was included in Series D convertible preferred stock in the consolidated balance sheet.

In March 2019, the Company issued 25,796 shares of Series A convertible preferred stock in exchange for 70,340 outstanding warrants in a cashless warrant exercise.

In June 2018, in connection with the issuance of the 2018 Convertible Notes, the Company amended and restated its Certificate of Incorporation to provide for a special mandatory conversion providing that for each five shares of Series A, Series B and Series C convertible preferred stock held by holders who did not participate in the 2018 Term Loan, such shares would automatically convert into one share of common stock (the "Mandatory Conversion"). The Mandatory Conversion resulted in the issuance of 1,590,668 shares of common stock in exchange for the cancellation and retirement of 2,641,882 and 5,311,494 shares of Series A and Series B convertible preferred stock, respectively.

#### Redemption

The convertible preferred stock is not unconditionally redeemable at the option of the holder thereof. However, the convertible preferred stock is contingently redeemable upon certain liquidation events. As redemption by the holders is not solely within the control of the Company, all of the outstanding convertible preferred stock is classified as temporary equity in the consolidated balance sheets.

#### Dividends

The holders of shares of convertible preferred stock are entitled to receive dividends, out of any assets legally available therefore, prior and in preference to any declaration or payment of any dividend on the common stock of the Company, at the applicable dividend rate, payable on a *pro rata*, *pari passu* basis when, as and if declared by the Company's board of directors. The dividend rate is \$0.07 per annum for each share of Series A

convertible preferred stock, \$0.11 per annum for each share of Series B convertible preferred stock and \$0.14 per annum for each share of Series C convertible preferred stock and Series D convertible preferred stock, as adjusted. The dividend rights are not cumulative.

#### Liquidation

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

#### Conversion

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

<u>Series</u>	I	version Price
Series A convertible preferred stock	\$	0.853
Series B convertible preferred stock	\$	1.375
Series C convertible preferred stock	\$	1.714
Series D convertible preferred stock	\$	1.714

Each share of convertible preferred stock will automatically be converted into fully-paid, non-assessable shares of common stock at the conversion rate at the time in effect for such series of preferred stock immediately upon: (i) the date, or the occurrence of an event, specified by vote or written consent or agreement of the requisite investors; or (ii) the closing of the sale of shares of common stock to the public, at a price of at least \$5.142 per share, as adjusted, in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$50 million of net proceeds to the Company.

#### Voting Rights

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

As long as any shares of Series D convertible preferred stock are outstanding, the holders of such shares of Series D convertible preferred stock (voting exclusively as a separate series) are entitled to elect one director. As long as any shares of Series C convertible preferred stock are outstanding, the holders of such shares of Series C

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

Any director may be removed during his or her term of office, either with or without cause, by, and only by, the affirmative vote of the holders of the shares of the class or series of stock entitled to elect such director or directors, given either at a special meeting of such stockholders duly called for that purpose or pursuant to a written consent of stockholders, and any vacancy thereby created may be filled by the holders of that class or series of stock represented at the meeting or pursuant to written consent.

### Note 14—Stockholders' Deficit

As of each of March 31, 2020 and December 31, 2019, the Company's Amended and Restated Certificate of Incorporation authorized the issuance of 220,000,000 shares of common stock, \$0.001 par value per share. As of December 31, 2018, the Company's Amended and Restated Certificate of Incorporation authorized the issuance of 111,508,000 shares of common stock, \$0.001 par value per share. Each share of common stock is entitled to one voting right. Common stock owners are entitled to dividends when funds are legally available and declared by the Board.

During the years ended December 31, 2019 and 2018, stock options to acquire 270,393 and 922,375 shares, respectively, were exercised for shares of common stock. The Company received \$0.1 million and \$0.3 million for the exercise price of the stock options for the years ended December 31, 2019 and 2018, respectively.

#### Note 15—Stock-Based Compensation

The Company's 2011 Equity Incentive Plan (the "2011 Plan") permits the granting of incentive stock options, non-statutory stock options, restricted stock, restricted stock units and other stock-based awards to employees, directors, officers and consultants. As of December 31, 2019, 37,516,162 shares of common stock were authorized for issuance under the 2011 Plan and 9,970,601 shares remain available for issuance under the 2011 Plan.

As of March 31, 2020, 37,516,162 shares of common stock were authorized for issuance under the 2011 Plan and 2,970,421 shares remain available for issuance under the 2011 Plan.

### **Stock Options**

The stock options generally vest over four years and have a ten-year contractual term. The fair value of each employee and non-employee stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. The Company is a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. Due to the lack of historical exercise history, the expected term of the Company's stock options has been determined using the "simplified" method for awards. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following assumptions were used to estimate the fair value of stock option for the three months ended March 31, 2020 and the years ended December 31, 2019 and 2018:

	March 31,	Dece	mber 31,
	2020 (unaudited)	2019	2018
Risk-free interest rate	0.9%	1.6% - 2.1%	2.4% - 3.2%
Expected dividend yield	—	—	_
Expected term in years	7.0	6.4 - 10.0	7.0
Expected volatility	70.0%	80.0%	77.0% - 80.0%

The following table summarizes stock option activity during the three months ended March 31, 2020 and the years ended December 31, 2019 and 2018:

	Stock Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2017	10,583,984	\$ 0.63	7.5	<u>_</u>
Options granted	7,203,413	1.06		
Options exercised	(922,375)	0.38		\$ 578
Options forfeited	(1,427,717)	0.72		
Outstanding as of December 31, 2018	15,437,305	\$ 0.84	8.0	\$ 6,012
Options granted	5,252,798	1.37		
Options exercised	(270,393)	0.40		\$ 264
Options forfeited	(569,401)	1.01		
Outstanding as of December 31, 2019	19,850,309	\$ 0.98	7.7	\$ 7,857
Options granted	8,431,411	1.52		
Options forfeited	(1,576,731)	1.30		
Outstanding as of March 31, 2020 (unaudited)	26,704,989	\$ 1.13	7.8	\$ 8,809
Options vested and exercisable as of March 31, 2020 (unaudited)	11,246,940	\$ 0.81	5.7	\$ 7,041
Options expected to vest in future periods	15,458,049	\$ 1.37	9.4	\$ 1,768

The aggregate intrinsic value in the above table is calculated as the difference between the fair value of the Company's common stock and the exercise price of the stock options. The weighted-average grant date fair value per share for the stock option grants during the years ended December 31, 2019 and 2018 was \$1.00 and \$0.79, respectively. As of December 31, 2019, the total unrecognized compensation related to unvested stock option awards granted was \$7.9 million, which the Company expects to recognize over a weighted-average period of approximately 2.76 years.

The weighted-average grant date fair value per share for the stock option awards granted during the three months ended March 31, 2020 was \$1.00. As of March 31, 2020, the total unrecognized compensation related to unvested stock option awards granted was \$13.4 million, which the Company expects to recognize over a weighted-average period of approximately 3.04 years.

# **Restricted Stock**

The Company's RSA activity for the three months ended March 31, 2020 and the years ended December 31, 2109 and 2018 was as follows:

	Number of Shares	Av Gra	ighted- erage nt Date r Value
Unvested as of December 31, 2017	—	\$	
Unvested as of December 31, 2018		\$	_
Granted	111,452		1.38
Vested	(111,452)		1.38
Unvested as of December 31, 2019	_	\$	_
Granted	145,500		1.52
Vested	(145,500)		1.52
Unvested as of March 31, 2020		\$	_

The following table summarizes the total stock-based compensation expense for the stock options and RSAs recorded in the consolidated statements of operations and comprehensive loss for the three months ended March 31, 2020 and 2019 and the years ended December 31, 2019 and 2018 (in thousands):

		Three Months Ended March 31,		Year Ended December 31,	
	2020	2020 2019		2018	
	(unau	dited)			
Cost of products sold	\$ 108	\$ 52	\$ 209	\$ 215	
Research and development	211	142	656	564	
Selling, general and administrative	1,422	365	2,129	1,292	
Total stock-based compensation	\$ 1,741	\$ 559	\$2,994	\$2,071	

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

In June 2019, the Company granted 5,518,463 PSUs, with a grant date fair value of \$1.38. Vesting of the PSUs is dependent upon the satisfaction of both a service condition and a performance condition, which is an initial public offering or a change of control. As the performance conditions for the PSU were not considered probable, no compensation expense related to these awards has been recorded for the three months ended March 31, 2020 and the year ended December 31, 2019.

#### Note 16—Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. Diluted net loss per common share excludes the potential impact of the Company's convertible notes, convertible preferred stock, common stock options and warrants because their effect would be anti-dilutive due to the Company's net loss. Since the Company had a net loss in the periods presented, basic and diluted net loss per common share are the same.

The table below provides potentially dilutive securities not included in the calculation of the diluted net loss per common share because to do so would be anti-dilutive:

	For the Three Months Ended March 31,				For the Yea Decemb	
	2020	2019	2019	2018		
	(unaudi	ited)				
Shares issuable upon conversion of Series A convertible preferred stock	3,804,152	3,804,152	3,804,152	3,778,356		
Shares issuable upon conversion of Series B convertible preferred stock	30,032,100	30,032,100	30,032,100	30,032,100		
Shares issuable upon conversion of Series C convertible preferred stock	43,757,292	43,757,292	43,757,292	43,757,292		
Shares issuable upon conversion of Series D convertible preferred stock	83,562,283	_	79,740,085	_		
Shares issuable upon exercise of stock options	26,704,989	15,338,136	19,850,309	15,437,305		
Shares issuable upon exercise of common stock warrants	4,955,017	4,955,017	4,955,017	4,955,017		
Shares issuable upon exercise of preferred stock warrants	4,346,557	262,543	4,346,557	332,883		
Shares issuable upon conversion of convertible notes <sup>(1)</sup>		17,979,107	_	17,573,097		
Total	197,162,390	116,128,347	186,485,512	115,866,050		

(1) Assuming the conversion of the aggregate principal amount, plus accrued interest, of the 2018 Convertible Notes into shares of the Company's common stock on March 31, 2019 and December 31, 2018. See Note 9 for additional information regarding the 2018 Convertible Notes.

For the three months ended March 31, 2020 and the year ended December 31, 2019, the PSUs are not included in the above table as awards with performance conditions are not included in the calculation of diluted earnings per share until the performance conditions for the PSU are considered probable.

## Pro Forma Net Loss Per Common Share (Unaudited)

Basic and diluted pro forma net loss per common share is computed to give effect to the automatic conversion of all convertible preferred stock using the if converted method as though the conversion had occurred as of March 31, 2020 and December 31, 2019. Pro forma net loss per common share does not give effect to potential dilutive securities where the impact would be anti-dilutive.

The following table represents the calculation of basic and diluted pro forma net loss per common share for the three months ended March 31, 2020 and the year ended December 31, 2019:

	Pro Forma March 31, 2020 (unaudited)	Pro Forma December 31, 2019 (unaudited)
Net loss, as reported and available to common stockholders	\$	\$
Weighted-average shares of common stock outstanding used to compute net loss per common share, basic and diluted		
Pro forma adjustments to reflect conversion of convertible preferred stock		
Weighted-average shares to compute pro forma net loss per common share, basic and diluted		
Pro forma net loss common share, basic and diluted	\$	\$

Due to net losses for the three months ended March 31, 2020 and the year ended December 31, 2019, basic and diluted pro forma net loss per common share were the same, as the effect of potentially dilutive securities would have been anti-dilutive. The following common share equivalent securities have been excluded from the calculation of diluted weighted-average common shares outstanding because the effect is anti-dilutive for the period presented:

	Pro Forma March 31, 2020 (unaudited)	Pro Forma December 31, 2019 (unaudited)
Shares issuable upon exercise of stock options		
Shares issuable upon exercise of common stock warrants		
Total		

# Note 17-401(k) Retirement Plan

The Company has a 401(k) retirement savings plan that provides retirement benefits to substantially all full-time U.S. employees. Eligible employees may contribute a percentage of their annual compensation, subject to Internal Revenue Service limitations. The Company did not provide any contributions to the 401(k) retirement savings plan for the three months ended March 31, 2020 and 2019 and the years ended December 31, 2019 and 2018.

#### Note 18—Income Taxes

No provision for federal or state income taxes has been recorded for the three months ended March 31, 2020 and 2019 and the years ended December 31, 2019 and 2018. Current income taxes are based upon the year's income taxable for federal, state and foreign tax reporting purposes. Deferred income taxes (benefits) are provided for certain income and expenses, which are recognized in different periods for tax and financial reporting purposes. Deferred tax assets and liabilities are computed for differences between the consolidated financial statements and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the period in which the differences are expected to affect taxable income, and NOL carryforwards and R&D tax credit carryforwards.

A reconciliation of the expected tax computed at the U.S. statutory federal income tax rate to the total benefit for income taxes for the years ended December 31, 2019 and 2018 is as follows (dollars in thousands):

		Year Ended December 31,		
	2019		2018	
Income tax benefit at federal statutory rate	\$(20,378)	21.00%	\$(10,060)	21.00%
Adjustments for tax effects of:				
State taxes, net	(1,315)	1.35%	(330)	0.69%
Permanent adjustments	820	(0.84)%	765	(1.60)%
Interest expense	230	(0.24)%	230	(0.48)%
Derivatives	150	(0.15)%	663	(1.38)%
R&D credit	(53)	0.05%	(698)	1.46%
Unrecognized tax benefit	16	(0.02)%	(221)	0.46%
Valuation allowance	20,500	(21.11)%	9,998	(20.87)%
Rate change	223	(0.23)%	(439)	0.92%
Other	(193)	0.19%	92	(0.20)%
Income tax benefit	\$	%	\$ —	%

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2019 and 2018 were as follows (in thousands):

	Decen 2019	<u>ıber 31,</u> 2018
Deferred tax assets:		2010
Net operating losses	\$ 45,455	\$ 31,387
Stock-based compensation	720	294
Research and development tax credit	3,116	3,074
Accrued vacation	187	139
Accrued expenses	484	324
IRC 263A	239	141
Intangible assets	3,047	644
Lease liability	605	
Other	153	37
Total gross deferred tax assets	54,006	36,040
Valuation allowance	(52,949)	(32,111)
Net deferred tax asset	1,057	3,929
Deferred tax liabilities:		
Property and equipment	(450)	(61)
Prepaid expenses	(122)	(66)
Right-of-use assets	(485)	
Debt discount		(3,802)
Total deferred tax liabilities	(1,057)	(3,929)
Net deferred tax assets (liabilities)	\$	\$

In assessing the realizability of deferred tax assets as of December 31, 2019 and 2018, management considered whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible or the NOL carryforwards and R&D tax credit carryforwards will be used. The Company has determined it is more likely than not that its deferred tax assets will not be realized. Accordingly, a valuation allowance has been recorded as of December 31, 2019 and 2018, to fully offset the net deferred tax assets of \$52.9 million and \$32.1 million, respectively.

As of December 31, 2019, the Company had approximately \$199.9 million of NOL carryforwards available for federal tax purposes which begin to expire in December 31, 2031. As a result of the Tax Act of 2017, for U.S. income tax purposes, NOLs generated prior to December 31, 2017 can still be carried forward for up to 20 years, but NOLs generated after December 31, 2017 carryforward indefinitely, but are limited to 80% utilization against taxable income. Of the total federal NOL of \$199.9 million, \$106.1 million will begin to expire in 2031 and \$93.8 million will not expire but will only offset 80 percent of future taxable income.

As of December 31, 2019, the Company also had approximately \$32.5 million of state NOL carryforwards. The state NOLs begin to expire in December 31, 2031.

As of December 31, 2019, the Company had approximately \$0.7 million of NOL carryforwards available for foreign tax purposes. Belgium NOLs do not expire.

As of December 31, 2019, the Company had approximately \$1.9 million of R&D credit carryforwards available for federal tax purposes, which begin to expire in December 31, 2031. As of December 31, 2019, the Company also had approximately \$3.2 million of R&D credit carryforwards for California. The state research credits do not expire.

NOL carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be used annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders. The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company's formation due to the complexity and cost associated with such study, and the fact that there may be additional such ownership changes in the future.

The Company conducts intensive research and experimentation activities, generating R&D tax credits for Federal and state purposes under section 41 of the Code. The Company has not performed a formal study validating these credits claimed in the tax returns. Once a study is prepared, the amount of R&D tax credits available could vary from what was originally claimed on the tax returns.

The following table summarizes the changes to unrecognized tax benefits as of December 31, 2019 and 2018 (in thousands):

	December 31,	
	2019	2018
Balance as of beginning of year	\$1,523	\$1,752
Decreases related to prior year tax positions	(493)	(379)
Increases related to current year tax positions	509	150
Balance as of end of year	\$1,539	\$1,523

As of December 31, 2019, the Company has unrecognized tax benefits of approximately \$1.5 million of which approximately \$1.3 million will affect the effective tax rate if recognized when the Company no longer has a valuation allowance offsetting its deferred tax assets.

The Company does not anticipate that there will be a significant change in unrecognized tax benefits over the next 12 months.

The Company is subject to U.S. federal and various state tax as well as Belgium tax jurisdictions. Since the Company formed in 2011, all filed tax returns are subject to examination. Generally, the tax years remain open for examination by the federal statute under a three-year statute of limitation; however, states generally keep their statutes open for four years. However, the Company's tax years from inception are subject to examination by the United States and California taxing authorities due to the carry forward of unused NOLs and R&D credits.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax benefit. The Company had no accrual for interest and penalties on its consolidated balance sheets and has not recognized interest and/or penalties in its consolidated statements of operations and comprehensive loss for the years ended December 31, 2019 and 2018.

#### **Note 19—Related Party Transactions**

The Company licenses certain patent rights from a director and shareholder. The license agreement provides for royalty payments to the shareholder of 3% of net product sales, as defined in the agreement. Royalties earned were \$21,000 and \$12,000 for the three months ended March 31, 2020 and 2019 and \$41,000 and \$12,000 for the years ended December 31, 2019 and 2018, respectively. Additionally, the director and shareholder also works for one of the Company's customers and can significantly influence the customer to purchase the Company's product. The Company recorded sales to this customer of \$0.3 million and \$0.1 million for the three months ended March 31, 2020 and 2019 and \$0.3 million and \$0.2 million for the years ended December 31, 2020 and 2019 and 2019 and \$0.3 million and \$0.2 million for the three months ended March 31, 2020 and 2019 and \$0.3 million and \$0.2 million for the years ended December 31, 2019 and 2018, respectively.

The Company has a consulting agreement with a director and chairman of the Company's board of directors. The Company recorded \$49,000 for the three months ended March 31, 2020 and \$0.2 million for the year ended December 31, 2019, respectively, in SG&A expense in the consolidated statements of operations and comprehensive loss, for the consulting services.

The Company has a consulting agreement with an officer of the Company. The Company recorded \$0.1 million for the three months ended March 31, 2019 and \$0.3 million and \$0.1 million for the years ended December 31, 2019 and 2018, respectively, included in SG&A expense in the consolidated statements of operations and comprehensive loss, for the consulting services.

The Company had a consulting arrangement with a current director and officer of the Company, prior to his full-time employment. The Company recorded \$0.1 million for the three months ended March 31, 2019 and \$0.4 million and \$0.4 million for the years ended December 31, 2019 and 2018, respectively, included in SG&A expense in the consolidated statements of operations and comprehensive loss, for the consulting services.

Multiple preferred stock shareholders entered into the 2018 and 2019 Convertible Notes that also contained detached warrants. Additionally, Orbimed Royalty Opportunities II, LP and Deerfield Private Design Fund II, L.P. entered into the 2019 Credit Agreement with the Company in 2019 for a total of \$70.0 million with \$40.0 million being drawn as of December 31, 2019. The Company recorded \$1.3 million and \$5.3 million for the three months ended March 31, 2020 and 2019 and \$21.4 million and \$4.5 million for the years ended December 31, 2019 and 2018, respectively, in interest expense related to these debt agreements.

### Note 20—Subsequent Events

The Company has completed an evaluation of all subsequent events through June 29, 2020 to ensure that these consolidated financial statements include appropriate disclosure of events both recognized in the consolidated financial statements and events which occurred but were not recognized in the consolidated financial statements. Except as described below, the Company has concluded that no subsequent event has occurred that requires disclosure.

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

## **Independent Auditor's Report**

Stockholders and Acutus Rhythm Xience, Inc. Eden Prairie, Minnesota

We have audited the accompanying financial statements of Rhythm Xience, Inc. (a Delaware corporation), which comprise the balance sheets as of December 31, 2018 and 2017, and the related statements of operations, stockholders' equity (deficit), and cash flows for the twelve months ended December 31, 2018 and 2017, and the related notes to the financial statements.

## Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of the financial statements that are free from material misstatement whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express opinions on these financial statements based on our audits; we conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our qualified audit opinion.

#### Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Rhythm Xience, Inc. as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the twelve months ended December 31, 2018 and 2017 in accordance with accounting principles generally accepted in the United States of America.

/s/ Meuwissen, Flygare, Kadrlik & Associates, P.A.

May 6, 2020

# RHYTHM XIENCE, INC. Balance Sheets

	December 31, 2018	December 31, 2017
ASSETS:		
Current assets:		
Cash	\$ 964,952	\$ 30,394
Accounts receivable	11,498	27,913
Inventories	98,920	19,500
Prepaid expenses	32,161	23,596
Total current assets	1,107,531	101,403
Property and equipment, net of accumulated depreciation	3,882	6,342
Security deposit	7,917	7,917
Total noncurrent assets	11,799	14,259
Total assets	\$ 1,119,330	\$ 115,662
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	38,890	256,802
Accrued expenses	118,332	23,139
Total current liabilities	157,222	279,941
Long-term debt	3,173,291	905,084
Total liabilities	3,330,513	1,185,025
Stockholders' equity (deficit):		
Common stock, \$0.001 par value; 7,500,000 shares authorized, 3,750,000 shares issued and outstanding	3,750	3,750
Additional paid-in capital	2,246,351	2,246,351
Retained deficit	(4,461,284)	(3,319,464)
Total stockholders' equity (deficit)	(2,211,183)	(1,069,363)
Total liabilities and stockholders' equity (deficit)	\$ 1,119,330	\$ 115,662

See independent auditor's report and notes to the financial statements.

# **RHYTHM XIENCE, INC.** Statements of Operations

		Twelve Months Ended December 31,		
	2018	2017		
Sales, net	\$ 69,340	\$ 47,782		
Cost of sales	49,176	30,716		
Gross profit	20,164	17,066		
Operating expenses	1,030,947	1,165,796		
Operating loss	(1,010,783)	(1,148,730)		
Other income (expense):				
Interest expense	(131,037)	(30,280)		
Net loss	\$ (1,141,820)	\$ (1,179,010)		

See independent auditor's report and notes to the financial statements.

# RHYTHM XIENCE, INC. Statements of Stockholders' Equity (Deficit)

	Common	Stock				
	Number of Shares	Par Value	Additional Paid-in Capital	Retained Deficit	S	Total stockholders' Equity (Deficit)
Balance, December 31, 2016	3,640,000	\$ 3,640	\$ 2,136,461	\$ (2,140,454)	\$	(353)
Stock issued	110,000	110	109,890	—		110,000
Net loss	—	—		(1,179,010)		(1,179,010)
Balance, December 31, 2017	3,750,000	\$ 3,750	\$ 2,246,351	\$ (3,319,464)	\$	(1,069,363)
Net loss	—	—		(1,141,820)		(1,141,820)
Balance, December 31, 2018	3,750,000	\$ 3,750	\$ 2,246,351	\$ (4,461,284)	\$	(2,211,183)

See independent auditor's report and notes to the financial statements.

# **RHYTHM XIENCE, INC. Statements of Cash Flows**

	Twelve Months Ended December 31,		
	2018 2017		
Cash flows from operating activities			
Net loss	\$ (1,141,820)	\$ (1,179,010)	
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation	2,460	3,561	
Changes in operating assets and liabilities:			
Accounts receivable	16,415	(27,913)	
Prepaid expenses and other current assets	(8,565)	(13,851)	
Inventory	(79,420)	(19,500)	
Accounts payable and accrued expenses	(122,719)	227,964	
Net cash used in operating activities	(1,333,649)	(1,008,749)	
Cash flows used in investing activities			
Purchases of property and equipment		(600)	
Net cash used in investing activities		(600)	
Cash flows provided by financing activities			
Proceeds from notes payable	2,268,207	905,084	
Issuance of common stock		110,000	
Net cash provided by financing activities	2,268,207	1,015,084	
Net change in cash	934,558	5,735	
Cash at the beginning of the period	30,394	24,659	
Cash at the end of the period	\$ 964,952	\$ 30,394	

See independent auditor's report and notes to the financial statements.

#### Note 1—Organization

Rhythm Xience, Inc. (the "Company"), is a medical device company specializing in catheter-based rhythm management solutions based in Minnesota with operations also in California. As developer and innovator, the solutions are clinically based and procedurally focused towards recognizing and resolving the challenges facing Electrophysiologists and healthcare facilities.

#### Note 2—Summary of Significant Accounting and Reporting Policies

## Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Management has identified inventories, income taxes, and fixed assets as areas where significant estimates and assumptions have been made in preparing the financial statements. Actual results could differ from these estimates.

#### **Concentrations of Credit Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments and trade accounts receivable. The Company maintains its cash balances in a financial institution located in Minneapolis, Minnesota. The balances are insured by the Federal Deposit Insurance Corporation ("FDIC") up to \$250,000 per company per financial institution. At times, during the twelve months ended December 31, 2018 and 2017, the Company had bank balances in excess of FDIC limits. The Company has not experienced any losses from such accounts.

#### Accounts Receivable

The accounts receivable balances are generally uncollateralized and comprised of credit and non-credit receivables. The accounts are typically paid within 45 days. Management provides for probable uncollectible amounts through a charge to earnings and a credit to a valuation allowance based on its assessment of the current status of individual accounts. Balances that are still outstanding after management has used reasonable collection efforts are written off through a charge to the valuation allowance and a credit to accounts receivable. There was no allowance for doubtful accounts for the twelve months ended December 31, 2018 and 2017, respectively. Management believes that accounts receivable is stated at estimated net realizable value.

#### Advertising

The company expenses advertising costs as they are incurred. Total advertising expense for the twelve months ended December 31, 2018 and 2017 was \$29,696, and \$54,328, respectively.

#### Inventories

Inventories are valued at the lower of cost (first-in, first-out method) or net realizable value.

#### **Property and Equipment**

Building, equipment, and leasehold improvements are carried at historical cost. Major additions and betterments are charged to the property accounts while replacements, maintenance, and repairs that do not improve or extend the life of the respective assets are expensed currently.

Depreciation is computed on the double declining method, using estimated useful lives ranging from five to seven years for financial reporting purposes.

## Income Taxes

The company files a federal income tax return and various state income tax returns. Income taxes are provided for the tax effects of transactions reported in the financial statements and consist of taxes currently due plus deferred taxes related primarily to differences between the bases of certain assets and liabilities for financial and tax reporting. The deferred taxes represent the future tax return consequences of those differences, which will be either deductible or taxable when the assets and liabilities are recovered or settled. The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Company determines that it would be able to realize the deferred tax assets in the future in excess of their net recorded amount, it would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. The federal and state income tax returns of the company for 2016 and after are subject to examination by the tax authority, generally for three years after the filing date.

## Shipping and Handling Costs

The Company classifies freight billed to certain customers as sales revenue and the related freight costs as cost of sales.

## Subsequent Events

Management has evaluated subsequent events through May 6, 2020, the date the financial statements were available to be issued.

## Note 3—Concentrations

For the twelve months ended December 31, 2018 and 2017, one customer comprised 100%, and 88% of sales, respectively. At December 31, 2018 and 2017, the same customer comprised 100% of accounts receivable. Management believes that these amounts will be collected.

For the twelve months ended December 31, 2018, a vendor comprised 15% of expenses and with two other vendors comprised 92% of accounts payable. For the twelve months ended December 31, 2017, another vendor comprised 26% of expenses and at December 31, 2017, comprised of 97% of accounts payable. Management believes these vendors could be replaced without any material effect on operations.

## Note 4—Property and Equipment

As of December 31, 2018 and 2017, property and equipment consist of the following:

	Decem	oer 31,
	2018	2017
Computer equipment	\$ 1,648	\$ 1,648
Office equipment and furniture	15,924	15,924
Less: accumulated depreciation	(13,690)	(11,230)
Property and equipment, net	\$ 3,882	\$ 6,342

Total depreciation expense for the twelve months ended December 31, 2018 and 2017 was \$2,460, and \$3,561, respectively.

# Note 5—Accrued Expenses

Accrued expenses at December 31, 2018 and 2017 were as follows:

	Decem	ber 31,
	2018	2017
Accrued compensation	\$ 16,195	\$ 15,580
Accrued interest	100,542	5,196
Accrued sales tax	1,595	2,363
Total accrued expenses	\$ 118,332	\$23,139

# Note 6—Leasing Arrangements

On August 1, 2015, the company leased its office space under a forty-eight-month operating lease, expiring on July 31, 2019, calling for monthly base rent payments of \$2,382 to \$2,603, increasing annually, and its share of operating expenses. Total rent paid for the twelve months ended December 31, 2018 and 2017, was \$48,672, and \$45,768, respectively.

The following is the total remaining minimum lease payments through July 2019:

Year Ending December 31,	Amount
2019	\$18,219

# Note 7—Notes Payable and Related Parties

Long-term notes payable as of December 31, 2018 and 2017 consist of the following:

	Decen	nber 31,
	2018	2017
Convertible note payable, including interest at 8%, due June 2021	\$ 843,750	\$ —
Convertible note payable, including interest at 8%, due June 2021	281,250	—
Convertible note payable, including interest at 8%, due August 2021	375,000	
Related party note payable, including compounding interest at 6%, due December 2021	220,275	206,608
Related party note payable, including compounding interest at 6%, due December 2021 (W)	770,516	698,476
Convertible note payable, including interest at 8%, due December 2021	112,500	
Note payable, including interest at 6%, due December 2021 (W)	10,000	—
Note payable, including interest at 6%, due December 2021 (W)	10,000	
Convertible note payable, including interest at 6%, due March 2022	50,000	—
Related party convertible note, including interest at 6%, due March 2022	250,000	
Convertible note payable, including interest at 6%, due March 2022	250,000	
Total notes payable	\$ 3,173,291	\$ 905,084

The following is a summary of principal maturities of long-term debt:

Years Ending December 31,	
2020	\$ —
2021	2,623,291
2022	550,000
Total principal payments	\$ 3,173,291

#### Note 8—Stock Purchase Warrants

The Company has notes payable with stock purchase warrants, marked with a (W) in the previous table. The number of shares is set at a maximum of 20% of the principal amount of loan. The warrants are exercisable prior to the earlier of the tenth anniversary of the effective date or a deemed liquidation event. The exercise price is \$1 per share of common stock. No warrants have been exercised as of December 31, 2018 and 2017.

## Note 9—Convertible Subordinated Notes

In 2018, the Company issued \$1,612,500 of 8% convertible subordinated notes due 2021 in a private offering. The notes are governed by debentures dated 2018. The notes bear interest at the rate of 8% and are convertible prior to December 2021 only upon specified events and during specified periods and, thereafter, at any time, in each case at various conversion rates.

In 2018, the Company also issued \$550,000 of 6% convertible subordinated notes due 2022 in a private offering. The notes are governed by debentures dated 2018. The notes bear interest at the rate of 6% and are convertible prior to March 2022 only upon specified events and during specified periods and, thereafter, at any time, in each case at conversion rate equal to eighty percent of the per share price of the Series A Preferred Stock of the Company sold. No notes have been converted as of December 31, 2018 and 2017.

#### Note 10—Research and Development Costs

Research and development costs are charged under operating expenses in the statements of operations. Total research and development costs for the twelve months ended December 31, 2018 and 2017 were \$113,022, and \$379,714, respectively.

#### Note 11—Deferred Tax Asset and Valuation Allowance

The Company has federal and state income tax net operating loss ("NOL") carryforwards of \$3,297,000, which will expire between 2034 and 2038, as of December 31, 2018. The Company believes that it is more likely than not that the benefit from certain NOL carryforwards will not be realized. In recognition of this risk, the Company has provided a valuation allowance on the deferred tax assets related to these NOL carryforwards as of December 31, 2018 and 2017, because of this, no tax provision has been recorded in the financial statements. The Company intends to continue maintaining a full valuation allowance on the deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of these allowances. Release of the valuation allowance would result in the recognition of certain deferred tax assets and a decrease to income tax expense for the period(s) the release is recorded. However, the exact timing and amount of the valuation allowance release are subject to change on the basis of the level of profitability that the Company is able to actually achieve. Further, a portion of the carryforwards may expire before being applied to reduce future income tax liabilities.

The Company's total deferred tax assets and deferred tax asset valuation allowances at December 31, 2018 and 2017, are as follows:

	Decem	December 31,		
	2018	2017		
Total deferred tax assets	\$ 1,015,000	\$ 1,027,000		
Less valuation allowance	(1,015,000)	(1,027,000)		
Net deferred tax asset	\$ —	\$ —		

## Note 12—Subsequent Event and Escrow

In early 2019, the unrelated party made an escrow payment in the amount of \$500,000 towards the acquisition of the Company.

On June 14, 2019, in anticipation of the sale of the Company, the key employee exercised his vested options. The stock was valued at \$2.84 per share at the time of exercise, based on a 5% discount rate and anticipated stream of future payments related to the sale in the amount of \$18,955. The remaining shares will not be vested due to the sale of the Company.

On June 18, 2019, a total of \$1,762,500 of convertible debt plus \$146,662 of accumulated interest was converted to equity in anticipation of the sale. All stock purchase warrants were exercised on June 18, 2019, prior to closing.

On June 18, 2019, all of the outstanding shares of stock of Rhythm Xience, Inc. were acquired by an unrelated party. At the time of closing, all long-term debt referenced in Note 7 was paid in full. In addition, one note paid at closing required a \$400,000 premium payment at time of early payment.

On January 31, 2020, the stockholders and State of Delaware approved the dissolution of the Company.

# RHYTHM XIENCE, INC. Balance Sheets

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS:		
Current assets:		
Cash	\$ 773,878	\$ 964,952
Accounts receivable	18,993	11,498
Restricted cash	500,000	—
Inventories	57,000	98,920
Prepaid expenses	12,813	32,161
Total current assets	1,362,684	1,107,531
Property and equipment, net of accumulated depreciation	3,390	3,882
Security deposit	7,917	7,917
Total noncurrent assets	11,307	11,799
Total assets	\$ 1,373,991	\$ 1,119,330
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	189,540	38,890
Accrued expenses	147,996	118,332
Escrow	500,000	
Total current liabilities	837,536	157,222
Long-term debt	3,201,014	3,173,291
Total liabilities	4,038,550	3,330,513
Stockholders' equity (deficit):		
Common stock, \$0.001 par value; 7,500,000 shares authorized, 3,750,000 shares issued and outstanding	3,750	3,750
Additional paid-in capital	2,246,351	2,246,351
Retained deficit	(4,914,660)	(4,461,284)
Total stockholders' equity (deficit)	(2,664,559)	(2,211,183)
Total liabilities and stockholders' equity (deficit)	\$ 1,373,991	\$ 1,119,330

See notes to the financial statements.

# RHYTHM XIENCE, INC. Statements of Operations (Unaudited)

		Three Months Ended March 31,		
	2019	2018		
Sales, net	\$ 60,109	\$ 28,590		
Cost of sales	44,524	15,857		
Gross profit	15,585	12,733		
Operating expenses	413,651	210,144		
Operating loss	(398,066)	(197,411)		
Other income (expense):				
Interest expense	(55,310)	—		
Insurance refund	—	1,460		
Total other income (expense)	(55,310)	1,460		
Net loss	\$ (453,376)	\$ (195,951)		

See notes to the financial statements.

# RHYTHM XIENCE, INC. Statements of Stockholders' Equity (Deficit) (Unaudited)

	Common	Stock			
	Number of Shares	Par Value	Additional Paid-in Capital	Retained Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2017	3,750,000	\$ 3,750	\$ 2,246,351	\$ (3,319,464)	\$ (1,069,363)
Net loss	—		—	(195,951)	(195,951)
Balance, March 31, 2018	3,750,000	\$ 3,750	\$ 2,246,351	\$ (3,515,415)	\$ (1,265,314)
Balance, December 31, 2018	3,750,000	\$ 3,750	\$ 2,246,351	\$ (4,461,284)	\$ (2,211,183)
Net loss	_			(453,376)	(453,376)
Balance, March 31, 2019	3,750,000	\$ 3,750	\$ 2,246,351	\$ (4,914,660)	\$ (2,664,559)

See notes to the financial statements.

# RHYTHM XIENCE, INC. Statements of Cash Flows (Unaudited)

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities		
Net loss	\$ (453,376)	\$ (195,951)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	492	931
Changes in operating assets and liabilities:		
Accounts receivable	(7,495)	4,425
Prepaid expenses and other current assets	19,348	4,570
Inventory	41,920	15,000
Accounts payable and accrued expenses	180,314	(223,632)
Other current liabilities	500,000	(19,879)
Net cash used in operating activities	281,203	(414,536)
Cash flows provided by financing activities		
Proceeds from notes payable	27,723	591,177
Net cash provided by financing activities	27,723	591,177
Net change in cash	308,926	176,641
Cash at the beginning of the period	964,952	30,394
Cash at the end of the period	\$ 1,273,878	\$ 207,035

See notes to the financial statements.

#### Note 1—Organization

Rhythm Xience, Inc. (the "Company"), is a medical device company specializing in catheter-based rhythm management solutions based in Minnesota with operations also in California. As developer and innovator, the solutions are clinically based and procedurally focused towards recognizing and resolving the challenges facing Electrophysiologists and healthcare facilities.

## Note 2—Summary Of Significant Accounting And Reporting Policies

## Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Management has identified inventories, income taxes, and fixed assets as areas where significant estimates and assumptions have been made in preparing the financial statements. Actual results could differ from these estimates.

## **Concentrations of Credit Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments and trade accounts receivable. The Company maintains its cash balances in a financial institution located in Minneapolis, Minnesota. The balances are insured by the Federal Deposit Insurance Corporation (FDIC) up to \$250,000 per company per financial institution. At times, during the three months ended March 31, 2019 and 2018, the Company had bank balances in excess of FDIC limits. The Company has not experienced any losses from such accounts.

#### Accounts Receivable

The accounts receivable balances are generally uncollateralized and comprised of credit and non-credit receivables. The accounts are typically paid within 45 days. Management provides for probable uncollectible amounts through a charge to earnings and a credit to a valuation allowance based on its assessment of the current status of individual accounts. Balances that are still outstanding after management has used reasonable collection efforts are written off through a charge to the valuation allowance and a credit to accounts receivable. There was no allowance for doubtful accounts for the three months ended March 31, 2019 and 2018, respectively. Management believes that accounts receivable is stated at estimated net realizable value.

## **Restricted Cash**

During the three months ended March 31, 2019, an unrelated party made an escrow payment in the amount of \$500,000 towards the acquisition of the Company.

#### Advertising

The company expenses advertising costs as they are incurred. Total advertising expense for the three months ended March 31, 2019 and 2018 was \$32,478, and \$11,400, respectively.

### Inventories

Inventories are valued at the lower of cost (first-in, first-out method) or net realizable value.

#### **Property and Equipment**

Building, equipment, and leasehold improvements are carried at historical cost. Major additions and betterments are charged to the property accounts while replacements, maintenance, and repairs that do not improve or extend the life of the respective assets are expensed currently.

Depreciation is computed on the double declining method, using estimated useful lives ranging from five to seven years for financial reporting purposes.

#### **Income Taxes**

The company files a federal income tax return and various state income tax returns. Income taxes are provided for the tax effects of transactions reported in the financial statements and consist of taxes currently due plus deferred taxes related primarily to differences between the bases of certain assets and liabilities for financial and tax reporting. The deferred taxes represent the future tax return consequences of those differences, which will be either deductible or taxable when the assets and liabilities are recovered or settled. The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Company determines that it would be able to realize the deferred tax assets in the future in excess of their net recorded amount, it would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. The federal and state income tax returns of the company for 2016 and after are subject to examination by the tax authority, generally for three years after the filing date.

#### Shipping and Handling Costs

The Company classifies freight billed to certain customers as sales revenue and the related freight costs as cost of sales.

#### Subsequent Events

Management has evaluated subsequent events through May 11, 2020, the date the financial statements were available to be issued.

#### Note 3—Concentrations

For the three months ended March 31, 2019 and 2018, one customer comprised 59% and 100% of sales, respectively. At March 31, 2019 and December 31, 2018, the same customer comprised 100% of accounts receivable. Management believes that these amounts will be collected.

For the three months ended March 31, 2019 and 2018, two vendors comprised 38% and 7% of expenses, respectively, and 84% and 71% of accounts payable, respectively. Management believes these vendors could be replaced without any material effect on operations.

## Note 4—Property and Equipment

As of March 31, 2019 and December 31, 2018, property and equipment consist of the following:

	March 31, 2019	December 31, 2018
Computer equipment	\$ 1,648	\$ 1,648
Office equipment and furniture	15,924	15,924
Less: accumulated depreciation	(14,182)	(13,690)
Property and equipment, net	\$ 3,390	\$ 3,882

Total depreciation expense for the three months ended March 31, 2019 and 2018 was \$492, and \$931, respectively.

## Note 5—Accrued Expenses

Accrued expenses at March 31, 2019 and December 31, 2018 were as follows:

	March 31, 2019	December 31, 2018
Accrued compensation	\$ 14,740	\$ 16,195
Accrued interest	128,127	100,542
Accrued sales tax	5,129	1,595
Total accrued expenses	\$147,996	\$ 118,332

## Note 6—Leasing Arrangements

On August 1, 2015, the company leased its office space under a forty-eight-month operating lease, expiring on July 31, 2019, calling for monthly base rent payments of \$2,382 to \$2,603, increasing annually, and its share of operating expenses. Total rent paid for the three months ended March 31, 2019 and 2018, was \$13,059, and \$16,027, respectively.

## Note 7—Notes Payable and Related Parties

Long-term notes payable as of March 31, 2019 and December 31, 2018 consist of the following:

	Ν	March 31, 2019	D	ecember 31, 2018
Convertible note payable, including interest at 8%, due June 2021	\$	843,750	\$	843,750
Convertible note payable, including interest at 8%, due June 2021		281,250		281,250
Convertible note payable, including interest at 8%, due August 2021		375,000		375,000
Related party note payable, including compounding interest at 6%, due December 2021		224,693		220,275
Related party note payable, including compounding interest at 6%, due December 2021 (W)		793,821		770,516
Convertible note payable, including interest at 8%, due December 2021		112,500		112,500
Note payable, including interest at 6%, due December 2021 (W)		10,000		10,000
Note payable, including interest at 6%, due December 2021 (W)		10,000		10,000
Convertible note payable, including interest at 6%, due March 2022		50,000		50,000
Related party convertible note, including interest at 6%, due March 2022		250,000		250,000
Convertible note payable, including interest at 6%, due March 2022		250,000		250,000
Total notes payable	\$	3,201,014	\$	3,173,291

The following is a summary of principal maturities of long-term debt:

Years Ending March 31,	
2020	\$ —
2021	—
2022	3,201,014
Total principal payments	\$ 3,201,014

#### Note 8—Stock Purchase Warrants

The Company has notes payable with stock purchase warrants, marked with a (W) in the previous table. The number of shares is set at a maximum of 20% of the principal amount of loan. The warrants are exercisable prior to the earlier of the tenth anniversary of the effective date or a deemed liquidation event. The exercise price is \$1 per share of common stock. No warrants have been exercised as of March 31, 2019.

#### Note 9—Convertible Subordinated Notes

In 2018, the Company issued \$1,612,500 of 8% convertible subordinated notes due 2021 in a private offering. The notes are governed by debentures dated 2018. The notes bear interest at the rate of 8% and are convertible prior to December 2021 only upon specified events and during specified periods and, thereafter, at any time, in each case at various conversion rates.

In 2018, the Company also issued \$550,000 of 6% convertible subordinated notes due 2022 in a private offering. The notes are governed by debentures dated 2018. The notes bear interest at the rate of 6% and are convertible prior to March 2022 only upon specified events and during specified periods and, thereafter, at any time, in each case at conversion rate equal to eighty percent of the per share price of the Series A Preferred Stock of the Company sold. No notes have been converted as of March 31, 2019.

## Note 10—Research and Development Costs

Research and development costs are charged under operating expenses in the statements of operations. Total research and development costs for the three months ended March 31, 2019 and 2018 were \$125,260, and \$0, respectively.

#### Note 11—Subsequent Event and Escrow

On June 18, 2019, all of the outstanding shares of stock of Rhythm Xience, Inc. were acquired by an unrelated party. During the three months ended March 31, 2019, the unrelated party made an escrow payment in the amount of \$500,000 towards the acquisition of the Company.

### UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

The following unaudited pro forma condensed combined financial information was prepared using the acquisition method of accounting under U.S. generally accepted accounting principles, ("U.S. GAAP"), and gives effect to the acquisition by Acutus Medical, Inc. ("Acutus" or the "Company") of Rhythm Xience, Inc. ("Rhythm Xience"), which we refer to as the "Rhythm Xience Acquisition". The Agreement and Plan of Merger (the "Merger Agreement") governs the transaction, which was accounted for as a business combination in accordance with Accounting Standards Codification 805, *Business Combinations* ("ASC 805").

Acutus was determined to be the accounting acquirer based upon the terms of the Merger Agreement and other factors including that Acutus stockholders own 100% of the voting interests of the combined company immediately following the closing of the transaction.

The following unaudited pro forma condensed combined financial information is based on the Company's historical consolidated financial statements and Rhythm Xience's historical financial statements as adjusted to give effect to Acutus' acquisition of Rhythm Xience, which closed on June 18, 2019. The unaudited pro forma condensed combined statement of operations for the year ended December 31, 2019 gives effect to the transaction as if it had occurred on January 1, 2019.

Rhythm Xience's assets and liabilities were measured and recognized at their fair values as of the transaction date, and combined with the assets, liabilities and results of operations of Acutus after the consummation of the transaction.

The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. The application of the acquisition method of accounting is dependent upon certain valuations.

The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the two companies. The unaudited pro forma condensed combined financial information has been prepared for illustrative purposes only and is not necessarily indicative of the results of operations in future periods or the results that actually would have been realized had Acutus and Rhythm Xience been a combined company during the specified period. The actual results reported in periods following the transaction may differ significantly from those reflected in this unaudited pro forma condensed combined financial information presented herein for a number of reasons, including, but not limited to, differences between the assumptions used to prepare this pro forma financial information.

The assumptions and estimates underlying the unaudited adjustments to the pro forma condensed combined financial information is described in the accompanying notes, which should be read together with the unaudited pro forma condensed combined financial information.

The unaudited pro forma condensed combined financial information should be read together with Acutus' historical consolidated financial statements and Rhythm Xience's historical financial statements included elsewhere in this prospectus.

## PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS YEAR ENDED DECEMBER 31, 2019 (in thousands, except share and per share amounts)

	Acutus year ended December 31, 2019	Rhythm Xience January 1, 2019 to June 18, 2019	Pro Forma Adjustment	Notes	2019 Pro Forma Combined
Revenue	\$ 2,836	\$ 97	\$ —		\$ 2,933
Costs and operating expenses:					
Cost of products sold	9,243	70	—		9,313
Research and development	23,029	—	_		23,029
Research and development—license acquired	15,000	—	—		15,000
Selling, general and administrative	26,847	1,011	(216)	2(a)	27,691
			(141)	2(b)	
			190	2(c)	
Impairment of property and equipment	786	—	—		786
Change in fair value of contingent consideration	500				500
Total costs and operating expenses	75,405	1,081	(167)		76,319
Loss from operations	(72,569)	(984)	167		(73,386)
Other income (expense):					
Change in fair value of warrant liability and embedded derivative	(1,919)	—			(1,919)
Loss on debt extinguishment	(1,447)	—			(1,447)
Interest income	1,164	2			1,166
Interest expense	(22,268)	(55)	55	2(d)	(22,268)
Other income		4			4
Total other income (expense), net	(24,470)	(49)	55		(24,464)
Loss before income taxes	(97,039)	(1,033)	222		(97,850)
Income tax benefit	_	140	(140)	2(e)	—
Net loss	\$ (97,039)	\$ (893)	\$ (82)		\$ (97,850)
Net loss per common share, basic and diluted	\$ (14.85)				\$ (14.97)
Weighted-average shares outstanding, basic and diluted	6,534,469				6,534,469

## NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

#### Note 1—Description of Transaction and Basis of Presentation

The unaudited pro forma condensed combined financial information was prepared in accordance with U.S. GAAP and pursuant to the rules and regulations of SEC Regulation S-X, and present the pro forma results of operations of the combined companies based upon the historical data of Acutus and Rhythm Xience.

For purposes of the unaudited pro forma condensed combined financial information, the accounting policies of Acutus and Rhythm Xience are aligned with no differences.

#### **Description of Transaction**

On June 18, 2019, the Company acquired Rhythm Xience, a medical device company specializing in catheter-based rhythm management solutions, for \$3.0 million in cash. The cash payment did not include the potential \$17.0 million in earn out consideration to be paid based on the achievement of certain regulatory milestones and revenue milestones. In accordance with ASC 805, the Rhythm Xience Acquisition is accounted for as a business combination.

## **Purchase Price Allocation**

The following table summarizes the allocation of the purchase price to the assets acquired and liabilities assumed for the Rhythm Xience Acquisition (in thousands):

	June 18, 2019
Accounts receivable, net	\$ 3
Prepaid expenses and other current assets	8
Property and equipment, net	3
Intangible assets	4,360
Goodwill	12,026
Contingent consideration	(13,400)
Cash consideration	\$ 3,000

As part of the Rhythm Xience Acquisition, the Company recorded a contingent consideration liability of \$13.4 million based on the fair value of the contingent consideration liability at the acquisition date. The Company recorded a \$0.5 million increase to the fair value of the contingent consideration liability from June 18, 2019 to December 31, 2019, which is included in change in fair value of contingent consideration in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2019.

#### Note 2—Pro Forma Adjustments

The following adjustments have been reflected in the unaudited pro forma condensed combined financial information:

- (a) Represents the elimination of the 2019 Acutus transaction expenses recognized in the period prior to the closing of the transaction on June 18, 2019.
- (b) Represents the elimination of the 2019 Rhythm Xience transaction expenses recognized in the period prior to the closing of the transaction on June 18, 2019.

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## NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

(c) Represents the amortization of intangible assets for the period prior to the closing of the transaction on June 18, 2019 (in thousands, except years):

		Estimated Useful Lives (Years)	Balances	Fo Amor of Int	9 Pro orma rtization tangible ssets
	Developed technology	10	\$ 3,600	\$	180
	In-process technology	Indefinite	600		
	Trademarks and trade names	0.5	60		
	Customer-related intangible	5	100		10
Т	Total		\$ 4,360	\$	190

- (d) Represents the elimination of the 2019 interest expenses related to Rhythm Xience's debt that was not assumed in the transaction.
- (e) Represents the elimination of Rhythm Xience's income tax benefit as Acutus has a full valuation allowance on its net deferred tax assets.

Shares



**Common Stock** 

Prospectus

J.P. Morgan

**Canaccord Genuity** 

**BofA Securities** 

**William Blair** 

BTIG

, 2020

#### 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	\$ *	

To be provided by amendment.

#### 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 XI of our current amended and restated certificate of incorporation and Article of the amended and restated certificate of incorporation that our board of directors expects to approve and we expect our stockholders to approve in connection with this offering will provide for the indemnification of directors to the fullest extent permissible under Delaware law.

Article V of our current bylaws and Article of the amended and restated bylaws that our board of directors expects to approve and we expect our stockholders to approve in connection with this offering will provide for the indemnification of officers, directors and third parties 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. Prior to the completion of this offering, we expect to enter into new indemnification agreements with each of our directors, executive officers and certain other officers, which will contain similar provisions. 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 asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions. Prior to the completion of this offering, we will procure additional insurance to provide coverage to our directors and officers against loss arising from claims relating to, among other things, public securities matters.

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, 2017:

(i) In June 2018, we issued warrants exercisable for up to 4,880,943 shares of our common stock at a price of \$0.01 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 \$22,815,231.50 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 18,325,558 shares of our Series D convertible preferred stock at a price of \$1.3712 per share.

(iii) In July 2018, we issued warrants exercisable for up to 262,543 shares of our Series C convertible preferred stock at a price of \$1.714 per share. These warrants were subsequently automatically converted to warrants to purchase up to 262,543 shares of our Series D convertible preferred stock at a price of \$1.714 per share.

(iv) In May 2019, we issued warrants exercisable for up to 4,084,014 shares of our Series C convertible preferred stock at a price of \$1.714 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 4,084,014 shares of our Series D convertible preferred stock at a price of \$1.714 per share.

(v) In May 2019, we issued \$37,000,000.00 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 21,625,369 shares of our Series D convertible preferred stock at a price of \$1.714 per share.

(vi) In June 2019, we sold an aggregate of 39,789,158 shares of our Series D convertible preferred stock at a price of \$1.714 per share for an aggregate purchase price of \$68,198,650.42.

(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 1,166,861 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 2,655,337 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, 2017 through June 26, 2020, we granted to certain employees, consultants and directors options to purchase an aggregate of 23,286,085 shares of our common stock under our 2011 Plan, at exercise prices ranging from \$0.79 to \$1.523 per share.

(x) From January 1, 2017 through June 26, 2020, we issued an aggregate of 2,025,852 shares of our common stock upon the exercise of options granted under our 2011 Plan, at exercise prices ranging from \$0.19 to \$1.06 per share, for an aggregate exercise price of \$738,374.97.

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.

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Exhibit Number

- (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.

Description

## EXHIBIT INDEX

# 1.1\* Form of Underwriting Agreement

- 2.1<sup>^</sup> 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
- 3.1<sup>^</sup> Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect
- 3.2\* Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect immediately prior to the completion of this offering
- 3.3<sup>^</sup> Bylaws of the Registrant, as currently in effect.
- 3.4\* Form of Amended and Restated Bylaws of the Registrant, to be in effect immediately prior to the completion of this offering
- 4.1^ Amended and Restated Investors' Rights Agreement, dated June 12, 2019, among the Registrant and certain of its stockholders
- 4.2\* Specimen common stock certificate of the Registrant
- 4.3<sup>^</sup> 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
- 4.4<sup>^</sup> 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
- 4.5<sup>^</sup> Form of warrant to purchase convertible preferred stock, dated July 31, 2018, issued by the Registrant to various parties, together with a schedule of material differences
- 4.6<sup>^</sup> Form of warrant to purchase convertible preferred stock, dated May 20, 2019, issued by the Registrant to various parties, together with a schedule of material differences
- 5.1\* Opinion of Davis Polk & Wardwell LLP
- 10.1<sup>^</sup> 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
- 10.2<sup>^</sup> Pledge and Security Agreement, dated May 20, 2019, between the Registrant and Wilmington Trust, National Association
- 10.3#^ License and Distribution Agreement, dated July 2, 2019, among the Registrant, Biotronik SE & Co. KG and VascoMed GmbH

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Exhibit <u>Number</u>	Description
10.4#	Bi-Lateral Distribution Agreement, dated May 11, 2020, between the Registrant and Biotronik SE & Co. KG (Acutus as distributor)
10.5#	Bi-Lateral Distribution Agreement, dated May 11, 2020, between the Registrant and Biotronik SE & Co. KG (Biotronik as distributor)
10.6#^	License Agreement, dated May 10, 2011, between the Registrant and Dr. Christoph Scharf
10.7^	First Amendment to License Agreement, dated September 30, 2011, between the Registrant and Dr. Christoph Scharf
10.8#^ 10.9#^	Master License Agreement, dated March 11, 2014, between the Registrant and Biotectix, LLC Exclusive Patent License Agreement, dated April 21, 2014, between the Registrant and Regents of the University of Minnesota
10.10^	First Amendment to Exclusive Patent License Agreement, dated October 20, 2014, between the Registrant and Regents of the University of Minnesota
10.11^	Lease Agreement, dated January 22, 2015, as amended, between the Registrant and Carlsbad 2210, LLC
10.12*†	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers
10.13†^	2011 Equity Incentive Plan, as amended, and forms of agreements thereunder
10.14*†	2020 Equity Incentive Plan and forms of agreements thereunder, to be in effect upon the completion of this offering
10.15*†	2020 Employee Stock Purchase Plan, to be in effect upon the completion of this offering
10.16†^	Executive Incentive Compensation Plan
10.17†^	Executive Chairman Agreement, dated June 30, 2019, between the Registrant and Scott Huennekens
10.18†^	Restricted Stock Unit Award Agreement, dated June 30, 2019 (2011 Equity Incentive Plan) (Scott Huennekens)
10.19†^	Employment Agreement, dated October 14, 2019, between the Registrant and Vince Burgess
10.20†^	Offer Letter, dated September 24, 2015, between the Registrant and Gary W. Doherty
10.21†^	Employment Agreement, dated September 6, 2016, between the Registrant and Steven McQuillan
10.22†	Consulting Agreement, dated January 4, 2019, between the Registrant and Elia Health Sciences, Inc.
21.1^	Subsidiaries of the Registrant
23.1*	Consent of KPMG LLP
23.2*	Consent of Meuwissen, Flygare, Kadrlik & Associates, P.A.
23.3*	Consent of Davis Polk & Wardwell LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included in signature page to this Form S-1)

To be filed by amendment. Previously submitted. 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. \* ^ † #

## 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 , 2020.

#### 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, Gary W. Doherty 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)	, 2020
Gary W. Doherty	Chief Financial Officer (Principal Financial Officer)	, 2020
R. Scott Huennekens	Chairman of the Board	, 2020
David Bonita, M.D.	Director	, 2020
Andrew ElBardissi, M.D.	Director	, 2020
	Director	, 2020
Jim Hinrichs Shahzad Malik, MB BChir	Director	, 2020
Shunzua munk, MD Denn		

[\*\*\*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

# **Global Alliance for Biotronik Product Distribution Agreement**

by and between

## **Biotronik SE & Co. KG** Woermannkehre 1, 12359 Berlin, Germany

and

Acutus Medical, Inc. 2210 Faraday Ave Suite 100, Carlsbad 92008, California, U.S.A.

(Biotronik and Acutus together the **Parties** and each a **Party**)

(Biotronik)

(Acutus)

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## Preamble

- A. Biotronik has developed and manufactures, *inter alia*, a portfolio of electrophysiology products for cardiac mapping and radiofrequency ablation therapy. Biotronik has also built a portfolio of OEM electrophysiology products, where Biotronik is not the manufacturer of record but owns certain resale and distribution rights. Some of these OEM electrophysiology products are exclusively designed, labelled, or produced for Biotronik.
- B Acutus is active, *inter alia*, in the field of distribution of medical devices.
- C. Biotronik intends to appoint Acutus as a distributor for Bio Products in the Territory, and Acutus intends to accept such appointment.
- D. Acutus wishes have access to the OEM Products for distribution in the Territory. Biotronik intends to grant Acutus for convenience access to the distribution of the OEM Products, which Biotronik may distribute according to certain distribution agreements Biotronik has concluded with Third Party OEM manufacturers, but Acutus is receiving the right to distribute the OEM Products under this Agreement only to the extent possible in accordance with the contractual restrictions of Biotronik according to such distribution agreements that are set forth in <u>Annex 2.1(b)</u>, as <u>Annex 2.1(b)</u> may be updated by Biotronik in accordance with this Agreement. Biotronik aims to support and align with Acutus regarding any claim Acutus might have regarding such Third Party OEM manufacturers due to the distribution of the OEM Products received via Biotronik. However Biotronik shall not be liable towards Acutus with regard to any claims stemming from of relating to such OEM Products except as set forth in this Agreement.
- E. Acutus also wishes remain free to access the OEM Products for distribution independently of this Agreement (e.g., directly from the OEM manufacturers); and Biotronik acknowledges and agrees that Acutus is free to obtain the OEM Products, negotiate, and enter into any agreements directly with the OEM manufacturers; except with regard to Qiona and Senovo products to the extent more particularly set forth in this Agreement below.

Now, therefore, the Parties agree as follows:

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#### Definitions and Interpretation

1.

- (a) The capitalized terms set out in <u>Annex 1(a)</u> have the meanings set forth in that Annex, whether used in the singular or plural form.
- (b) The words "includes", "including", "in particular", "such as" and "inter alia" and the examples given in the Agreement are to be construed without limitation.
- (c) Obligations on a Party to provide information or notification to the other Party will be construed to mean "without undue delay", unless agreed otherwise.
- (d) References to a person include an individual, a body corporate, an unincorporated association of persons, government, state, state agency, corporation, association or partnership.
- (e) References to "days" mean calendar days unless specified to be Business Days.
- (f) References to a Party in this Agreement include references to the successors or permitted assigns of that Party.
- (g) A document is a reference to that document as modified or replaced from time to time.
- (h) Any reference to an enactment (which includes any legislation in any relevant jurisdictions) includes references to (i) that enactment as re-enacted, amended, extended or applied by or under any other enactment (before, on or after the Effective Date); (ii) any enactment which that enactment reenacts (with or without modification); and (iii) any subordinate legislation made (before, on or after the Effective Date) under that enactment, as reenacted, amended, extended or applied as described; (iv) any enactment, statute, legislation or law in any relevant jurisdictions.
- (i) The Parties acknowledge that this Agreement has been individually negotiated, and each had the opportunity to consult with independent counsel of their own choice. They have entered into this Agreement based on their own judgment and not on any promises or representations other than those contained in the Agreement. This Agreement will be construed as a whole, according to its fair meaning, and not in favor of or against any Party.
- (j) References in this Agreement to EU/EEA countries means the countries that are in the European Economic Area, as defined under the EEA Agreement that formally establishes the European Economic Area, as such agreement is updated from time to time.

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## 2. Appointment as Distributor and Principles of Distribution

#### 2.1 Appointment

- (a) Biotronik hereby appoints Acutus as distributor for the Bio Products in the Territory, and Acutus hereby accepts such appointment.
- Biotronik hereby appoints Acutus as distributor for the OEM Products in the Territory, as OEM Products is defined in <u>Annex 2.1(b)</u>, (b) only to the extent Annex 2.1(b) indicates that Biotronik can authorize Acutus to distribute the OEM Product. Such distribution shall be subject to the contractual terms and conditions of Biotronik for such OEM Products agreed with the Third Party suppliers of such OEM Products, but subject to (and without limiting) the terms of this Agreement. Acutus hereby acknowledges and agrees that distribution of OEM Products by Acutus is subject to any such conditions and limitations with regard to the OEM Products. Biotronik will notify Acutus in writing of any change to such terms and conditions that may impact Acutus in advance (i.e. before such change becomes effective), but solely to the extent such change affects <u>Annex 2.1(b)</u>, and the Parties will promptly discuss in good faith any accommodations that are necessary or desirable to be made in light of such changes, it being understood that Biotronik shall be free to negotiate the terms of conditions for such OEM Products with the Third Party suppliers. Annex 2.1(b) sets out the OEM Products, the Manufacturer of Record of the OEM Products, the term of the respective contracts between Biotronik and the Manufacturer of Record of the OEM Products that may impact Acutus, and the countries where the OEM Products may be sold as of the Effective Date of this Agreement, Biotronik shall update Annex 2.1(b) as and when required to reflect additional or changed terms under the OEM agreements that are applicable to and may impact the OEM Products or Acutus by providing at least sixty (60) days advance written notice to Acutus; and updates will be applicable only to OEM Products ordered by Acutus more than sixty (60) days after the date of such notice.
- (c) Acutus will not import into the Territory or distribute in the Territory any Bio Products received from any source other than Biotronik or a reseller (to the extent the reseller is authorized by Biotronik to sell Bio Products to Acutus for the Territory).
- (d) Biotronik acknowledges and agrees, however, that Acutus has the right to obtain all of the OEM Products directly from the OEM manufacturers and other sources and to commercialize the OEM Products worldwide, including if desired by Acutus under Acutus branding; except that (i) without limiting and subject to all rights of Acutus under the License and Distribution Agreement, the Qiona OEM Product can be obtained by Acutus only from Biotronik; and (ii)

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the Senovo OEM Product can be obtained by Acutus from OEM manufacturers directly, but without Biotronik's proprietary trademarks and branding (e.g., can be purchased by Acutus from the OEM manufacturer under manufacturer or Acutus branding). Except for the terms in this Section 2.1(d), none of the terms of this Agreement apply with regard to any OEM Products obtained by Acutus from a source other than Biotronik. Under no circumstances shall any OEM Product commercialized by Acutus be considered a Competing Product to any Bio Product, and under no circumstances shall any activities of Acutus with regard to any OEM Product obtained from a source other than Biotronik be governed by or considered a breach of this Agreement. As used in this Agreement below, the terms "Product" and "OEM Product" exclude such OEM product obtained by Acutus other than from Biotronik under this Agreement.

## 2.2 Distributorship

- (a) Subject to Section 2.4, the appointment of Acutus as a distributor for the Bio Products is non-exclusive.
- (b) The appointment of Acutus as distributor for the OEM Products is non-exclusive.
- (c) Subject to Section 2.4, Biotronik may appoint any Third Party as distributor for Bio Products inside and outside of the Territory; provided that distributors of Biotronik in the Territory must be non-exclusive only. Similarly, Biotronik acknowledges and agrees that Acutus is authorized to make sales of Products throughout the EU/EEA, UK and Switzerland even outside the Territory to the extent restriction of such sales is not authorized by applicable law. Subject to Section 2.4, Acutus acknowledges that other distributors or resellers may conduct sales in the Territory.
- (d) Prior to the Effective Date, Biotronik will have provided Acutus with a list of all Third Party distributors and agents currently appointed by Biotronik for Bio Products that have rights to sell in or into the U.S. and Canada. For the countries of the Territory other than the U.S. and Canada, Biotronik shall use reasonable endeavours to inform Acutus on a regular basis of the name of all Third Party distributors of the Bio Products.
- (e) Subject to Section 2.4, Biotronik, its Affiliates and Third Party distributors retain the right to conduct sales of Products inside and outside of the Territory.
- (f) Acutus, its Affiliates and Sub-Distributors have the right to conduct sales of Bio Products in and into the Territory and for countries in the EU/EEA, UK and Switzerland both inside and outside the countries of the Territory which are

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part of the EU/EEA, UK and Switzerland except as otherwise provided in Section 2.3(d).

## 2.3 Ramp-Up Periods for distribution of Bio Products

- (a) Acutus and Biotronik shall share market development costs in the Territory incurred during the Ramp-Up Periods solely to the extent mutually agreed by both Parties in writing. The Parties agree that the ramp-up periods for the distribution of Bio Products in each country in the Territory are set forth in <u>Annex 2.1</u> of this Agreement, subject to adjustment as set forth in Section 2.3(b) or 2.3(c) (the **Ramp-Up Periods**).
- (b) The Ramp-Up Period for each country in the Territory shall commence in the respective country upon the granting of the respective Marketing Authorization Approval by the Governmental Authorities in the country (or upon the Effective Date if already granted as of the Effective Date) and shall end in such country at the end of the number of consecutive months after Marketing Authorization Approval in such country (or after the Effective Date if a Marketing Authorization Approval is already granted as of the Effective Date) as indicated in <u>Annex 2.1</u>, except such duration shall be adjusted as follows. Because the Parties desire to have the Annual Purchase Targets for all countries begin on January 1, and end on December 31, of each calendar year, the duration of each Ramp-Up Period shall be determined as if the Ramp-Up Period began on: (i) for Marketing Authorization Approvals existing as of the Effective Date, January 1, 2021; (ii) for all other Marketing Authorization Approval was obtained prior to July 1 of a calendar year in which the Marketing Authorization Approval was obtained); and (iii) for Marketing Authorization Approvals obtained on or after July 1 of a calendar year, the January 1 immediately following the date on which the Marketing Authorization Approval was obtained (i.e., January 1 of the calendar year following the calendar year in which the Marketing Authorization Approval was obtained); and (iii) for Marketing Authorization Approval was obtained on or after July 1 of the calendar year following the calendar year in which the Marketing Authorization Approval is obtained (i.e., January 1 of the calendar year following the calendar year in which the Marketing Authorization Approval was obtained); and (iii) for Marketing Authorization Approval was obtained (i.e., January 1 of the calendar year following the calendar year in which the Marketing Authorization Approval was obtained).
- (c) In all countries of the Territory where Biotronik, its Affiliate or a Third Party designee is responsible for maintaining the Marketing Authorization Approval, if Marketing Authorization Approval is lost, then the Annual Purchase Targets for all such countries affected by the loss shall be reduced as reasonably necessary to account for the loss, as follows. In each calendar year in which the MAA was not in effect for any part of such year, the Annual Purchase Target for the applicable Bio Product for which the MAA was lost shall be reduced in the affected countries pro-rata based upon the duration of the loss as a percentage of the duration of the calendar year. The Parties acknowledge that such loss is a serious obstacle to conduct sales in such affected countries of the

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Territory and may have negative effects beyond the actual time period during which or Bio Product for which no MAA exists, however. Accordingly, Acutus will have the right to provide an estimate for the impact on the sales on Bio Product beyond such adjustment and request an additional reduction of the Annual Purchase Targets. The Parties will discuss in good faith the impact of Biotronik's loss of the MAA, and each Party will attempt in good faith to reasonably resolve issues caused by the loss collaboratively with the other and to minimize adverse impact on Bio Product sales. For clarity, adjustments to Annual Purchase Targets beyond the automatic adjustment described in this paragraph above will be made solely as mutually agreed.

(d) Biotronik, as of the Effective Date, is contractually obligated to Third Parties in a manner that prevents Biotronik from adding the entire countries of [\*\*\*\*] to the Territory on the Effective Date. As a result, Biotronik shall use reasonable efforts to terminate such contractual obligations within one year after the Effective Date. [\*\*\*\*] shall only be deemed added to the Territory on the termination of all the respective obligations towards Third Parties in the respective country. If the respective obligations in such a country cannot be terminated with effect for the entire country or for all customers in that country, but solely with effect for parts of a country or specific accounts of the country or some customers in that country, the respective country shall be added to the Territory, but any distribution of Bio Products under this Agreement in [\*\*\*\*] shall be subject to Biotronik's remaining obligations to Third Parties in that country that have been communicated to Acutus. If a Third Party is only willing to terminate a relevant obligation towards Biotronik against payment, Biotronik may offer Acutus to reimburse Biotronik for such payment and may terminate such Third Party obligations if Acutus undertakes in writing, prior to such termination, to reimburse Biotronik for such payment. Biotronik will keep Acutus reasonably informed of steps and progress made to add [\*\*\*\*] to the Territory.

## 2.4 Exclusive Distributorship of Bio Products

(a) If and for as long as Acutus has an exclusive distribution right for certain Bio Products in the U.S. or in China pursuant to Section 4.2.3(b) or Section 4.2.4(b), and if and for as long as Acutus has an exclusive distribution right for certain Bio Products in any other country within the Territory pursuant to Section 4.2.2, respectively, Biotronik and its Affiliates will, for the duration of such exclusive distribution right, not appoint or maintain any other distributor for these countries and will not allow any Third Party to make sales of the relevant Bio Products (in any configuration) in or into such countries where an exclusive distribution right is granted by Biotronik.

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- (b) If a Competing Company acquires control of Acutus, and if such Competing Company distributes at or after the closing date of the respective Change of Control a Competing Product or a series of Competing Products which competes with (i) the Bio Product or Bio Products covered by the respective IDE clinical study according to Section 4.2.3(b) or Section 4.2.4(b) respectively or (ii) the relevant Bio Product according to Section 4.2.2(c); then the respective exclusive distribution rights of Acutus shall immediately become non-exclusive distribution rights. For the avoidance of doubt, Acutus' exclusivity will only terminate with respect to the Bio Product with which such Competing Product competes and only in the country in which the Competing Company is distributing the Competing Product, and Acutus will retain a non-exclusive distribution right for the relevant Bio Product for the remaining term of this Agreement. Any other Change of Control shall not affect Acutus' exclusive distribution rights. As an example, if a Competing Company acquires Acutus but does not distribute an irrigated RF catheter with an FDA approved indication for use in paroxysmal atrial fibrillation at the time of the acquisition, then Acutus' exclusive right to distribute the corresponding Bio Product remains in place (until such time and in such country as such Competing Company distributes a Competing Product to such Bio Product).
- (c) Biotronik, its Affiliates, and their distributors for the duration of such exclusive distribution right, shall not sell or represent the relevant Bio Products in or into countries where Acutus has an exclusive distribution right.

## 2.5 Sales Outside the Territory

Acutus will not, and will cause its Affiliates and Sub-Distributors not to, (i) conduct sales of or accept orders for Bio Products outside the Territory; or (ii) sell the Bio Products to any Third Party if Acutus or its Affiliate knows or should know, in the exercise of good faith business judgement and without the need to investigate, that such sale will result in the distribution of any Bio Product outside of the Territory. In the case of each of (i) and (ii), Acutus, its Affiliates and Sub-Distributors remain free to sell Bio Products into all countries in the EU/EEA, UK, and Switzerland except as otherwise provided in Section 2.3(d).

#### 2.6 Status of Acutus

- (a) The relationship between Acutus and Biotronik will be that of independent contractors. Nothing contained in this Agreement will be construed to imply a joint venture or principal-agent relationship between the Parties.
- (b) Acutus will act in its own name and for its own account. All financial obligations associated with the business of Acutus are the sole responsibility of Acutus.

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- (c) Neither Party has nor will hold itself out as having any right, power or authority to create a contract or obligation, whether either expressed or implied, on behalf of, in the name of or binding on the other Party.
- (d) Acutus, its Affiliates, and their Sub-Distributors have and shall have the right to use sales representatives and agents in connection with marketing, sales and support of Product in the Territory, including to perform, support, enable and facilitate all aspects of customer interaction and engagement.

## 2.7 Sub-Distributors

- (a) Acutus may appoint third-party sub-distributors in countries in the Territory other than those in the EEA/EU, UK and Switzerland (together the Sub-Distributors), such appointment to be made solely with the prior written consent of Biotronik, which will not be unreasonably withheld, provided that Acutus does not have a sales force in the country, the scope and duration of rights (including exclusivity) granted to Sub-Distributors does not exceed the scope or duration of rights granted to Acutus under this Agreement and the agreements with Sub-Distributors are subject to the same rights of termination and conversion by Biotronik as Acutus' rights. Acutus shall be responsible for the actions and inactions of its Affiliates and Sub-Distributors in connection with this Agreement as if such actions and inactions were by Acutus. It shall be considered reasonable for Biotronik to withhold consent based upon any good faith questions or concerns in Biotronik's reasonable business judgement. For clarity, no MAA for a Bio Product will be owned or controlled by a Sub-Distributor except to the extent Biotronik expressly indicates that the Sub-Distributor is authorized to own or control the MAA in such written approval by Biotronik.
- (b) Acutus will impose terms on its Sub-Distributors that are materially as protective of Biotronik as the following terms in this Agreement:
  - (i) the terms in Sections 2.1(c), 2.2(e), 2.5, 2.6, 3.1, 3.2, 3.3, 3.4, 3.6, 3.7, 3.8, 3.9, 3.10, and Biotronik's rights to make changes to, discontinue, and remove Products;
  - (ii) subject to Biotronik's obligations under Section 3.11, Acutus will be solely responsible for ensuring Sub-Distributors have sufficient training;
  - (iii) the terms in Section 4, including those obligations of Acutus regarding quality, regulatory and compliance and in the Quality Management Agreement;

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- (iv) the terms in Section 5.7(b) and the obligation not to modify Products according to Section 5.8;
- no Product shall display branding, labelling, or the like of any Sub-Distributor without the prior written approval of Biotronik;
- (vi) the warranty exclusions and remedy limitations in Section 5.11;
- (vii) the terms in Sections 6, 7.3, 8, 9, 10, 11, and 13; and
- (viii) Sections 12.1, 12.2 (excluding 12.2(d)), and Section 12.3.

#### 2.8 Resale Prices

Acutus is free to determine the resale prices for the Products.

## 2.9 Bio Products

## 2.9.1 Range of Bio Products

The Bio Products available for purchase from Acutus under this Agreement are specified in <u>Annex 2.1</u>.

## 2.9.2 Bio Products Changes

- (a) Acutus may submit to Biotronik non-confidential written proposals for changes to Bio Products and the Product Specifications. These proposals will be promptly reviewed in good faith and, if approved by Biotronik, adopted by Biotronik. Biotronik will advise Acutus in writing of acceptance or rejection of the proposed changes and additional costs and expenses involved with implementing accepted changes (if any). The Parties shall agree on the allocation of costs and expenses for such changes prior to the implementation of such changes to the Bio Products.
- (b) No later than the time at which Biotronik first communicates with a Regulatory Authority or other Government Authority about a change or issue, but subject to Section 2.9.2(e) and in each case excluding changes to the extent implemented without prior notice or approval being required to a Regulatory Authority, Biotronik will inform Acutus in writing of any:
  - (i) intended design change that affects the form, fit or function of Bio Products;
  - (ii) intended change of clinical indication, contraindication or intended use of Bio Products;

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- (iii) intended changes that require a change of the Product Specification; and
- (iv) intended change of Bio Products that is visible to the user of the Bio Products (including labelling and packaging);
- (v) any other intended changes, including to manufacturing of a Bio Product, that Biotronik concludes will require a regulatory notice, submission or approval;

it being understood that with respect to the OEM Products such notice can be provided by Biotronik to Acutus only upon being informed of such change by the Third Party manufacturer of the applicable OEM Products.

- (c) Unless changes to Bio Products notified to Acutus pursuant to Section 2.9.2(b) are rejected by Acutus in writing on reasonable grounds within thirty (30) days from receipt of notification, stating its reasons, these changes will be deemed accepted by Acutus. If notified by Acutus of rejection of a change in accordance with this Section 2.9.2(c), Biotronik, subject to Section 2.9.2(e), will continue to provide the unchanged Bio Products until the earlier of (i) obtaining MAA for such changed Bio Products or (ii) eighteen (18) months after rejection by Acutus, and in no event (other than as described in Section 2.9.2(e)) for a longer period of time then necessary to serve tenders; provided that Acutus shall transition each customer to the updated Bio Product as soon as possible and in all cases such transition shall be completed within such eighteen (18) month period.
- (d) Acutus acknowledges that with respect to OEM Products, such legacy OEM Products can be supplied by Biotronik to Acutus only for as long as Biotronik is able to procure supply of such OEM Products from the applicable OEM manufacturers.
- (e) Acutus acknowledges and agrees that in the event Biotronik, acting in good faith, considers it necessary to change a Bio Product on notice shorter than that set forth in Section 2.9.2(b) or 2.9.2(c) (i) due to unforeseeable material sourcing problems that Biotronik has reasonable grounds to believe will create undue risk of safety or quality issues or of a violation of regulation or applicable law or other supply disruption, and/or (ii) due to unforeseeable changed regulatory requirements, then Biotronik will nonetheless notify Acutus in writing of the change and issue as early as reasonably possible, and in all cases no later than the time at which Biotronik first communicates with a Regulatory Authority or other Government Authority about the change or issue. Biotronik will discuss its reasons for such a change or issue reasonably with Acutus and will provide to Acutus the information set out in Section 2.9.2(b). Notwithstanding anything to the contrary, Biotronik is under no obligation to

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provide Bio Products to Acutus for which Biotronik has notified Acutus in accordance with this Section 2.9.2(e), or for which Biotronik requires suspension under Section 8.4.2(c), for as long as the relevant change or issue is not resolved, and provided that Biotronik uses commercially reasonable efforts to resolve the change or issue (or discontinues the Bio Product in light of the significance of the issue). In the event of such changes or issues, (i) the Parties will use good faith efforts to address and solve such situations in a mutually acceptable and reasonable manner, including good faith efforts to mitigate customer and partner impact, and (ii) Biotronik will have the right to issue binding instructions to Acutus regarding the Bio Products affected by such changes or issues that are reasonable in light of the issue(s).

(f) Prior to implementing any change in Bio Product units supplied to Acutus under this Agreement, Biotronik shall provide Acutus with the technical file for the applicable Bio Product reflective of such change.

#### 2.9.3 New Products

- (a) Subject to agreement by the Parties on applicable terms under this Section 2.9.3(a), improvements and successor products of Bio Products and new Biotronik products, in each case that fall within the Field will be added to <u>Annex 2.1(a)</u>, provided their application lies within the Field (together the **New Products In The Field**). Biotronik will promptly inform Acutus of New Products In The Field and submit to Acutus specifications of New Products In The Field. The Parties will in good faith negotiate in an effort to agree upon the terms applicable to the New Products In The Field which may include terms of the type set out under Sections 2.3 and 3.11. Notwithstanding anything to the contrary, neither Party will have any further obligation under this Agreement with regard to any New Product in the Field if the Parties fail to reach agreement on such terms within thirty (30) days.
- (b) Biotronik will inform Acutus of new or additional products of Biotronik for electroporation (ablation devices and/or catheters), single shot PV-isolation systems with any energy source (cryo, radiofrequency, heat, or laser), and left atrial appendage occluder devices (the **New Products Outside The Field**). If either Party wishes to add any such New Products Outside The Field to <u>Annex 2.1(a)</u>, that Party will inform the other Party accordingly, and they will in good faith negotiate in an effort to agree upon the terms applicable to New Products Outside The Field should the Parties agree these should be included in this Agreement. Biotronik will be under no obligation to agree to add New Products Outside The Field to <u>Annex 2.1(a)</u>, including if no agreement has been reached within thirty (30) days on the terms applicable to New Products Outside to New Products Outside The Field.

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(c) Notwithstanding anything to the contrary, this Section 2.9.3 shall not apply (i) in the event of a Change of Control of Biotronik, to require addition to this Agreement of any product not listed in <u>Annex 2.1(a)</u> at the time of the closing of the Change of Control of Biotronik; and (ii) in the specific country of the Territory, to require the addition of any product for which the other Party or its Affiliate is distributing a Competing Product.

## 2.9.4 Discontinued Products

- Biotronik reserves the right to discontinue Bio Products without replacement during the term of this Agreement, subject to Section 2.9.4(b) and provided a Bio Product will be considered "discontinued" only if Biotronik no longer manufactures the relevant Bio Product (and no longer has the relevant Bio Product manufactured by a Third Party for sale or distribution in the Territory) (each a **Discontinued Product**).
- (b) Excluding the changes pursuant to Section 2.9.2, if Biotronik intends to discontinue a Bio Product, Biotronik will notify Acutus no less than (i) thirty-six (36) months in advance of the intended discontinuation for the AlCath Bio Products and (ii) twelve (12) months in advance of the intended discontinuation for any other Bio Product, and the Parties will discuss in good faith a resolution for the discontinuation, which may (in the absence of issues of the type contemplated in Section 2.9.2(e)) include (i) a right for Acutus to place a reasonable final Individual Purchase Order for the Discontinued Product in order to fulfil its obligations from tender business; (ii) transferring the manufacture of the Discontinued Product to a manufacturing site of Acutus and allowing Acutus to continue the manufacture under a license or after sale of the Intellectual Property Rights necessary to manufacture the Discontinued Product; or (iii) an adjustment to Annual Purchase Targets pursuant to Section 3.5(i). Biotronik will, however, be under no obligation to accept any final Individual Purchase Order that seeks delivery beyond the period of time set forth in this Section 2.9.4(b) above (i.e., thirty-six (36) months for the AlCath Bio Products and twelve (12) months for any other Bio Product), to transfer manufacture to Acutus or any other party or to license or sell any Intellectual Property Rights to Acutus or any other party.
- (c) If Biotronik becomes aware of a discontinuation of an OEM Product, Biotronik will notify Acutus thereof promptly upon becoming aware of such discontinuation. The Parties will discuss in good faith a reasonable resolution for such discontinuation. Biotronik shall use commercially reasonable efforts to procure from the applicable Third Party manufacturers the longest possible continuing supply period for such discontinued OEM Products, provided that Biotronik may increase the prices for the OEM Products to be paid by Acutus accordingly as necessary to maintain Biotronik's existing margin.

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## 2.9.5 Removed Products

- (a) If Acutus or any of its Affiliates (or a Sub-Distributor) distributes a Competing Product in any country in the Territory (irrespective of whether Acutus or its Affiliates or the Sub-Distributor have developed such Competing Product, have acquired such Competing Product from a Third Party, or such Competing Product is otherwise distributed by Acutus or its Affiliates or a Sub-Distributor), Biotronik will have the right to remove any Bio Product with which the Competing Product competes from <u>Annex 2.1(a)</u> with effect for each of the countries within the Territory where the Competing Product is distributed (a **Removed Product**).
- (b) Biotronik will inform Acutus in writing of removal under Section 2.9.5(a). While Acutus will not be required to delay any removal, the Parties will negotiate in good faith in an effort to agree upon the consequences of such removal, which may include a transition period in which Acutus retains nonexclusive rights if required to serve tenders and provide seamless customer support provided that Section 12.3.4 will apply by analogy if the Parties cannot reach agreement.
- (c) Upon removal of a Removed Product from <u>Annex 2.1(a)</u>, Acutus will (and will cause its Affiliates and Sub-Distributors to), at no cost or expense to Biotronik, assign and transfer all right, title and interest in and to any and all Marketing Authorization Approvals Acutus or its Affiliate or their Sub-Distributor may own or hold for such Removed Products to Biotronik or Biotronik's Affiliate or designee, subject to applicable regulatory requirements.
- (d) For the avoidance of doubt, Biotronik will have the right but not the obligation to distribute (and authorize Affiliates and third parties to distribute) Removed Products in each country in the Territory for which the Removed Product was removed, including countries where the relevant Competing Product is distributed.

## 3. Sales Promotion

## 3.1 Principles Governing Sales Promotion

(a) Commencing with Marketing Authorization Approval for a Bio Product in the respective country in the Territory or, if the Marketing Authorization Approval exists in the respective country as of the Effective Date, commencing on the Effective Date, and with respect to the relevant Bio Products that do not require Marketing Authorization Approval for distribution, Acutus and its Affiliates will use commercially reasonable effort to:

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- (i) promote and increase the sales of that Bio Product in such country in the Territory; and
- (ii) maintain and enhance the reputation and acceptance of such Bio Product in such country in the Territory.
- (b) Acutus will distribute the Bio Products in each country in the Territory and provide sales and customer training, product support and field clinical support, carry out price negotiations with customers, submit tender offers, and provide first line service (first level support) that offers, *inter alia*, trouble shooting, subject to the provisions of this Agreement regarding Biotronik's support of Bio Products to be provided to Acutus, all consistent with Section 3.1(a).
- (c) Except as otherwise provided in this Section 3, and except to the extent the Parties have agreed to share costs under Section 2.3(a), Acutus will bear all costs and expenses for Acutus to comply with the obligations under this Section 3, including costs and expenses for sales promotion, marketing, advertising, workshops, sales meetings, seminars, conventions, or exhibitions.

## 3.2 Sales Organization

Acutus will set up and maintain an adequate sales organization and after-sales services (including first level support and second level support, as the case may be), with all means and personnel necessary to ensure the fulfilment of its obligations under this Agreement for all Bio Products in each country in the Territory, all consistent with Section 3.1(a).

## 3.3 General Compliance

Without prejudice to any other obligations under this Agreement, Acutus will comply with all legal and technical requirements that apply or have to be observed in any country in the Territory in respect to the distribution of the Products.

#### 3.4 Annual Business Plan Session

In each September, or at such other time as mutually agreed to by the Parties, the Parties will together conduct an annual face-to-face business plan session, unless the Parties agree that such session can be conducted via teleconference (the Annual Business Plan Session). During the Annual Business Plan Session, the Parties will, without limitation and all consistent with Section 3.1(a):

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- (i) review Acutus' performance in the past year, including sales promotion of Bio Products in each country throughout the Territory, as well as the Parties' expectations for the next calendar year;
- (ii) discuss Acutus' marketing program for the next calendar year;
- (iii) discuss and possibly renegotiate the Annual Purchase Targets pursuant to Section 3.5(b);
- (iv) discuss and possibly renegotiate the Prices pursuant to Section 5.9(c) and
- (v) review and discuss Affiliates and the Sub-Distributors performance, including with respect to the foregoing (except for pricing information, which may be redacted or omitted).
- (b) In addition, the Parties will review performance anytime on a Parties' reasonable request or at agreed times.

## 3.5 Annual Purchase Targets

- (a) For the time after the end of the respective Ramp-Up Periods, the Parties will agree on country-specific annual purchase targets for each country in the Territory for the total aggregate quantity of all AlCath Bio Product, Multicath Bio Product, and ViaCath Bio Product to be purchased by Acutus from Biotronik for that country in the Territory (the Annual **Purchase Targets**) For clarity, Annual Purchase Targets do not apply during the Ramp-Up Period.
- (b) The Annual Purchase Targets will be established jointly by the Parties, consistent with Section 3.1(a), taking into account market conditions, cardiac mapping and ablation therapy development, the competitive environment, clinical acceptance of the AlCath Bio Product, Multicath Bio Product, and ViaCath Bio Products, reimbursement, and all other factors related to the AlCath Bio Product, Multicath Bio Product, and ViaCath Bio Product, including functionality, quality, and availability. A non-binding, preliminary example of country-specific Annual Purchase Targets for the AlCath Bio Product, Multicath Bio Product, and ViaCath Bio Product is provided in <u>Annex 3.5</u>. If the Parties have not agreed on the Annual Purchase Targets for a given or several countries for the first year after the Ramp-Up Period, the Annual Purchase Targets for the countries for such year will be the total aggregate quantity of AlCath Bio Product, Multicath Bio Product, and ViaCath Bio Product, and ViaCath Bio Product set forth in <u>Annex 3.5</u> for the particular country.
- (c) At the Annual Planning Session prior to the end of each calendar year, the Parties will annually renegotiate in good faith the Annual Purchase Targets for

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the next calendar year for the total aggregate quantity of AlCath Bio Product, Multicath Bio Product, and ViaCath Bio Product to be purchased by Acutus from Biotronik for each country in the Territory in that next calendar year, consistent with Section 3.1(a). If the Parties cannot agree to the Annual Purchase Targets for a given or several countries prior to the beginning of a calendar year, the Annual Purchase Targets for that year will be increased by fifteen percent (15 %) in each country of the Territory, as compared to the Annual Purchase Targets to the preceding calendar year.

- (d) If any of the following occurs, then Acutus shall have the right to notify, and initiate discussions with, Biotronik in accordance with Section 3.5(i):
  - (i) Biotronik ceases to provide Bio Products under Section 2.9.2(e);
  - (ii) Bio Products are discontinued under Section 2.9.4;
  - (iii) Bio Products are removed under Section 2.9.5;
  - (iv) Bio Products that Biotronik is obligated to supply under this Agreement are not available for order by Acutus from Biotronik in accordance with this Agreement due to a material breach of this Agreement by Biotronik.
  - (v) Bio Products are otherwise not available for order for any reason that is unavoidable, unforeseeable, outside the reasonable control of Acutus or Acutus' Affiliates due to Biotronik's material breach of this Agreement.
- (e) Acutus will provide to Biotronik no later than January 15<sup>th</sup> of each calendar year a report indicating for the respective Bio Products the quantity of each such Bio Product sold to customers and to and by Sub-Distributors during the previous calendar year, broken down by quantity of each Bio Product distributed in each country.
- (f) Annual Purchase Targets are deemed to be met if, on a country-by-country basis, Acutus has placed Individual Purchase Orders for at least the total aggregate quantity of the AlCath Bio Product, Multicath Bio Product, and Via- Cath Bio Product required for the respective country of the Territory during the respective calendar year. Units of Bio Products provided as a repair or replacement by Biotronik under warranty or service will not be counted as an additional unit, and demonstration units will not be counted, toward the Annual Purchase Targets.
- (g) If any of the following occurs, then Acutus shall have the right to notify, and initiate discussions with, Biotronik in accordance with Section 3.5(i):

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- (i) Bio Products were not delivered within the Lead Time from receipt of the respective Individual Purchase Order pursuant to Section 5.3 as a result of a breach by Biotronik of its obligations under this Agreement;
- (ii) Bio Products were not delivered by Biotronik in the calendar year(s) in which Biotronik was obligated to deliver the Bio Products under Section 5.3(d) in breach of Biotronik's obligations under this Agreement;
- (iii) Bio Products have been properly rejected in accordance with Section 5.5(c) and are not remedied by Biotronik in accordance with this Agreement;
- (iv) Individual Purchase Orders have been cancelled in accordance with Section 5.6(c);
- (v) Bio Products have not all been free from defects in accordance with Section 5.11.1(a) and are not remedied by Acutus in accordance with this Agreement;
- (vi) Biotronik has required Acutus to suspend shipment of Bio Products under Section 7.3(e);
- (vii) Biotronik has suspended or terminated Bio Products under Section 8.4.2(c);
- (viii) any other material breach by Biotronik of its obligations in this Agreement have interfered with Acutus' ability to sell Bio Products, including the obligations under Section 3.11 and 3.12; or
- (ix) Bio Products have not been sold by Acutus due to a Force Majeure event.
- (h) If, for any country in the Territory, Acutus fails to meet the total aggregate quantity of Annual Purchase Target for the AlCath Bio Product, Multicath Bio Product, and ViaCath Bio Product in such country during each of any three (3) consecutive calendar years after the end of the respective RampUp Period, Biotronik shall have the right to terminate this Agreement for the relevant country in the Territory for all Bio Products, on condition that the Parties have not agreed on a remediation plan within thirty (30) days after the end of the third consecutive calendar year. The Parties will transition distribution of Products to Biotronik in accordance with the terms of this Agreement.
- (i) If an issue of the type described Section 3.5(d) or 3.5(g) occurs that is caused by a material breach by Biotronik of its obligations under this Agreement and that Acutus believes is materially adversely impacting the efforts of Acutus to scale up sales, marketing or commercialization during the Ramp-Up Period or

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to meet Annual Purchase Targets, then Acutus will have the right to provide written notice to Biotronik, reasonably describing the issue. The Parties will meet within thirty (30) days after such notice to Biotronik to discuss the issue(s), the details of the impact on Acutus, and the extent to which any Ramp Up Period or Annual Sales Targets should be adjusted as a result of the issue. Acutus will be responsible for substantiating the extent of the impact. Each Party will reasonably discuss and consider the information provided by Acutus in evaluating whether or not the Annual Purchase Target should be reduced and each Party will attempt in good faith to identify a reasonable resolution of issues, provided that adjustments will be made solely as mutually agreed.

### 3.6 Marketing

- (a) Acutus will advertise and promote the Bio Products at its own cost and expense in each country throughout the Territory, consistent with Section 3.1(a), as follows:
- (b) Acutus will clearly demonstrate in all its marketing and communication that it acts as an independent distributor of the Bio Products and does not act on behalf of Biotronik.
- (c) Each Party will bear the marketing expenses it has incurred, unless agreed otherwise.
- (d) Acutus will submit all documents concerning advertising, promotion of sales, public relations or product information that it intends to use in relation to the distribution of the Products under this Agreement to Biotronik for prior approval, which will not be unreasonably withheld or conditioned Acutus will make sure that all pricing information in such material is blackened prior to submission to Biotronik. Biotronik will approve or reject each such submission within thirty (30) Business Days, otherwise such submission will be deemed approved by Biotronik.
- (e) Acutus will independently participate in the main international congresses, fairs and industry events in the Field, and may independently participate in any other congresses, fairs and industry events. In each case the Parties will use commercially reasonable efforts to coordinate their participation and presence.
- (f) On Acutus' reasonable request Biotronik will participate in Acutus' national or regional electrophysiology sales meetings in the Territory. Biotronik will bear its own costs and expenses (including for travel, food and accommodation) for participating in such sales meetings.

## 3.7 Information to Biotronik

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- (a) Acutus will keep Biotronik informed about its activities as distributor of the Products, about the number of sales of the Bio Products and about market conditions in each country in the Territory. Biotronik will provide reasonable responses to reasonable requests by Biotronik for information.
- (b) Acutus will use reasonable efforts to keep Biotronik informed about significant changes in:
  - (i) the laws and regulations that apply to obtaining any MAA (to the extent Acutus is responsible for obtaining the MAA) or the sale of the Bio Products in the Territory (without limitation import regulations, labelling, technical specifications, and safety requirements) of which Acutus becomes aware, and
  - (ii) the laws and regulations concerning Acutus' activity (e.g. regarding any permits, MAAs that Acutus is responsible for obtaining, or reporting or record keeping requirements associated with such MAAs) of which Acutus becomes aware, as far as they are relevant for Biotronik.

### 3.8 Stocks and Expired Bio Products

Acutus will,

- (a) at its own expense, perform stock keeping in accordance with the Quality Management Agreement and keep a balanced inventory of Products in quantity and assortment sufficient to meet customer demand in each country in the Territory; and
- (b) not sell any Products beyond the use-by-date indicated on the respective Products.

## 3.9 Insurance

Each Party will secure and maintain in effect, during the term of this Agreement, comprehensive general liability insurance, underwritten by a reputable insurance carrier, in a form and with liability limits as are standard and customary for entities in the medical device industry in each country within the Territory, taking into account such Party's activities and indemnification obligations under this Agreement. Each Party will provide the other Party with written evidence of such insurance promptly on request.

#### 3.10 After-Sales Services

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Subject to the terms and conditions of this Agreement that require Biotronik to provide repair or replacement for Products, including the applicable warranty terms, and conditional upon Acutus having received sufficient training by Biotronik pursuant to Section 3.11, Acutus will be responsible for providing all after-sales customer service to the extent mutually agreed.

## 3.11 Training

- (a) Biotronik will provide Acutus at no cost to Acutus with initial training support sufficient to enable Acutus to train its own employees and representatives (and those of its Affiliates and any Sub-Distributors and agents) regarding use of the Products as necessary to enable Acutus to perform its obligations under this Agreement, including distributing the Products in accordance with this Agreement, and developing customers into proficient Products users. It is agreed that Biotronik provides trainings to the initial Acutus personnel in the same quality as for Biotronik's own personnel. Subject to Acutus making such personnel available for such activities, Biotronik shall test, qualify and certify the successful trainings of the initial Acutus personnel. The details of the training sufficient to meet Biotronik's obligations shall be reasonably agreed by the Parties prior to Biotronik commencing the training. Acutus will bear all costs and expenses (for travel, food, accommodation etc.) of Acutus and its employees in connection with their attendance to such initial training support.
- (b) Any additional training will be subject to the Parties' agreement. Unless agreed otherwise in writing, all reasonable costs and expenses (for travel, food, accommodation etc.) of Biotronik and its employees in connection with such additional training will be reimbursed by Acutus subject to Acutus applicable reimbursement conditions. Acutus will bear any costs and expenses of its employees in connection with such additional training.

#### 3.12 Documentation and Specimens

(a) Without prejudice to any of Biotronik's other obligations under this Agreement, Biotronik will provide Acutus with a reasonable number of samples of the available documentation relating to the Products reasonably needed (and requested) by Acutus to carry out its obligations under this Agreement (such as marketing material, user manuals etc.). In particular, Biotronik hereby grants Acutus the rights to the brochures relating to the Bio Products, Clinical Data relating to the Bio Products that has been generated by or under the authority of Biotronik to the extent necessary for Acutus to obtain an MAA, advertising and selling information and promotional literature relating to the Bio Products, as reasonably requested by Acutus and in control of Biotronik, at no additional cost to Acutus, as necessary for Acutus to market and distribute the Bio

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Products and otherwise exercise its rights and perform its obligations under this Agreement; it being acknowledged that Acutus shall be responsible for obtaining and generating information, materials and data not provided by Biotronik if and to the extent such information is not necessary to be provided by Biotronik or an OEM manufacturer as the legal manufacturer of the Products. Biotronik will pass on to Acutus the available documentation and information relating to the OEM Products which Biotronik receives from the OEM manufacturers necessary for the distribution of OEM Products.

- (b) Acutus will, at its own costs and expense, translate any materials into local language and into Acutus' branding with the private label product names, if applicable. Any use, disclosure or distribution of any brochures, Clinical Data, advertising and sales information and promotional literature produced by Acutus will require approval by Biotronik, which will not be unreasonably withheld or delayed. Biotronik will approve or reject such materials submitted by Acutus within thirty (30) Business Days, otherwise such submission will be deemed approved by Biotronik.
- (c) Biotronik will provide Acutus with non-functional non-sterile specimens of each Product to be used for promotional purposes at a price to be agreed by the Parties. Acutus will not resell such specimens and will return them to Biotronik if no longer needed.

# 4. Quality, Regulatory and Compliance

### 4.1 Quality Management

The Parties will enter into the Quality Management Agreement as attached as <u>Annex 4.1</u> on or before the Effective Date. The Quality Management Agreement will govern all communication and interaction between Acutus and Biotronik with regard to quality management, change management, regulatory compliance and reporting, preventive and corrective action including field safety corrective action. In case of any conflict between any provision of this Agreement and any provision of the Quality Management Agreement, the provision of the Quality Management Agreement will prevail.

## 4.2 Marketing Authorization Approvals

#### 4.2.1 Principles Governing Marketing Authorization Approvals

(a) Biotronik will, directly or through its Affiliates, file, secure, own and hold at its own cost and expense all Marketing Authorization Approvals for the Bio Products in the Territory under this Agreement.

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- (b) Biotronik will own all right, title and interest in and to any and all Marketing Authorization Approvals in the Territory for Bio Products if Biotronik has, in full or in part, undertaken and paid for obtaining a given Marketing Authorization Approval.
- (c) Notwithstanding the foregoing if the applicable laws and regulations in any country require that any MAAs for any Bio Products are owned and/or held in the name of Acutus in order to enable Acutus to exercise its rights under this Agreement for such Bio Products in such country, then such MAAs shall be owned and/or held in the name of Acutus, subject to Acutus' obligations to transfer such MAAs to Biotronik upon termination of Acutus' rights applicable to such Bio Products in such country as set forth in this Agreement.
- (d) Unless otherwise provided in this Agreement, Biotronik will use commercially reasonable efforts to seamlessly maintain in its own name and on its own expense any Marketing Authorization Approvals for the Bio Products in each country in the Territory that have been issued to Biotronik as of the Effective Date or at any time thereafter, to the extent necessary for Acutus to distribute the Bio Products under this Agreement.
- (e) Prior to the Effective Date, Biotronik will inform Acutus of all Marketing Authorization Approvals that it has for each Product and provide Acutus with a copy of the respective certificates. In addition, Biotronik will promptly (within five (5) Business Days) inform Acutus of any withdrawal or expiration without renewal of any such Marketing Authorization Approvals.

### 4.2.2 New Marketing Authorization Approvals in Countries of the Territory other than the U.S. and China

- (a) If Biotronik does not own or hold a Marketing Authorization Approval for a Bio Product in a country of the Territory (other than the U.S. or China), directly or through its Affiliates, and Acutus intends to distribute that Bio Product in the relevant country, Biotronik will, at its own cost and expense and subject to regulatory requirements, use commercially reasonable efforts to obtain a Marketing Authorization Approval for the relevant Bio Product in the relevant country. Acutus will inform Biotronik in writing if it intends to distribute a Bio Product in a country of the Territory (other than the U.S. and China) where Biotronik does not own or hold a Marketing Authorization Approval for such Bio Product.
- (b) If Clinical Trials are required in order to obtain or maintain Marketing Authorization Approval in a country of the Territory (other than the U.S. and China), the Parties will negotiate in good faith a clinical study plan that defines the responsibilities of the Parties with respect to such Clinical Trial, the

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allocation of resources to the planning, execution and evaluation, and the cost sharing for such Clinical Trial.

(c) If Biotronik, directly or through its Affiliates, does not own or hold a Marketing Authorization Approval for a Bio Product in a country of the Territory other than the U.S. or China and does not obtain Marketing Authorization Approval in accordance with this Section 4.2.2, Acutus will have the right to obtain Marketing Authorization Approval for the relevant Bio Product in the relevant country at its own cost and expense. Biotronik will inform Acutus in writing if it does not intend to seek Marketing Authorization Approval for the relevant Bio Product in the relevant Bio Product in the relevant country at its own cost and expense in accordance with this Section, the Parties will negotiate in good faith additional preferential rights that may apply to such Bio Product in such country, which may include exclusivity rights similar to those granted to Acutus under Sections 4.2.3(b) and 4.2.4(b) under similar circumstances. However, Biotronik shall be under no obligation to grant any such exclusivity rights.

#### 4.2.3 Marketing Authorization Approvals in the U.S.

- (a) Acutus will, at its own cost and expense and subject to regulatory requirements, use commercially reasonable efforts to develop and execute a Marketing Authorization Approvals strategy for the Bio Products in the U.S. in such a way that Biotronik, directly or through its Affiliates, will be the owner and holder of these Marketing Authorization Approvals. Biotronik will share all technical documentation reasonably necessary for Acutus to obtain MAAs in the U.S. For the avoidance of doubt, Biotronik will own all right, title and interest in and to any such Marketing Authorization Approval.
- (b) If an IDE clinical study is required in order to obtain Marketing Authorization Approval in the U.S. for a Bio Product, including all configurations of the Bio Product, Acutus will bear all cost and expense of the respective IDE clinical study. Biotronik will provide Acutus with the quantity of such Bio Product necessary for such IDE clinical study free of charge. Provided that such IDE clinical study (enrollment plus follow-up) is completed within three (3) years of the Effective Date (as such date may be extended upon mutual agreement of the Parties upon Acutus' reasonable request and backed by evidence in the event of certain extenuating circumstances outside of Acutus' reasonable control, such as regulatory authority delays, study subject enrolment issues and events attributable to clinical site performance), Acutus' right to distribute the relevant Bio Product in the U.S. will be exclusive for the shorter of (i) a period of five (5) years after the date of the respective Marketing Authorization Approval by the FDA or similar Governmental Authority, or (ii) the remaining period of the Initial Term. The Parties agree that, as a result of

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the COVID-19 pandemic, the Parties will meet within twelve (12) months after the Effective Date to discuss whether Acutus' obligations to obtain MAA within the United States within three years after the Effective Date should be extended due to the effects of the COVID-19 pandemic.

### 4.2.4 Marketing Authorization Approvals in China

- (a) Acutus will, at its own cost and expense and subject to regulatory requirements, use commercially reasonable efforts to develop and execute a Marketing Authorization Approvals strategy for the Bio Products in China in such a way that Biotronik, directly or through its Affiliates, will be the owner and holder of these Marketing Authorization Approvals. Biotronik will share all technical documentation reasonably necessary for Acutus to obtain MAAs in China. For the avoidance of doubt, Biotronik will own all right, title and interest in and to any such Marketing Authorization Approval.
- (b) If a clinical study is required in order to obtain Marketing Authorization Approval for a Bio Product in China, Acutus will bear all cost and expense of the respective clinical study. Biotronik will provide Acutus with the quantity of such Bio Product necessary for such clinical study free of charge. Provided that such clinical study (enrollment plus follow-up) is completed within four (4) years of the Effective Date, Acutus' right to distribute the relevant Bio Product, including all configurations of the BIO Product, in China will be exclusive for the shorter of (i) a period of five (5) years after the date of the respective Marketing Authorization Approval by the respective Chinese Governmental Authority, or (ii) the remaining period of the Initial Term. The Parties agree that, as a result of the COVID-19 pandemic, the Parties will meet within twelve (12) months after the Effective Date to discuss whether Acutus' obligations to obtain MAA within China within three years after the Effective Date should be extended due to the effects of the COVID-19 pandemic.

### 4.2.5 Sale or Import without Marketing Authorization Approval

Biotronik will not sell or import any Products into countries or regions without Marketing Authorization Approval if such Marketing Authorization Approval is required by applicable law. Acutus will have no responsibility for any such sales or imports.

### 4.3 Clinical Trial Coordination

(a) Biotronik will have the right to undertake Clinical Trials whether or not necessary to obtain Marketing Authorization Approvals in relation to the Bio Products at any time and in any jurisdiction and territory, with the exception of those Bio Products in the U.S. and China for which Acutus has exclusive

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distribution rights pursuant to Section 2.4 and in those countries in which Acutus obtains the right to undertake Clinical Trials in relation to the Bio Products pursuant to Section 4.2.2. Biotronik will inform Acutus of its Clinical Trial plans and the Parties will coordinate and work together on the design, execution, analysis, regulatory submission and publication of clinical studies on the Bio Products and on the collection of Clinical Data required by applicable regulatory rules.

- (b) Unless agreed otherwise, Biotronik will bear full financial responsibility for these trials and all benefit resulting from such trials will accrue exclusively to Biotronik, and all Clinical Data and information in Regulatory Materials (including copyrights and trade secrets embodied therein) will exclusively belong to Biotronik; provided that Biotronik will share such Clinical Data with Acutus and Acutus shall have the right to use such data (including such copyrights and trade secrets) as reasonably necessary to exercise its rights under this Agreement.
- (c) Acutus may inform Biotronik of non-confidential ideas of customers concerning clinical studies and/or investigations and collection of Clinical Data related to the Bio Products or New Products. Biotronik will have the right but not the obligation to support and fund the study or data collection, in which case any and all rights in the Clinical Data will exclusively belong to Biotronik. If Biotronik decides not to exploit such customer ideas, Acutus will have the right to further develop such ideas and to conduct a Clinical Trial, in all cases solely upon Biotronik's prior written consent not to be withheld unreasonably.

#### 4.4 Government Reimbursement

In countries of the Territory where Biotronik has not developed or implemented and has no intention to develop or implement a plan for securing reimbursement for BIO Products, Acutus will, at its own cost and expense, develop and implement such plan. Biotronik will reasonably support Acutus in such plan, including providing Acutus with the information required in order to receive reimbursement approval.

# 5. Sales to Acutus

### 5.1 Terms of Sale

All sales of Products by Biotronik to Acutus will be pursuant to the terms and conditions of this Agreement. No other terms of either Party will apply, even if referenced or contained in an order, acknowledgement, acceptance or otherwise.

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### 5.2 Forecasts

- (a) Each calendar month, no later than by the fifth (5th) Business Day, Acutus will provide Biotronik with a rolling forecast for the immediately succeeding twelve (12) months period (i.e., commencing with the following calendar month). This forecast will be provided in writing and will specify the anticipated purchases for each Product for each calendar month covered by the forecast. A first forecast will be provided prior to signing on the Effective Date.
- (b) For each forecast, the volumes of Products forecasted for:
  - (i) the forecast for the immediately succeeding two (2) calendar months, i.e., months one (1) and two (2) covered by the respective forecast, will be binding;
  - (ii) the forecast for the two (2) calendar months following that period, i.e., months three (3) and four (4) covered by the respective forecast, will each not vary more by than twenty percent (20%) from the volumes forecasted for the respective calendar month in the last forecast; and
  - (iii) the forecast for the two (2) calendar months following that period, i.e., months five (5) and six (6) covered by the respective forecast, will each not vary by more than fifty percent (50%) from the amounts forecasted for the respective calendar month in the last forecast.

### 5.3 Order Process

- (a) Acutus will order the Products from Biotronik by issuing Individual Purchase Orders in writing to Biotronik. The terms and conditions of this Agreement, including Section 13.8, will apply to all supplies of Bio Products and, to the extent specifically referred to, to the OEM Products, to Acutus even if the Individual Purchase Order does not specifically refer to this Agreement.
- (b) Individual Purchase Orders will be in English. Acutus will be entitled to use its standard purchase order form to place Individual Purchase Orders, provided that the terms and conditions of this Agreement will control and no different, conflicting, or additional terms on Acutus' purchase order, Biotronik's acknowledgement, invoice, or similar document will apply. All additional and different terms on any document issued by either Party are hereby rejected and objected to. Each Individual Purchase Order will comply with the terms and conditions of this Agreement and will, in particular, contain the following information:
  - (i) name and part number of each Product ordered;

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- (ii) the quantity of each Product ordered;
- (iii) the requested delivery date, considering the Lead Times for each Product;
- (iv) any other instructions and terms (consistent with this Agreement) as may be appropriate under the circumstances.
- (c) Acutus will send the Individual Purchase Order to the address listed in this Agreement or to any other address communicated by Biotronik to Acutus from time to time. An Individual Purchase Order will be binding on Acutus on receipt of that Individual Purchase Order by Biotronik.
- (d) Biotronik will accept or refuse Individual Purchase Orders in writing within five (5) Business Days of receipt. Biotronik will accept Individual Purchase Orders that comply with the applicable Lead Times and with the volumes forecasted pursuant to Section 5.2, provided that the respective forecast complies with Section 5.2. Biotronik will only be bound upon acceptance of an Individual Purchase Order. Biotronik will use commercially reasonable efforts to accept Individual Purchase Order to the extent they reasonably exceed the applicable forecast. Any Individual Purchase Order that is not refused within five (5) Business Days of receipt will be deemed accepted.
- (e) In case of discrepancies between order and acceptance, Biotronik's acceptance will prevail, unless (i) the acceptance is not in accordance with this Agreement; or (ii) Biotronik's acceptance modifies the order in accordance with the terms of this Agreement and Acutus immediately objects in writing to the modifications. For the avoidance of doubt, Biotronik will be entitled, in particular, to adjust delivery dates in order to comply with Lead Times and to adjust quantities to typical packaging quantities or avoid splitting of production lots, provided the quantity to be delivered must not deviate more than five percent (5 %) from the ordered quantity for each Product.
- (f) Each Party may request changes of the delivery terms of an Individual Purchase Order, including the cancellation or rescheduling of an Individual Purchase Order. Any such requested change is subject to written agreement by the Parties. For the avoidance of doubt, only the final Individual Purchase Order, i.e. after any such changes, will be considered as ordered for all purposes of the Annual Purchase Targets.

## 5.4 Delivery Terms

(a) The Products will be delivered suitably packed for shipment in Biotronik's standard shipping cartons marked for shipment. Biotronik shall only ship OEM

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Products to Acutus for which Biotronik has carried out an optical inspection for transport damages but without opening the sterile packaging upon receipt of such OEM Products from the Third Party supplier.

- (b) Biotronik will deliver the Products according to FCA (Incoterms 2020) at a pick-up point in Germany designated by Biotronik to a carrier designated by Acutus. Biotronik will be entitled to designate different pick-up points for different Products, even if such Products have been ordered in one.
- (c) Acutus will obtain all export licenses and other governmental approvals required, if any. Acutus will obtain all import licenses, if any, and will comply with any legislation or regulations governing the importation of the ordered Products into the country of destination.

#### 5.5 Receipt of the Deliveries

- (a) Acutus will take delivery of the Products even in case of partial deliveries provided that all additional transportation costs and expense due to partial deliveries will be borne by Biotronik and that the Lead Times are complied with regardless of such partial deliveries.
- (b) Acutus will inspect each delivery of Products. Acutus will, in accordance with Section 5.11.3(a), give written notice within twenty (20) Business Days of the day of receipt by Acutus of the respective Products from the respective carrier of any:
  - (i) shortage or overage;
  - (ii) apparent defect or damage to any Products or non-conformity with the Product Specifications or the Individual Purchase Order.

However, Acutus will not be required to open sealed boxes or sterile packaging that would make the Products unusable, or to perform any testing that might destroy any Products.

(c) Acutus will have the right to reject any delivered Products if the use-by-dating indicated on the individual Products did not, on the date of actual delivery by Biotronik to the carrier pursuant to Section 5.4(b), correspond to the Shelf Life Period less two (2) months. Acutus will reject such Products in writing provided to Biotronik within twenty (20) Business Days of the day of receipt by Acutus of the respective Products from the respective carrier in writing. If Products are not rejected pursuant to this Section 5.5(c), they are deemed accepted with respect to their use-by date, quantities and absence of apparent defects or damage. Biotronik has no responsibility if the use-by date does not meet such

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requirement as a result of delays to the extent attributable to the carrier or Acutus.

(d) Acutus will not accept a visibly damaged delivery from the carrier without reservation. Furthermore, Acutus will properly document the damages and the circumstances in order to preserve the Parties' rights against the carrier and any insurance.

## 5.6 Late Delivery

- (a) Biotronik will notify Acutus promptly of expected delays of the ordered Products, in whole or in part, stating the reasons for and the estimated duration of the delay and proposed remediation measures.
- (b) Biotronik will be deemed to be in default if it fails to deliver the ordered Products of an Individual Purchase Order at the delivery date (or within the agreed delivery date range) which Biotronik is obligated to meet under Section 5.3(d), provided such failure is not caused in full or in part by any event under Acutus' control.
- (c) After twenty-five (25) Business Days of default, Acutus may cancel the respective Individual Purchase Order, in full or in part, except for Products already delivered, without liability of Acutus to Biotronik.

#### 5.7 Packaging and Labelling

- (a) Biotronik will supply the Products ready for sale in accordance with the Product Specifications. Biotronik will, at its own cost and expense, provide the Products with instructions for use and labelling in accordance with the Product Specifications.
- (b) If for any country of the Territory the instructions for use are required in a different language, Acutus will arrange for translation at its own cost and expense and Biotronik will review and release the translation in accordance with the provisions of its quality management system at its own cost and expense prior to the distribution in accordance with Sections 3.6 and 3.12.
- (c) The Parties acknowledge that Acutus has the right to distribute the Bio Products under Biotronik branding or the Acutus private label in the Territory, provided that Biotronik shall obtain a Marketing Authorization Approval for such branding or label as soon as reasonably possible (if required). Upon Acutus' request, the Parties will promptly discuss and agree upon the private label specifications for such Bio Products. Subject to an agreement by the Parties, Biotronik will adopt packaging, whereas Acutus agrees and

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acknowledges that for all packaging Biotronik will use white boxes, marking and labelling (including any box labels, pouch labels, instructions for use) of the respective Bio Products (but not the products themselves) to provide an Acutus "look-and-feel" by applying colors, Acutus' Trademarks, labels, labelling styles and other visual elements of Acutus' branding, subject to regulatory requirements in the respective countries and provided that Biotronik will act and will be labelled as the manufacturer of record of these Bio Products. Acutus will provide Biotronik its design requirements for the packaging, marking and labelling of the respective Bio Products and, subject to Biotronik's approval, the respective design requirements will be integrated in the Product Specifications.

#### 5.8 No Modifications to the Products

Acutus will not make any modification or alteration to the Products as delivered by Biotronik, including their packaging, their labelling or any product description without Biotronik's prior written approval. Notwithstanding the foregoing, Acutus may affix on all Products a label stating that the Products are distributed by Acutus, provided that such labels do not obscure in any way Biotronik's or the OEM manufacturers name, labelling, or branding for or on the Products.

## 5.9 Prices

- (a) The Products are sold by Biotronik to Acutus at the prices according to the price list in force at the time when the Individual Purchase Order is sent to Biotronik by Acutus (the **Prices**).
- (b) The price lists applicable on the Effective Date of this Agreement are attached as <u>Annex 2.1(a)</u> and <u>Annex 2.1(b)</u>.
- (c) The Prices set forth in <u>Annex 2.1(a)</u> and <u>Annex 2.1(b)</u> will be firm until 31 December 2020. The Parties will renegotiate in good faith the Prices annually for the following calendar year not later than by 30 September, for the first time until 30 September 2020 for the year 2021, considering, *inter alia*, manufacturing yield improvements and other applicable manufacturing cost reductions of Biotronik or its contract manufacturers. As a result of successful negotiations, an amended price list will be agreed and will become <u>Annex 2.1(a)</u> and <u>Annex 2.1(b)</u>. Such amended price list will become effective as of 1 January of the calendar year following agreement on the amended prices and will apply to all Individual Purchase Orders received by Biotronik after the effective date of the Price change. If no agreement is reached, the Prices of the preceding year will continue to apply.

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(d) Biotronik warrants, undertakes and represents that the Prices are, as of Effective Date, and will remain during the term of this Agreement no less favorable to Acutus than the prices contained in Biotronik's other agreements with other Third Party distributors of the Products in the Territory. Except where expressly stated otherwise, all prices are quoted exclusive of VAT, and custom tariffs and duties applicable from the time of transfer of ownership (FCA, Incoterms 2020), which will all be borne by Acutus. Acutus will pay all taxes or other charges associated with the supply to Acutus, distribution and delivery of the ordered Products, including insurance costs, sales, use, exercise, value-added and similar taxes and customs, duties or governmental impositions. Any tax or duty Biotronik is required to collect or pay upon delivery of the Products will be paid by Acutus and will be due and payable to Biotronik upon being invoiced.

### 5.10 Payment Conditions

- (a) Biotronik will issue an invoice for each delivery, including partial deliveries. Biotronik will submit the invoice on or after the respective pick-up date.
- (b) All payments will be made by Acutus in EUR in immediately available funds by wire transfer to the bank account designated by Biotronik in the respective invoice, or otherwise in writing, within forty-five (45) calendar days from receipt of invoice. If Acutus does not pay the invoiced amount in full within the payment deadline, Acutus will be deemed to be in default, and default interest of five percent (5%) per year will apply on the outstanding amount. In addition, if outstanding invoices and default interest in an amount set forth above, to the extent not disputed in good faith by Acutus, are not paid within thirty (30) days after Biotronik's notice of payment default, Biotronik will have the right to hold back any deliveries to Acutus.

## 5.11 Warranty

## 5.11.1 In General

(a) Biotronik warrants to Acutus that the Bio Products will be, at the time of delivery by Biotronik to Acutus' carrier, free and clear from defects in material and workmanship and will conform, at the time of such delivery, to the applicable Product Specification (the Warranty). For OEM Products, all representations and warranties whatsoever by Biotronik, express or implied, are excluded and disclaimed, subject to the following. Except to the extent that doing so would be a breach by Biotronik of the OEM manufacturer agreement, Biotronik will seek to obtain remedies for Acutus for defects in OEM Products under the warranties against defects provided by OEM manufacturers to

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Biotronik in the same manner as Biotronik seeks to obtain such remedies relating to defective OEM Products on Biotronik's own behalf. For clarity, such commitment (and the similar commitment for indemnity) shall be sole and exclusive remedy for defective OEM Products.

- (b) The Warranty does not apply:
  - to Bio Products that have been modified after delivery without prior written approval of Biotronik, it being understood and agreed that the removal, alteration or defacing of any serial number will be deemed to be a modification in the sense of this Section 5.11.1(b)(i);
  - (ii) to defects not existing at the time of delivery by Biotronik to Acutus' carrier, for example defects caused by the handling after pick-up, by normal wear and tear or otherwise due to the normal aging of the Bio Products;
  - (iii) to consumable parts of or for the Bio Products, such as batteries; and
  - (iv) any issues caused by misuse, abuse, improper handling or storage, contamination, damage, out of specification environmental conditions, or the like.
- (c) Except for this Warranty set forth in this Section 5.11.1 above, no representation or warranty whatsoever, express or implied, is made by or on behalf of Biotronik, and all other representations and warranties are hereby expressly excluded and disclaimed.
- (d) This Section 5.11 as well as Sections 8.4.2 will apply by analogy to defects of title in the Bio Products (*Rechtsgewahrleistung*).

#### 5.11.2 Warranty Period

The Warranty period will, for non-sterile Bio Products, be twelve (12) months after invoicing date and will, for sterile Bio Products, correspond to the use-by-dating indicated on the individual Bio Products (the **Warranty Period**). The Warranty Period for repaired or replaced Bio Products shall be the longer of ninety (90) days from the date Biotronik ships the repair or replacement, the remaining Warranty Period, or the use by dating on the repaired or replacement Bio Product.

#### 5.11.3 Notice of Breach

(a) If Acutus wishes to claim a breach of Warranty (a **Warranty Claim**), Acutus will deliver written notice to Biotronik stating the facts then known about any Warranty Claim in reasonable detail (a **Notice of Breach**) and on the earlier of:

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- twenty (20) Business Days after (i) Acutus gained actual knowledge of the Warranty Claim, or (ii) receipt by Acutus of notice of any claim made or threatened by a Third Party if claim is reasonably likely to give rise to a Warranty Claim by Acutus against Biotronik; or
- (ii) upon Acutus receiving any submission to, or a decision or order rendered by any Governmental Authority, which is reasonably likely to result in a Warranty Claim, provided that such Notice of Breach must be delivered to Biotronik sufficiently early for Biotronik to have reasonable opportunity to, at its option, (i) respond to or (ii) require Acutus to respond to such submission, or (iii) submit a timely appeal or other challenge against such decision or order.
- (b) Failure to give Notice of Breach within the time periods set forth in Section 5.11.3(a) and Section 5.5(b), respectively, will, if the notice has been given within the Warranty Period, not exclude Biotronik's liability under this Agreement. Biotronik's liability will, however, be reduced or excluded if and to the extent a damage has been caused or aggravated by virtue of Acutus' failure to give timely notice in accordance with Section 5.11.3(a) or Section 5.5(b), respectively. The Parties expressly waive Acutus' duty to immediately notify Biotronik pursuant to, and the application of article 201 CO.

### 5.11.4 Warranty Claims Management

- (a) All Bio Products that are affected by the Warranty Claim (the **Claimed Products**) will be returned to Biotronik for inspection within generally not more than twenty (20) Business Days following the later of (i) receipt by Biotronik of Acutus' Notice of Breach and (ii) receipt by Acutus of the relevant Bio Products from its Sub-Distributors or end users. The Parties may agree that only samples of Claimed Products will be returned to Biotronik.
- (b) Biotronik will respond to the Warranty Claim within twenty (20) Business Days following receipt of the later of (i) the Notice of Breach, or (ii) the Claimed Products pursuant to Section 5.11.4(a), stating Biotronik's acceptance or rejection of the Warranty Claim.
- (c) If Biotronik accepts a Warranty Claim, the remedies pursuant to Section 5.11.5 will apply.
- (d) If Biotronik rejects a Warranty Claim or if Biotronik replaces or repairs Claimed Products with a reservation that Biotronik does not accept the respective Warranty Claim, each Party will have the right but not the obligation to request a Third Party analysis through a mutually agreed neutral Third Party acting as expert (the **Third Party Analysis**). The findings of such Third Party Analysis will be duly considered by each Party, but will not be final or binding in terms of an

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expert or arbitrator opinion. The costs and expenses for the Third Party Analysis will be borne by the Party who requested the Third Party Analysis or, if both Parties requested the Third Party Analysis, each Party will bear half of the costs and expenses for the Third Party Analysis.

(e) If the Parties do not resolve the Warranty Claim, each Party will be entitled to initiate proceedings pursuant to Section 13.8, subject to Section 5.11.5.

#### 5.11.5 Remedies

- (a) In case of a breach of Warranty, Biotronik will, at its option, replace or repair the Claimed Products or reimburse the purchase price paid for the Claimed Products by issuing a credit note to Acutus.
- (b) After a Warranty Claim has been resolved, defective Claimed Products for which a replacement has been provided to Acutus will, at the option and cost and expense of Biotronik, either be returned to Acutus or destroyed.
- (c) Except for the Warranty and limited remedies in this Section 5.11.5, the Products are provided "AS IS," "AS-AVAILABLE" and "WITH ALL FAULTS." Biotronik hereby disclaims any and all other warranties and conditions, whether express, implied, or statutory, and any warranties that may arise from course of dealing, course of performance or usage of trade. No oral or written information or advice given by Biotronik or its representatives shall create any additional warranty. Acutus shall not make or pass on any representation or warranty or commitment on behalf of Biotronik to any customer, Sub-Distributor or other party.

#### 5.11.6 Time Limitations (Verjährung) and Forfeiture (Verwirkung) of Claims

- (a) Any Warranty Claim by Acutus against Biotronik will become time-barred and forfeited upon the lapse of the Warranty Period, even if the breach of Warranty is discovered after that lapse. However Biotronik shall grant Acutus a period often (10) Business Days following the expiration of the applicable warranty period, to submit to Biotronik only those warranty claims that were submitted to Acutus by end users and Sub-Distributors within the applicable Warranty Period.
- (b) Subject to Section 5.11.3, it is hereby understood and agreed that if a Notice of Breach is properly delivered to Biotronik within the Warranty Period, the relevant Warranty Claim may be resolved after lapse of the Warranty Period, provided that the Warranty Claim specified in such Notice of Breach will remain to be time-barred and forfeited should Acutus fail to initiate arbitration proceedings against Biotronik in accordance with Section 5.11.4 within ninety (90) days following expiry of the Warranty Period.

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#### 6. Liability

- (a) To the extent permitted by law, neither Party nor any of its Affiliates will be liable to the other Party for breach of this Agreement to the extent causing loss of present or prospective profits, revenue, or savings; loss of present or prospective sales; loss of use; loss of data; or cost of substitute goods or services in each case suffered by the other Party or any of its Affiliates as a result of such breach. This limitation of liability will not apply to (i) a breach of Section 10 and (ii) the unauthorized exploitation of the other Party's Intellectual Property Rights. This limitation of liability will apply to the indemnification pursuant to Section 7 and whether or not either Party is aware or has been advised of the possibility of such damages.
- (b) Except for breach by Biotronik of its obligations in Sections 5.11.1 and 7.1(a) this Agreement with regard to OEM Products, any liability for damages related to OEM Products is hereby excluded and disclaimed. Subject to the foregoing, this exclusion of liability will apply to the indemnification pursuant to Section 7, and Biotronik will under no circumstances have to indemnify and hold harmless Acutus or any Third Party in relation to any OEM Products. To the extent permitted under the respective applicable law, Biotronik assigns to Acutus all damage claims Biotronik may have against an OEM manufacturer relating to OEM Products sold by Biotronik to Acutus under this Agreement.

### 7. Indemnification

## 7.1 Indemnification of Acutus by Biotronik

(a) Biotronik will hold harmless and indemnify Acutus from all non-Affiliate third-party claims against Acutus, including for reasonable legal expenses associated with such claims, which are the result of Biotronik's negligence, wilful misconduct or illegal conduct or for physical injury or death in connection with the use of the Bio Products to the extent the injury or death is caused by a defect in the Bio Product that existed at the time of supply by Biotronik, or Biotronik otherwise has responsibility for the injury or death in accordance with statutory product liability provisions; in each case except to the extent such claims are the result of Acutus' negligence, illegal conduct, willful misconduct or breach of this Agreement and in each case which are based on a final judgment or settlement agreement, provided Acutus complied with all obligations under Section 7.3. Biotronik also agrees to seek to extend to Acutus the benefit of defense and indemnification commitments obtained by Biotronik from OEM manufacturers under the OEM manufacturer agreement for OEM Products, but only to the extent Biotronik is authorized to pass through such commitments. Biotronik will have no responsibility or liability

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under this Section 7.1(a) as a result of any injury or death that occurs as a result of any failure by Acutus to follow Biotronik's instructions in accordance with this Agreement to suspend or discontinue distribution of or recall any Product. Rather, Acutus will be responsible for indemnifying Biotronik for such injury or death under Section 7.2. Additionally, Biotronik is not responsible under this Section 7.1(a) based upon any representations, warranties, or commitments beyond the Warranty and limited remedies provided by Biotronik in Section 5.11 (or failure to limit remedies as set forth in this Agreement); or for any modification, alteration, or misuse of a Product by Acutus, its Affiliate, Sub-Distributor, or any customer of Acutus or such an Affiliate or Sub-Distributor.

(b) Biotronik will hold harmless and indemnify Acutus from any non-Affiliate third-party claims against Acutus, including for reasonable legal expenses associated with such claims, claiming that the Bio Products infringe or misappropriate third-party Intellectual Property Rights as a result of the distribution or use (to the extent the use is described in the Product Specification) of the Bio Products by Acutus in the Territory; in each case which are based on a final judgment or settlement agreement, provided Acutus complied with all obligations under Section 7.3. Biotronik will have no responsibility or liability under this Section 7.1(b) as a result of (i) any infringement that occurs after Biotronik requests that use or distribution of the Product that is the target of the claim be discontinued or suspended in accordance with Section 8.4.2(c), (ii) any use or distribution of Products in the manner not intended or of any software other than the most recent version and release, or (iii) any unauthorized modification of any Product or any combination with any product or technology not supplied by Biotronik unless the infringement occurred in the absence of the modification or combination.

### 7.2 Indemnification of Biotronik by Acutus

Acutus will hold harmless and indemnify Biotronik from all non-Affiliate third-party claims against Biotronik, including for reasonable legal expenses associated with such claims, which are the result of (i) Acutus' negligence, illegal conduct, or wilful misconduct, (ii) any unauthorized modification of or failure to maintain any Product, or (iii) any representations, warranties, or commitments beyond the warranty and limited remedies provided by Biotronik in Section 5.11 (or failure to limit remedies as set forth in this Agreement); in the case of each of (i) and (ii) only, except to the extent such claims are the result of Biotronik's or any Biotronik Affiliate's negligence, illegal conduct, wilful misconduct or breach of this Agreement and in each case which are based on a final judgment or settlement agreement, provided Biotronik complied with all obligations under Section 7.3.

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### 7.3 Third-party claims

- (a) If a Party (the **Indemnitee**) believes that the other Party (the **Indemnitor**) is responsible for defending or indemnifying the Indemnitee under this Section 7 above, the Indemnitee will promptly but in no event more than five (5) Business Days from the date it becomes aware of the good-faith Third Party claim notify the Indemnitor in writing of the third-party claim, describing the claim in reasonable detail, provided that failure to give notice as provided in this Section 7.3(a) will not relieve the Indemnitor of its indemnification obligation under this Agreement except to the extent such Indemnitor is actually and materially prejudiced as a result of such failure.
- (b) Neither the Indemnitee nor the Indemnitor will make any admission of liability in respect of any third-party claim without the prior written consent of the other Party, and the Indemnitee will use reasonable efforts to mitigate losses arising from such third-party claim.
- (c) The Indemnitor will have the exclusive right to conduct and control defense, negotiations and settlement of claims for which the Indemnitor is responsible under this Section 7 and will assume, conduct and control the defence and settlement of any suit or action against the Indemnitee using counsel selected by the Indemnitor. The Indemnitee will, at the Indemnitor's expense, cooperate and cause its Affiliates and agents to cooperate as reasonably requested by Indemnitor in the defence and settlement of the third-party claim.
- (d) The Indemnitor will not be responsible for any costs, expenses or settlement agreement incurred or made without the prior written consent of Indemnitor, which will not be unreasonably withheld or delayed. The Indemnitor will not have authority to bind the Indemnitee except to a settlement in which the sole relief to be provided is for monetary damages that are paid in full by the Indemnitor and any other commitments by the Indemnitor that do not adversely impact the Indemnitee.
- (e) If Biotronik becomes aware of a good faith third-party product liability claim relating to a Bio Product, Biotronik will have the right, acting reasonably and in good faith, to require Acutus to suspend further sales of such Bio Product, provided that Biotronik uses commercially reasonable efforts, in addition to Biotronik's indemnification obligations hereunder, to replace or modify the affected Bio Product so that it becomes conforming to all applicable requirements hereunder in all respects while giving equivalent performance and without undue delay or interruption of sales. Notwithstanding anything to the contrary, if Biotronik requires suspension of Bio Product sales under this Section 7.3(e) due to a breach by Biotronik of its obligations under this Agreement or the Quality Management Agreement, and if as a result of such

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breach Bio Product that have been previously delivered to Acutus and that remain in Acutus' inventory are not suitable to be sold, then (i) in accordance with this Section and to the extent Biotronik has not otherwise required such return, Acutus shall have the right to return to Biotronik, at Biotronik's cost and expense, (aa) all sterile Bio Products immediately and (bb) all Bio Products not supplied by Biotronik in sterile form, within three (3) months after receipt of the notification of suspension by Acutus. If Biotronik becomes aware of a good faith third-party product liability claim relating to an OEM Product, Biotronik will notify Acutus Immediately in writing, reasonably describing the claim in such notice. Acutus agrees to suspend further sales to the extent Biotronik is obligated to suspend further sales under Biotronik's agreement with the OEM manufacturer, and Biotronik agrees to remedy the issue for Acutus in no less favorable of a manner as the OEM manufacturer agreed to remedy the issue for Biotronik.

## 8. Intellectual Property

### 8.1 Principle

- (a) Except for the licenses granted by a Party to the other in this Agreement, each Party and its Affiliates will retain all right, title and interest in and to its and their respective Intellectual Property Rights.
- (b) Intellectual Property Rights for works or inventions to the extent created or conceived solely by either Party will be owned exclusively to the Party creating or conceiving such Intellectual Property Rights; and Intellectual Property Rights for works or inventions to the extent created or conceived jointly by both Parties will be owned jointly to the Parties, and neither Party shall have the duty to account or obtain the consent of the other Party to exploit or license any jointly owned Intellectual Property Rights notwithstanding any contrary provisions of applicable law in any country.

#### 8.2 Use of Biotronik Intellectual Property Rights by Acutus

(a) For the term of this Agreement and subject to its terms and conditions, Biotronik hereby grants Acutus a limited, non-exclusive, non-assignable (except as set forth in Section 13.7) and royalty-free license to use the Biotronik Trademarks for the sole purpose of identifying and distributing the Bio Products purchased by Acutus from Biotronik pursuant to this Agreement. For the avoidance of doubt, no license to use the Biotronik Trademarks or any other Intellectual Property Rights of Biotronik on or in connection with any

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products other than Bio Products is being granted hereunder. This Section 8.2 does not limit any rights expressly granted in the Agreement.

- (b) Acutus will have the right to grant sublicenses to its Sub-Distributors and agents to use the Biotronik Trademarks, provided that the scope of rights granted to Sub-Distributors and agents does not exceed the scope of rights granted to Acutus under this Agreement.
- (c) Acutus will not register, and hereby represents it has not registered, any Intellectual Property Rights that are identical or confusingly similar to the Biotronik Trademarks or to those used or registered by Biotronik.
- (d) The use of the Biotronik Trademarks by Acutus will inure to the benefit of Biotronik. To the extent necessary or desirable to preserve rights or remedies with regard to the Biotronik Trademarks in a country of the Territory, Acutus will execute and file a registered user agreement in such country that is acceptable to Biotronik. Biotronik will pay any registration fee, provided that Acutus shall remain responsible for determining whether a registered user agreement is needed in the particular country in the Territory.

#### 8.3 Use of Acutus Intellectual Property Rights by Biotronik

- (a) For the term of and subject to this Agreement, Acutus hereby grants Biotronik a limited, non-exclusive, non-assignable, non-sublicensable and royalty-free license to use the Acutus Trademarks for the sole purpose of manufacturing, packaging and delivering Bio Products to Acutus in accordance with this Agreement, in particular Bio Products distributed under the Acutus private label pursuant Section 5.7(c). For the avoidance of doubt, no license to use the Acutus Trademarks or any other Intellectual Property Rights of Acutus on or in connection with any products other than Bio Products is granted hereunder.
- (b) Biotronik will not register, and hereby represents it has not registered, any Intellectual Property Rights identical or confusingly similar to the Acutus Trademarks or to those used or registered by Acutus.
- (c) The use of the Acutus Trademarks by Biotronik will inure to the benefit of Acutus. To the extent necessary to preserve Acutus' rights or remedies with regard to the Acutus Trademarks in a country, Biotronik will execute and file, at Biotronik's sole cost and expense, a registered user agreement in such country that is acceptable to Acutus. Acutus will pay any registration fee, provided that Biotronik shall remain responsible for determining whether a registered user agreement is needed in the particular country in the Territory.

#### 8.4 Infringements

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#### 8.4.1 Infringements of Biotronik Intellectual Property Rights

Acutus will Immediately notify Biotronik of any actual or potential infringement of Intellectual Property Rights of Biotronik that comes to Acutus' attention. Acutus will reasonably assist Biotronik at Biotronik's request and at Biotronik's sole cost and expense in any action against such infringements. For the avoidance of doubt, Biotronik will have no obligation to take such action.

#### 8.4.2 Infringements of Third-Party Intellectual Property Rights

- (a) Acutus will Immediately notify Biotronik of any alleged infringement of third-party Intellectual Property Rights by the Bio Products that comes to Acutus' attention.
- (b) Biotronik will:
  - (i) have the right to conduct negotiations with the Third Party;
  - (ii) assume, conduct and control the defence and settlement of any suit or action for infringement against or resulting from a Bio Product provided that Biotronik will not be responsible for any costs, expenses or settlement agreements incurred without the prior written consent of Biotronik; and
  - (iii) have the right to issue binding instructions to Acutus regarding continued sales of Bio Products affected by such claims as more particularly contemplated in Section 8.4.2(c).
- (c) If Biotronik becomes aware of a good faith third-party claim relating to an infringement or misappropriation of Intellectual Property Rights relating to a Bio Product affected by such third-party claim, Biotronik, acting reasonably and in good faith, has the right to require Acutus to suspend further sales of such Bio Product, provided that Biotronik shall use commercially reasonable efforts, in addition to Biotronik's indemnification obligations hereunder: (i) to obtain for Acutus the right to continue distributing the affected Product, or (ii) replace or modify the affected Product so that it becomes non-infringing while giving equivalent performance and without undue delay or interruption of sales; provided that Biotronik shall have the right to terminate or suspend Acutus' right to continue to distribute the affected Product to the extent Biotronik determines is appropriate in its reasonable business judgment as a result of the infringement risk. Failure by Biotronik to obtain the right to continued distribution or replacing or modifying the affected Bio Product so that it becomes non-infringing within three (3) months from receipt of notice under Section 8.4.2(a) or, if no notice was given under Section 8.4.2(a), from receipt by Acutus of the notification of suspension under this Section 8.4.2(c), will be

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deemed termination of the affected Product. Notwithstanding anything to the contrary, to the extent Biotronik requires Acutus to suspend or terminate sales of any Product under this Section 8.4.2(c), such occurrence shall not be considered a breach of this Agreement by Biotronik, and Acutus shall also have the right (if Biotronik has not already required such return) to return to Biotronik at Biotronik's cost and expense all Products terminated by Biotronik under this Section 8.4.2(c). Notwithstanding anything to the contrary, the sole remedy, and Biotronik's sole responsibility, as a result of any infringement by a Product are adjustments to Acutus' minimums under Section 3.5(i) and Biotronik's obligation to indemnify Acutus in accordance with Section 7.1(b). If Biotronik becomes aware of such a claim relating to an OEM Product, Biotronik will notify Acutus Immediately in writing, reasonably describing the claim in such notice. Acutus agrees to suspend further sales to the extent Biotronik is obligated to suspend further sales under Biotronik's agreement with the OEM manufacturer, and Biotronik agrees to remedy the issue for Acutus in no less favorable of a manner as the OEM manufacturer agreed to remedy the issue for Biotronik.

## 9. Force Majeure

- (a) If a Party is prevented from performing its obligations under this Agreement as a result of any unforeseeable contingency beyond its reasonable control (a Force Majeure), including any unforeseeable, out of the ordinary actions of Governmental Authorities, war, terrorism, hostilities between nations, riots, strikes, lockouts, sabotage, shortages in supplies (but only to the extent such shortages are not caused and their effects could not reasonably have been mitigated by the nonperforming Party), energy shortages, fire, floods, epidemics, pandemics, and acts of nature, the Party so affected will not be responsible to the other Party for any delay or failure of performance of its obligations hereunder, for so long as Force Majeure prevents such performance; provided that the non-performing Party notifies the other Party in writing Immediately upon the occurrence of the Force Majeure as set forth in Section 9(b) below and the Parties discuss how to mitigate and eliminate the effects of the Force Majeure. Except to the extent otherwise agreed by the Parties in writing pursuant to such discussions, a Party shall have the right to terminate this Agreement by providing written notice of termination to the non-performing Party if a Force Majeure impacts such non-performing Party for a period of longer than ninety (90) days. This clause shall not excuse a failure to make payments.
- (b) In the event of Force Majeure, the Party immediately affected thereby will give Immediate written notice to the other Party specifying the Force Majeure and

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## 10. Confidentiality

#### 10.1 Handling of the Confidential Information

During the term of this Agreement and for a period of ten (10) years thereafter, each Party will:

- (a) keep Confidential Information of the other Party or the other Party's Affiliates confidential, not make it available to third parties and protect it from unauthorized access, unauthorized disclosure and unauthorized use;
- (b) use Confidential Information of the other Party or the other Party's Affiliates for the performance of its obligations or exercise of its rights under this Agreement only;
- (c) only make available the Confidential Information of the other Party or the other Party's Affiliates to its own employees and consultants as well as to the employees and consultants of its Affiliates or Sub-Distributors and to its Affiliates or Sub-Distributors (approved in accordance with Section 2.7(a)) themselves, provided that these:
  - (i) require knowledge of the Confidential Information for the performance of the receiving Party's obligations under this Agreement;
  - (ii) have been informed about the confidentiality of such Confidential Information; and
  - (iii) are bound to keep such Confidential Information confidential in a manner consistent with the receiving Party's obligation under this Agreement;
- (d) inform the other Party if Confidential Information of that Party or that Party's Affiliates becomes known without authorization or is inappropriately used and take reasonable measures in order to prevent improper distribution and use of such Confidential Information;
- (e) upon request and at the option of the disclosing Party, upon expiry of this Agreement at the latest, return the Confidential Information received from the disclosing Party to that Party, and destroy or delete all copies of Confidential Information and confirm this in writing to such Party. The following will be excluded from these obligations:

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- (i) the secure retention of copies of Confidential Information, to the extent retention is required by law, guidelines from professional or self-regulating organizations or an order of a Governmental Authority or a self-regulating organization;
- (ii) back-up copies in accordance with customary business practice and by means of an automated, secured data back-up system.
- (f) For clarity, Acutus' rights above to use and disclose exclude the right to do so for the benefit any product that is not a Product or for any product that is a Competing Product relative to any Bio Product.

### 10.2 Exceptions

- (a) If a Party is obliged to disclose Confidential Information received from the other Party by law or by order of a Governmental Authority or a self-regulating organization, the following will apply:
  - (i) the disclosure will be limited to the necessary extent;
  - (ii) the receiving Party will inform the disclosing Party to the extent permitted prior to the disclosure, will coordinate the next steps with the disclosing Party in order to guarantee that Confidential Information received from the other Party is kept confidential to the greatest extent possible.
- (b) If a Party is obliged to disclose Confidential Information received from the other Party to internal or external auditors due to compliance regulations, such disclosure is to be limited to the necessary extent and the provisions of Section 10.2(a) will apply by analogy.

# 11. Data Protection

(a) The Parties represent that, regarding any operation or set of operations which is performed upon information relating to identified or identifiable natural persons in relation with this Agreement (**Personal Data**), each Party determines the purposes and means of the processing of Personal Data individually (**Sole Controller**) in accordance with the data protection laws applicable to the processing of Personal Data by a Party (**Data Protection Legislation**). Each Party individually must determine whether it has the lawful basis for any processing of Personal Data and will comply with its obligations under applicable Data Processing Legislation. Each Party will share Personal Data with the other Party if necessary for purposes of this Agreement or for fulfilment of statutory functions, provided such sharing is lawful. Each Party

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will process Personal Data received from or pertaining to the employees of the other Party and the other Party's Affiliates, agents, auxiliaries and contractors only for purposes of this Agreement or for fulfilment of statutory functions.

- (b) The Parties will ensure that Personal Data is limited to what is necessary in relation to the purposes they are processed by applying data minimisation techniques where possible such as reducing or replacing personal identifiers or aggregating data. Each Party will respond to enquiries from data subjects and supervisory authorities concerning its processing of Personal Data within a reasonable time. Requests concerning the other Party's processing of Personal Data will be forwarded to the other Party without delay. Each Party will appoint a contact person authorized to receive such forwarded requests.
- (c) If the transfer or disclosure of Personal Data by a Party to recipients in the receiving Party's jurisdiction is restricted under the Data Protection Legislation, the Parties will, on either Party's request, take appropriate measures as may be required or permitted by the Data Protection Legislation for the lawful transfer of Personal Data to the receiving Party, including, in particular, the Set II controller—controller clauses set forth in the European Commission Decision 2004/915/EC, dated 27 December 2004—in which the Commission approved an alternative set of model clauses for transfers from data controllers in the EEA to data controllers outside the EEA, which are hereby incorporated by reference.

## 12. Term and Termination of this Agreement

## 12.1 Term

- (a) This Agreement will come into effect on the Effective Date and will continue for a period of seven (7) years (the **Initial Term**).
- (b) The Parties will agree in writing until the fifth (5th) anniversary of the Effective Date whether or not this Agreement is to be extended beyond the Initial Term. If the Parties agree on an extension, this Agreement will continue after the Initial Term for an additional three (3)-year period (a **Prolongation Term**). In each Prolongation Term, the Parties will conduct good faith negotiations on whether or not the Agreement will be extended for a successive Prolongation Term (i.e., an additional three (3) year period) and will seek to determine whether or not there will be prolongation (if applicable) no later than one (1) year prior to the expiration of the then current Prolongation Term. If the Parties do not agree to extend this Agreement beyond the Initial Term or the then current Prolongation Term, it will terminate on expiry of such Initial Term or Prolongation Term.

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#### 12.2 Termination for Good Cause

- (a) Each Party will have the right to terminate this Agreement with immediate effect by written notice for good cause *(aus wichtigem Grund)*, provided that the other Party has failed to cure such good cause within thirty (30) days of being informed by the terminating Party in writing of the good cause, unless such cure can reasonably be excluded. Good cause is deemed to mean any material failure to comply with any term of this Agreement or the Quality Management Agreement. Good cause includes any event caused or controlled by one Party that makes continuation of this Agreement unconscionable for the other Party due to the adverse effect of such event on the business and/or the reputation of the other Party, and includes any material breach of Section 2.5 (Sales Outside the Territory), Section 4.2.5 (Sale or Import without Marketing Authorization Approval), Section 5.8 (No Modifications to the Products), and Section 10 (Confidentiality). For the avoidance of doubt, a Party enforcing the obligations under this Agreement will not constitute good cause entitling the other Party to terminate the Agreement.
- (b) Each Party will have the right to terminate this Agreement with immediate effect by written notice in case of insolvency, moratorium, receivership or liquidation with regard to the other Party, or any similar circumstances that are likely to substantially affect the other Party's ability to carry out that Party's material obligations under this Agreement, provided that the Party that is subject to the insolvency, moratorium, receivership, liquidation, or similar circumstances has failed to provide adequate assurances of continued performance within thirty (30) days of the terminating Party requesting such assurances in writing, unless it can reasonably be excluded that the other party will provide such assurances. In the case of insolvency, moratorium, receivership or liquidation of any Sub-Distributor, or any similar circumstances that are likely to substantially affect the Sub-Distributor's ability to carry out its material obligations under this Agreement, Acutus shall notify Biotronik in writing of such circumstance and Acutus shall terminate the Sub-Distributor upon request by Biotronik.
- (c) Biotronik will have the right to terminate this Agreement for all countries or on a country-by-country basis by giving written notice of termination to Acutus specifying in the notice that it is being provided by Acutus pursuant to this Section 12.2(c):
  - (i) in the event of a Change of Control of Biotronik that closes during the Initial Term, with termination of this Agreement to be effective on the earlier of (i) the third (3<sup>rd</sup>) anniversary of the closing date of the respective Change of Control, or
     (ii) the end of the Initial Term. In the event of a Change of Control of Biotronik that closes during a

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Prolongation Term, unless this Agreement has already been terminated or expires earlier pursuant to its terms, Biotronik will have the right to terminate this Agreement with termination to be effective on the earlier of (i) the third (3<sup>rd</sup>) anniversary of the closing date of the respective Change of Control, or (ii) the end of the then-current Prolongation Term. All notices of termination pursuant to this Section 12.2(c)(i) must be given no later than six (6) months after the closing date of the respective Change of Control.

- (ii) in the event of a Change of Control of Acutus that closes during the Initial Term, with termination of this Agreement to be effective on the earlier of (i) the third (3<sup>rd</sup>) anniversary of the closing date of the respective Change of Control, or (ii) the end of the Initial Term. In the event of a Change of Control of Acutus that closes during a Prolongation Term, unless this Agreement has already been terminated for any other reason or expires earlier pursuant its terms, Biotronik will have the right to terminate this Agreement with termination to be effective on the earlier of (i) the third (3<sup>rd</sup>) anniversary of the closing date of the respective Change of Control, or (ii) the end of the then-current Prolongation Term. All notices of termination pursuant to this Section 12.2(c)(ii) must be given no later than six (6) months after the closing date of the respective Change of Control.
- (iii) In the event of a Change of Control of a Sub-Distributor, Biotronik has the right to withdraw its approval of the Sub-Distributor by providing written notice of such withdrawal to Acutus. Acutus agrees that no Bio Product will be distributed by any such Sub-Distributor more than twelve (12) months after Biotronik provides such notice.
- (iv) Acutus shall diligently, and in a manner that minimizes adverse impact on Product sales and relationships, transition distribution of Products to Biotronik for all countries in the Territory during the six month period following the date of Biotronik's or Acutus' notice (unless Biotronik specifies a shorter transition period).
- (v) If notice of termination pursuant Section 12.2(c)(i) or 12.2(c)(ii) is given during the Initial Term and if at the time of the notice of termination, Acutus has an exclusive distribution right for certain Bio Products in the U.S. or in China pursuant to Section 4.2.3(b) or Section 4.2.4(b), then this Agreement (including Acutus' distribution rights and exclusivity) shall survive termination for the Bio Products for which Acutus has such exclusive distribution right, but solely in the countries where Acutus has such exclusive distribution right (i.e., partial termination), and the Agreement shall terminate with regard to such Bio Products in such

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countries at the end of the Initial Term, unless terminated earlier by either Party in accordance with the other terms of this Agreement. Additionally, in such event, any obligation for Acutus to assign MAA's to Biotronik for such countries shall not apply until the end of the Initial Term, notwithstanding anything to the contrary.

(d) Acutus will have the right to terminate this Agreement by giving written notice of termination to Biotronik for all countries or on a country by country basis in the event of a Change of Control of Biotronik where the Acquiring Party of Biotronik is a Competing Company, with effect as of thirty (30) days after such notice by Acutus, provided that such notice must be given by Acutus to Biotronik no later than ninety (90) days after the closing date of the Change of Control.

### 12.3 Effects of Termination

#### 12.3.1 Surviving Obligations

The following Sections will survive termination or expiry of this Agreement (including as imposed on Sub-Distributors in accordance with Section 2.7(b), if applicable): Section 2.9.5(c) (until any applicable assignment has been completed), Section 3.3 (for Products that have been distributed under this Agreement), Section 3.5(e) (a final report covering all Product sales under this Agreement, including any after termination or expiration), Section 3.7(a) (until all Bio Product distribution has ended), Section 3.10 (After-Sales Services), Section 4.1 (Quality Management), Section 5.10, Section 5.11 (Warranty), Section 6 (Liability), Section 7 (Indemnification), Section 9, Section 10 (Confidentiality), Section 11, Section 12.3 (Effects of Termination), and Section 13. Acutus' responsibility for Affiliates and Sub-Distributors, as stated in Section 2.7(a), shall survive any termination or expiration of this Agreement. Obligations of a Party to reimburse the other in accordance with the terms of this Agreement shall survive to the extent the reimbursement obligation accrued during the term of the Agreement. All sublicenses granted by Acutus to any Sub-Distributors shall terminate upon any termination or expiration of this Agreement. All other provisions of this Agreement shall terminate, and have no further force or effect, upon any termination or expiration of this Agreement.

## 12.3.2 Right to Represent the Products

- (a) On the effective date of any termination or expiry of this Agreement and after the Sell-Off Period, the right of Acutus to represent and sell the Products ends.
- (b) On the effective date of termination or expiry of this Agreement and after the Sell-Off Period, Acutus will avoid any remarks and the use of any materials or equipment giving rise to the impression that it continues to be an appointed

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distributor for sales of or authorized to provide service, maintenance or support for any Products.

(c) In the event of any termination or expiration of this Agreement (as a whole or in any country), Acutus shall cooperate reasonably with Biotronik, for a period of up to six (6) months after any termination or expiration, in order to transition distribution of the Products back to Biotronik or its designee smoothly and without adverse impact to ongoing distribution of the Products and relationships. To the extent Acutus continues sales under Section 12.3.4 after such six (6) month period, Acutus shall continue such collaboration and efforts to effect a smooth transition so long as Acutus continues such sales. Acutus shall cause all Sub-Distributors to cooperate in the same manner if a Sub-Distributor is terminated.

### 12.3.3 Intellectual Property

On the effective date of termination or expiry of this Agreement and after the Sell-Off Period, each Party's rights to use the other Party's Intellectual Property Rights pursuant to this Agreement cease; except that Biotronik's rights to use any Intellectual Property Rights of Acutus in or to any Regulatory Materials or Clinical Data shall survive.

### 12.3.4 Products in Stock

(a) Biotronik will have the right but not the obligation to repurchase from Acutus a part of or all Bio Products that Acutus and its Affiliates have in stock as of the effective date of termination or expiry of this Agreement and that Acutus has purchased from Biotronik, at the net price originally paid by Acutus (FCA Carlsbad, Incoterms 2020), except to the extent Bio Products have already been sold to Third Party customers as of the date of receipt by Acutus of Biotronik's notice of intent to repurchase stock or to the extent Acutus is obligated to fulfil its existing contractual or tender obligations, as provided in Section 12.3.4(b) below. Biotronik may exercise its option according to this Section 12.3.4(a) in writing no later than on the effective date of the termination. Acutus will, on Biotronik's request, inform Biotronik of the Bio Products in Acutus' and its Affiliates' stock. Biotronik has the right to exercise its rights under this Section 12.3.4 on a country-by-country basis with regard to Bio Products in stock in the respective country if Acutus' rights are terminating for less than the entire Territory. Acutus has the right to retain and sell all OEM Products after any termination or expiration of this Agreement.

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- (b) If Biotronik exercises its option according to Section 12.3.4(a), Biotronik will for a period of twenty-four (24) months after the effective date of the termination permit Acutus to:
  - (i) fulfill contractual obligations to Third Parties that Acutus entered into before notice of termination, and
  - (ii) serve tenders for which Acutus has submitted offers to Third Parties before notice of termination,

provided that, on Biotronik's reasonable request, Acutus produces documentary evidence that the requirements of (i) and (ii) are fulfilled. For this purpose Biotronik will allow Acutus to keep existing Bio Products in stock, and Biotronik will sell additional Products to Acutus during such twenty four (24) month period under the terms and conditions of this Agreement as in force at the when Acutus' request under this Section 12.3.4(b) is provided to Biotronik. Notwithstanding anything to the contrary, under no circumstances shall any Bio Product be sold by or under authority of Acutus (i) after any expiration of this Agreement; and (ii) more than twenty (24) months after any termination of this Agreement.

- (c) If Acutus keeps existing Bio Products in stock or has purchased additional Bio Products in order to serve tenders according to Section 12.3.4(b)(ii) and Acutus has not won such tender, Acutus will inform Biotronik within ten (10) days of the final decision relating to such tender, and Biotronik will have the right but not the obligation to repurchase from Acutus some or all of the Bio Products that Acutus has in stock or has bought from Biotronik in view of such tender at the net price originally paid by Acutus. Biotronik may exercise its option according to this Section 12.3.4(c) in writing within thirty (30) days of Acutus informing Biotronik of the final decision relating to such tender.
- (d) If Biotronik chooses not to exercise its option pursuant to 12.3.4(a), Acutus will have the right for a period of twelve (12) months starting from the effective date of termination, in accordance with this Agreement, to sell the remaining Bio Products purchased from Biotronik (the **Sell-Off Period**). After the Sell-Off Period, Biotronik will for a period of twelve (12) months permit Acutus to:
  - (i) fulfill contractual obligations that Acutus has entered into before notice of termination, and
  - (ii) serve tenders for which Acutus has submitted offers before notice of termination,

provided that, on Biotronik's reasonable request, Acutus produces documentary evidence that the requirements of (i) and (ii) are fulfilled. For this

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purpose, Biotronik will sell additional Bio Products to Acutus at the terms and conditions of this Agreement. Thereafter, Acutus will not be authorized to sell Bio Products. Acutus will inform Biotronik of any remaining Bio Products purchase from Biotronik, and Biotronik will have the right to take these Bio Products back at no cost to Acutus. Otherwise, Acutus will destroy of them as waste.

(e) Nothing contained in this Agreement shall restrain Acutus from selling OEM Products in stock after termination or expiry of this Agreement.

### 12.3.5 Marketing Authorization Approvals

- (a) If, upon the effective date of termination or expiry of this Agreement and after the Sell-Off Period, Acutus, its Affiliate, or any Sub-Distributor owns or holds any Marketing Authorization Approvals for any Bio Products in any country of the Territory, Acutus, the Affiliate and Sub-Distributor will at no cost or expense to Biotronik, assign and transfer all right, title and interest in and to any and all such Marketing Authorization Approvals to Biotronik, subject to applicable regulatory requirements.
- (b) If an assignment or transfer of a Marketing Authorization Approval according to Section 12.3.5(a) is not possible, then Acutus, the Affiliate and Sub-Distributor shall take such action to the extent allowed by applicable law to enable Biotronik to otherwise benefit from the respective Marketing Authorization Approval after the effective date of termination or expiry of this Agreement to the extent reasonably possible, including providing copies of all MAA's, Clinical Data, and Regulatory Materials as well as rights of reference .

### 12.3.6 No Indemnity

Acutus agrees that the terms of this Agreement enable Acutus to recover equitable benefits from its investments in the marketing of the Products, and that the position of Acutus is not similar to that of an agent. Accordingly, Acutus will not be entitled to an indemnity for goodwill or similar compensation, or any other damages or compensation in case of any termination or expiration of this Agreement, even if Acutus has significantly developed Biotronik's business in the Territory and Biotronik continues to derive substantial benefits from the business generated by Acutus after the date of termination or expiration; including if such termination is a termination under Section 12.2(c).

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## 13. Miscellaneous

## 13.1 No Set-Off

Each Party waives its right to set off any claim made by the other Party against it under or in connection with this Agreement against a claim that it has itself against the other Party.

# 13.2 Entire Agreement and Annexes

- (a) This Agreement including all Annexes, which are an integral part of this Agreement, and the Quality Management Agreement, and those portions of the License and Distribution Agreement (if any) which are incorporated by reference, constitutes the complete agreement between the Parties regarding its subject matter and supersedes all other prior and contemporaneous oral and/or written agreements, representations and/or communications, concerning the subject matter hereof.
- (b) To the extent of any conflict between any provision of the body of this Agreement and any provision of an Annex, the provision of the body of this Agreement will prevail, provided that appropriate measures according to Section 11 will prevail over conflicting provisions of the body of this Agreement.

## 13.3 Written Notices

Any written notice with regard to this Agreement will be delivered by mail, e-mail or fax to

Acutus:

Acutus Medical, Inc. 2210 Faraday Ave Suite 100 Carlsbad 92008, California U.S.A.

]
]
]

Biotronik:

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Biotronik SE & Co. KG Woermannkehre 1 12359 Berlin Germany

Attn.: [ ] Phone: [ ] Email: [ ]

Each change of address will be communicated to the other Party in the same way.

#### 13.4 Severability

If any provision of this Agreement is held to be unenforceable or invalid, then that provision is to be construed either by modifying it to the minimum extent necessary to make it enforceable and valid (if permitted by law) or disregarding it (if not). If an unenforceable or invalid provision is modified or disregarded in accordance with this Section 13.4, the rest of the Agreement is to remain in effect as written, and the unenforceable and invalid provision is to remain as written in any circumstances other than those in which the provision is held to be unenforceable and invalid; provided that such continuation of the Agreement, with the modified and/or disregarded provision, is not materially inconsistent with the original intent of the Parties in entering into this Agreement. This rule applies by analogy to contractual omissions, intended or unintended.

## 13.5 Amendments

Any amendment or supplementation of this Agreement will require a written document executed by both Parties. The written form requirement may be dispensed only in writing.

### 13.6 No Waiver

Failure by either Party to take any action or assert any right hereunder will not be deemed to be a waiver of such right in the event of the continuation or repetition of the circumstances giving rise to such right, except if expressly agreed otherwise.

### 13.7 Assignment

(a) Except as provided in Section 13.7(b), neither Party may assign or otherwise transfer this Agreement or its rights or obligations under this Agreement, in

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whole or in part, to any Third Party except with the prior written consent of the other Party.

- (b) Each Party has the right to assign this Agreement to any of its Affiliates. In the event of a Change of Control with respect to a Party, such Party has the right to assign this Agreement to the Third Party that acquires control of such Party or an affiliate of such Third Party, subject to Section 13.7(c) below.
- (c) If Acutus or Biotronik undergoes a Change of Control during the Initial Term of the Agreement, the Party undergoing the Change of Control (or its successor or permitted assign) shall be bound in all respects to the terms and conditions of this Agreement for a period of the shorter of (a) the 3 year anniversary of the closing of the Change of Control, or (b) the remaining period of the Initial Term of the Agreement. If Biotronik or Acutus undergoes a Change of Control during a Prolongation Term, the Party undergoing the Change of Control (or its successor or permitted assign) shall be bound in all respects to the terms and conditions of Agreement for the shorter of (a) the remaining duration of the Prolongation Term or (b) 3 year anniversary of the closing of the Change of Control.

#### 13.8 Applicable Law and Jurisdiction

- (a) This Agreement will be governed by the substantive laws of Switzerland, to the exclusion of the UN Convention on Contracts for International Sale of Goods (CISG) of 11 April 1980.
- (b) In the event of any dispute arising out of or in relation to this Agreement, the Parties will refer the dispute to senior executive officers and such senior executive officers will attempt in good faith to resolve such dispute. If the Parties are unable to resolve a given dispute according to this Section 13.8(b) within thirty (30) days of referring such dispute to senior executive officers, if it cannot reasonably be expected that the dispute will resolved according to this Section 13.8(b) within thirty (30) days and in case of urgency, any such dispute will be resolved pursuant to Section 13.8(c).
- (c) Any dispute, controversy or claim arising out of or in relation to this Agreement and all purchases and deliveries within the framework of this Agreement, including the validity, invalidity, breach, or termination thereof, as well as pre-contractual and extra-contractual related issues, will be resolved by arbitration in accordance with the Swiss Rules of International Arbitration of the Swiss Chambers' Arbitration Institution in force on the date on which the Notice of Arbitration is submitted in accordance with these Rules. The number of arbitrators will be three (3). The seat of the arbitration will be Zurich. The arbitral proceedings and all pleadings, filings, written evidence, decisions and

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other relevant documents shall be in English and any written evidence in a language other than English shall be submitted with an English translation. All and any awards will be final and binding on the Parties, but subject to any rights of appeal and rights of revision from all and any awards insofar allowed under applicable law. All and any awards may be entered as final judgment in any court of competent jurisdiction as necessary to enforce the award.

\* \* \* \* \*

# (THE NEXT PAGE IS THE SIGNATURE PAGE)

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# Signatures

<b>BIOTRONIK SE &amp; CO. KG</b>	
Berlin, 11 MAY 2020	/s/ Dr. Daniel Bühler
Place, date	By: Dr. Daniel Bühler Title: Managing Director

Berlin, 11 MAY 2020 Place, date

or

/s/ Dr. Ralf Lieb By: Dr. Ralf Lieb Title: Managing Director

# ACUTUS MEDICAL, INC.

Carlsbad, California May 10, 2020 Place, date

/s/ Vince Burgess By: Vince Burgess Title: Chief Executive Officer

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# Annex 1(a) – Definitions

Acutus Trademark means any trademark, trade name, trade dress, service mark, logo or similar mark, whether or not registered or registerable, of Acutus or its Affiliates.

Acquiring Party shall have the meaning as defined in the Change of Control definition.

Affiliate means, with respect to any person or entity specified, any other person or entity that Controls or is Controlled by or is under common Control with the person or entity specified. For the purpose of this Agreement, **Control** means direct or indirect beneficial ownership by any person or entity of more than fifty percent (50%) of shares of stock entitled to vote for the election of directors in the case of a corporation, or more than fifty percent (50%) of the corresponding equity interest in the case of any other type of legal entity or status as a general partner in any partnership, in each case sufficient to, directly or indirectly through one or more intermediaries, control the board of directors or equivalent governing body of a corporation or other entity and cause the direction of the management and policies of the corporation or other entity.

Agreement means this distribution agreement including all of its Annexes.

AlCath Bio Products means Bio Products with the letters "AlCath" being a part of the product name.

**Annex** means an annex attached to this Agreement on the Effective Date, as such annexes are updated from time to time solely in accordance with this Agreement.

Annual Business Plan Session has the meaning defined in Section 3.4.

Annual Purchase Targets has the meaning defined in Section 3.5(a).

Bio Products means the products listed in <u>Annex 2.1(a)</u>, excluding the OEM Products.

**Biotronik Trademark** means any trademark, trade name, trade dress, service mark, logo or similar mark, whether or not registered or registerable, of Biotronik or its Affiliates.

**Business Day** means every calendar day except (i) Saturdays and Sundays, (ii) public holidays in Berlin, Germany or San Diego, California, USA, and (iii) 24 and 31 December.

Change of Control means, with respect to a Party, any of the following events:

(a) a Third Party becomes the beneficial owner, directly or indirectly, of more than sixty-seven percent (67%) of the total voting power of the capital stock then outstanding of such Party normally entitled to vote in elections of directors;

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(b) a Party conveys, transfers, leases or assigns all or substantially all of its business and assets to any Third Party, whether resulting from merger, acquisition, consolidation, or otherwise.

For purposes of this definition of "Change of Control" only, references to (A) "beneficial ownership" (and other correlative terms) means beneficial ownership as defined in Rule 13d-3 under the Exchange Act, and (B) "group" means group as defined in the Exchange Act and the rules of the SEC thereunder as in effect on the date hereof. The Third Party or other corporation or entity which effects a Change of Control with respect to a Party shall be referred to as the "Acquiring Party". Notwithstanding the foregoing, in no event shall a sale of capital stock for the purpose of financing Acutus, Biotronik, and/or their Affiliate, including to underwriters of a public offering of the capital stock of Acutus, Biotronik, and/or their Affiliate, constitute a Change of Control.

# Claimed Bio Product has the meaning defined in Section 5.11.4(a).

**Clinical Data** means all data, information, and documentation (each in draft or complete form) generated by conducting and/or analyzing a Clinical Trial (whether or not completed) hereunder, in whatever form, whether stored as hard copy or in electronic form, including raw data to the extent legally permissible, study data, all study reports, case reports, filings, monitor reports, notices, books, records, informed consent forms, other files (or parts thereof), or any information related thereto.

**Clinical Trial** means a human clinical study conducted on human subjects that is designed to (a) establish that a medical device is reasonably safe for continued testing; (b) investigate the safety and efficacy of the medical device for its intended use, and to define warnings, precautions, and adverse reactions that may be associated with the medical device in the manner to be prescribed; or (c) support Marketing Authorization Approval or label expansion of such medical device.

CO means the Swiss Code of Obligations (OR).

**Competing Product** means, with respect to a Bio Product, a product with the same or substantially the same indication as such Bio Product, including having the ability for on-label use in similar procedures, provided that such product can reasonably be considered to directly compete with such Bio Product. For the avoidance of doubt, non-electrophysiology products of Biotronik and its Affiliates will not be considered Competing Products.

**Competing Company** means the entities listed in <u>Annex 2.3</u> and their respective Affiliates. Biotronik will have the right, upon written notice to and subject to reasonable consultation with Acutus, to adapt <u>Annex 2.3</u> at any time to include new entities; provided that such new entity is an actual or potential competitor of Biotronik. Biotronik will without undue delay remove any entity from <u>Annex 2.3</u> that is no longer an actual or potential competitor of Biotronik. Biotronik will inform Acutus about any such adaptions of <u>Annex 2.3</u> in writing.

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**Confidential Information** of a Party or that Party's Affiliates means any and all information, regardless of its form and the type of disclosure (in particular documents, data files, charts, sketches, plans, e-mails, and oral information), which:

(a) such Party or an Affiliate of such Party's makes directly or indirectly available to the other Party in connection with this Agreement or has already made available prior to the conclusion of this Agreement under obligations of confidentiality; and

has been identified as "confidential" or which is confidential by nature (in particular financial data, sales figures, know-how, and customer lists).

Information made available by either Party or an Affiliate will not be deemed Confidential Information in the event:

(a) it was or has become publicly known without the receiving Party being involved in breach of its obligations or otherwise being responsible for it;

the receiving Party has created or obtained the information itself independently of the disclosure by the disclosing Party, whether prior to or after such disclosure by the disclosing Party, provided that the receiving Party may assume in good faith that no confidentiality obligations have been breached thereby and that it may use and/or disclose this information; or

the disclosing Party has explicitly excluded from the confidentiality obligations in writing.

Control has the meaning set forth in the definition of Affiliate above.

**Data Protection Legislation** has the meaning defined in Section 11(a).

Effective Date means the date of execution of this Agreement by both Parties.

**EU Model Clauses** means the standardized contractual clauses issued or approved by the EU Commission or other competent EU authorities during the Agreement for the transfer of Personal Data to third country recipients.

**Field** means atrial and ventricular catheter-based heart rhythm diagnostics and radiofrequency point-by-point cardiac ablation with 3D imaging and mapping. For the avoidance of doubt, the following product categories are included in the Field: Diagnostic, steerable, introducer and transseptal catheters, high-power-short-duration (SW adaptation and/or ablation device hardware adaptation and/or catheter improvement), ECG recording systems, irrigation pumps, esophageal temperature probes, deviators, and transseptal access tools. For the avoidance of doubt, and without limitation, the following product categories are considered to be outside of the Field: Products for electroporation (ablation devices and/or catheters), single shot PV-isolation systems with any energy source (cryo, radiofrequency, heat, or laser), and left atrial appendage occluder devices.

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**Force Majeure** has the meaning defined in Section 9(a).

**Governmental Authority** means any court, agency, department, authority, or other instrumentality of any multi-national, national, state, county, city, province, or other political subdivision.

**IDE** means investigational device exemption.

**Immediately** means, with respect to any obligation of a Party hereunder to act in a certain manner upon the occurrence of any event, as soon as possible upon becoming aware of such event and without delay, and in any case within one (1) Business Day.

**Indemnitee** has the meaning defined in Section 7.3(a).

Indemnitor has the meaning defined in Section 7.3(a).

Individual Purchase Order means any purchase order placed by Acutus with Biotronik for Products.

Initial Term has the meaning defined in Section 12.1(a).

**Intellectual Property Rights** means all and any intellectual property rights, including any copyrights, utility model rights, design rights, patent rights, trademark rights, topography rights, trade secret rights, know-how rights, rights in databases as well as any other proprietary rights, in all cases whether or not registered or registerable.

**Lead Time** means eight (8) calendar weeks. In case of FCA (Incoterms 2020), the Lead Time will be calculated from the date of the respective Individual Purchase Order receipt by Biotronik to the date the purchased Bio Products are ready to be picked up from the pick-up point designated by Biotronik, provided that if the last day of the Lead Time is not a Business Day, the Lead Time will end on the following Business Day.

**License and Distribution Agreement** means the agreement titled "License and Distribution Agreement," entered into between the Parties and VascoMed GmbH, having an effective date of June 28, 2019

**Manufacturer of Record** shall mean the natural or legal person responsible for the design, manufacture, packaging and labelling of a medical device before it is placed on the market, regardless of whether these operations are carried out by that person or on his behalf by a Third Party.

**Marketing Authorization Approval** or **MAA** means, with respect to a product in any country or jurisdiction, any approval, registration, license, or authorization from a Regulatory Authority or other Governmental Authority in that country or jurisdiction that is necessary to offer for sale, market, and sell such product in such country or jurisdiction.

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Multicath Bio Products means Bio Products with the letters "MultCath" being a part of the product name.

New Products means the New Products in the Field and the New Products Outside The Field.

New Products In The Field has the meaning defined in Section 2.9.3(a).

New Products Outside The Field has the meaning defined in Section 2.9.3(b).

Notice of Breach has the meaning defined in Section 5.11.3(a)

OEM Products mean products of which neither Biotronik nor any of its Affiliates are the Manufacturer of Record as defined Annex 2.1(b).

**Personal Data** has the meaning defined in Section 11(a).

Price has the meaning defined in Section 5.9(a).

**Product Specification** means, with respect to a Bio Products, any and all requirements to the respective Bio Products, including technical, physical, chemical, environmental, labelling, packaging and supplementary requirements as exclusively described in respective product specification as included in <u>Annex 2.1(a)</u>.

Products means, collectively, Bio Products and OEM Products.

Prolongation Term has the meaning defined in Section 12.1(a).

Quality Management Agreement or QMA means the agreement attached to this Agreement in Annex 4.1.

Ramp-Up Period has the meaning set forth in Section 2.3(b) and further specified on a country-by-country basis in Annex 2.1.

Regulatory Authority means any Governmental Authority responsible for granting Marketing Authorization Approval for a product the Territory.

**Regulatory Materials** means all filings and supporting documents submitted to (or retained for purposes of satisfying requirements of) any Regulatory Authority relating to any Bio Product, and all data contained therein, including, without limitation, advertising and promotion documents, adverse event files, complaint files and manufacturing records.

**Removed Product** has the meaning defined in Section 2.9.5(a).

Section means a section of this Agreement.

Sell-Off Period has the meaning defined in Section 12.3.4(d)

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Shelf-Life Period means, with respect to sterile Products, their maximum approved shelf life.

**Sub-Distributor** has the meaning defined in Section 2.7(a).

**Territory** means the territory defined in <u>Annex 2.1</u>.

Third Party means a party other than Acutus, Biotronik and the Affiliates of each.

Third Party Analysis has the meaning defined in Section 5.11.4(d).

ViaCath Bio Products means Bio Products with the letters "ViaCath" being a part of the product name.

Warranty has the meaning defined in Section 5.11.1(a)

Warranty Claim has the meaning defined in Section 5.11.3(a).

**Warranty Period** has the meaning defined in Section 5.11.2.

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# Annex 2.1 – Territory and Ramp-Up Period

The Territory will comprise of the following countries, for which the defined Ramp Periods will apply respectively:

Territory	Ramp-Up Period	Notes
USA	12 months	
Canada	12 months	
China	24 months	
Hong Kong	24 months	
Sweden	12 months	
Denmark	12 months	
Iceland	12 months	
Finland	12 months	
Norway	12 months	
UK	24 months	
Ireland	24 months	
The Netherlands	24 months	
Belgium	24 months*	[****]
Luxemburg	24 months	
France	24 months	
Italy	24 months*	[****]
Spain	24 months*	[****]
Portugal	24 months	

\* Ramp-Up period for this country begins once Acutus is cleared to begin distribution in accordance with Section 2.3(d) in such country.

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# Annex 2.1(b) – OEM Products

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# Annex 2.5 – Competing Companies

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# Annex 3.5 – Annual Purchase Targets

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[\*\*\*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

# **Global Alliance for Acutus Product Distribution Agreement**

by and between

**Biotronik SE & Co. KG** Woermannkehre 1,12359 Berlin, Germany

and

Acutus Medical, Inc.

2210 Faraday Ave Suite 100, Carlsbad 92008, California, U.S.A.

(Biotronik and Acutus together the Parties and each a Party)

(Biotronik)

(Acutus)

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#### Preamble

- A. Acutus has developed and manufactures, *inter alia*, a portfolio of electrophysiology products for cardiac mapping and radiofrequency ablation therapy.
- B. Biotronik is active, *inter alia*, in the field of distribution of medical devices.
- C. Acutus intends to appoint Biotronik as a distributor for ACM Products in the Territory, and Biotronik intends to accept such appointment.

Now, therefore, the Parties agree as follows:

#### 1. Definitions and Interpretation

- (a) The capitalized terms set out in <u>Annex 1(a)</u> have the meanings set forth in that Annex, whether used in the singular or plural form.
- (b) The words "includes", "including", "in particular", "such as" and "inter alia" and the examples given in the Agreement are to be construed without limitation.
- (c) Obligations on a Party to provide information or notification to the other Party will be construed to mean "without undue delay", unless agreed otherwise.
- (d) References to a person include an individual, a body corporate, an unincorporated association of persons, government, state, state agency, corporation, association or partnership.
- (e) References to "days" mean calendar days unless specified to be Business Days.
- (f) References to a Party in this Agreement include references to the successors or permitted assigns of that Party.
- (g) A document is a reference to that document as modified or replaced from time to time.
- (h) Any reference to an enactment (which includes any legislation in any relevant jurisdictions) includes references to (i) that enactment as re-enacted, amended, extended or applied by or under any other enactment (before, on or after the Effective Date); (ii) any enactment which that enactment reenacts (with or without modification); and (iii) any subordinate legislation made (before, on or after the Effective Date) under that enactment, as reenacted, amended, extended or applied as described; (iv) any enactment, statute, legislation or law in any relevant jurisdictions.

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- (i) The Parties acknowledge that this Agreement has been individually negotiated, and each had the opportunity to consult with independent counsel of their own choice. They have entered into this Agreement based on their own judgment and not on any promises or representations other than those contained in the Agreement. This Agreement will be construed as a whole, according to its fair meaning, and not in favor of or against any Party.
- (j) References in this Agreement to EU/EEA countries means the countries that are in the European Economic Area, as defined under the EEA Agreement that formally establishes the European Economic Area, as such agreement is updated from time to time.

#### 2. Appointment as Distributor and Principles of Distribution

#### 2.1. Appointment

- (a) Acutus hereby appoints Biotronik as exclusive (subject to Section 2.2) distributor for the ACM Products in the countries of the Territory which are defined in <u>Annex 2.1</u> as belonging to the Biotronik Sphere of Commercialization, and Biotronik hereby accepts such appointment.
- (b) Acutus hereby appoints Biotronik as co-exclusive (subject to Section 2.2) distributor (together with Acutus and Acutus' Affiliates) for the ACM Products in the countries of the Territory which are defined in <u>Annex 2.1</u> as belonging to the Joint Sphere of Commercialization, and Biotronik herby accepts such appointment.
- (c) Biotronik will not import into the Territory or distribute in the Territory any ACM Products received from any source other than Acutus or a reseller (to the extent the reseller is authorized by Acutus to sell ACM Products to Biotronik for the Territory).

## 2.2. Exclusive and Co-Exclusive Distributorship

- (a) The appointment of Biotronik as a distributor for the ACM Products is (i) exclusive solely to the extent set forth in Section 2.2(b) and (ii) co-exclusive solely to the extent set forth in Section 2.2(c).
- (b) **Biotronik Sphere Exclusivity.** If and for as long as Biotronik has an exclusive distribution right for an ACM Product in a country in the Biotronik Sphere of Commercialization, Acutus shall not (i) appoint any Third Party as a distributor that has the right to distribute such ACM Product inside or into such country; and (ii) Acutus and its Affiliates shall not sell or represent such ACM Product in such country (in the case of each of (i) and (ii), other than passive sales as contemplated in Section 2.2(d)).
- (c) **Joint Sphere Co-Exclusivity.** If and for as long as Biotronik has a co-exclusive distribution right for an ACM Product in a country in the Joint Sphere of Commercialization, Acutus shall not appoint any non-Affiliate Third Party as a

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distributor that has the right to distribute such ACM Product actively inside or into such country.

- (d) Reserved Rights. Acutus and its Affiliates retain the right to conduct and maximize sales of ACM Products outside the Territory (including using distributors), and inside the Joint Sphere of Commercialization (not using distributors). Additionally, Acutus, its Affiliates, and distributors remain free to sell ACM Products passively (i.e. responding to unsolicited requests from individual customers including delivery of goods to such customers in the sense of para 51 of the Vertical-Guidelines (2010/C 130/01)) into all countries in the EU/EEA, UK and Switzerland.
- (e) Prior to the Effective Date, Acutus will have provided Biotronik with a list of all distributors currently appointed by Acutus for ACM Products in the Territory.
- (f) Biotronik, its Affiliates and, to the extent approved by Acutus under Section 2.7(a), its Sub-Distributors will have the right to conduct sales of ACM Products inside and into the Biotronik Sphere of Commercialization and the Joint Sphere of Commercialization of the Territory.

#### 2.3. Rental program for ACM Console Products

- (a) During the first two (2) years of the Initial Term of the Agreement, Acutus shall maintain a rental program for ACM Console Product units on the terms and conditions in this Agreement, including those attached as <u>Annex 2.3</u>. Biotronik shall have the right to purchase ACM Console Product units from Acutus under Section 5 below at any time during the term of this Agreement and to rent up to fifty (50) ACM Console Product units from Acutus under Section 5 below at any time during these first two (2) years; such rental also being subject to <u>Annex 2.3</u>. The fixed rental fees for the ACM Console Product units are outlined in <u>Annex 2.3</u>. The costs for standard service and maintenance of such rented ACM Console Products are included in the rental fee to the extent set forth in <u>Annex 5.12</u>, and Acutus shall perform its service obligations under <u>Annex 5.12</u> for the rental ACM Console Product units.
- (b) After the end of the first two (2) years of the Initial Term of the Agreement, Biotronik may continue to rent the then rented ACM Console Products in accordance with the terms and conditions of this Agreement, including <u>Annex 2.3</u>, and may do so indefinitely during the term of this Agreement to the extent Biotronik retains any distribution rights (excluding passive sales rights) for the ACM Console Products in the country within the Territory under this Agreement into which the unit is being distributed, including Biotronik's right according to Section 2.3(c)(i). There will be no option to rent ACM Console Products additional to the ACM Console Product units rented during the first two (2) years of the Initial Term after the first two (2) years of the Initial Term, and rental units returned during or after this first two (2) years of the Initial Term cannot be rented again (each return reducing the total quantity that may be rented by Biotronik by one). Biotronik and its customers will not have an

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option to buy rental units. Rather, all sales by and under authority of Biotronik must be of new units purchased from Acutus under Section 5 below.

- (c) Subject to the terms and conditions of this Agreement, including <u>Annex 2.3</u>, Biotronik shall have the right to
  - (i) freely move the rented ACM Console Product units to another customer account in the Territory, with or without a refurbishment of such ACM Products in accordance with Section 5.11 of this Agreement, during the term of this Agreement to the extent Biotronik retains the right to distribute the ACM Console Product under this Agreement into the country within the Territory into which the ACM Console Product is being moved; and
  - (ii) return rented ACM Console Product units to Acutus with thirty (30) days' notice when Biotronik wants to remove the rental units from its rental inventory.

While Acutus has the right to update the terms and conditions set out in <u>Annex 2.3</u> to reflect Acutus' then standard rental practices, Acutus will not update <u>Annex 2.3</u> to prevent Biotronik from moving or returning units in the manner described in this Section 2.3(c).

#### 2.4. Ramp-Up Periods for distribution of ACM Products

#### 2.4.1. Sharing of market development costs

- (a) Acutus and Biotronik shall share market development costs in the Territory incurred during the Ramp-Up Periods solely to the extent mutually agreed by both Parties in writing. The Parties agree that the ramp-up periods for the distribution of ACM Products in each country in the Territory are set forth in <u>Annex 2.1</u> of this Agreement, subject to adjustment as set forth in Section 2.4.1(b) or 2.4.1(c) (the **Ramp-Up Periods**).
- (b) The Ramp-Up Period for each country in the Territory shall commence in the respective country upon the granting of the respective Marketing Authorization Approval by the Governmental Authorities in the country (or upon the Effective Date if already granted as of the Effective Date) and shall end in such country at the end of the number of consecutive months after Marketing Authorization Approval in such country (or after the Effective Date if a Marketing Authorization Approval is already granted as of the Effective Date) as indicated in <u>Annex 2.1</u>, except such duration shall be adjusted as follows. Because the Parties desire to have the Annual Purchase Targets for all countries begin on January 1, and end on December 31, of each calendar year, the duration of each Ramp-Up Period shall be determined as if the Ramp-Up Period began on: (i) for Marketing Authorization Approvals existing as of the Effective Date, January 1, 2021; (ii) for all other Marketing Authorization Approvals obtained prior to July 1 of a calendar year, the January 1 preceding the date on which the Marketing Authorization Approval was obtained (i.e.,

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January 1 of the calendar year in which the Marketing Authorization Approval was obtained); and (iii) for Marketing Authorization Approvals obtained on or after July 1 of a calendar year, the January 1 immediately following the date on which the Marketing Authorization Approval is obtained (i.e., January 1 of the calendar year following the calendar year in which the Marketing Authorization Approval was obtained).

(c) In EU/EEA countries of the Territory where Acutus is responsible for maintaining the Marketing Authorization Approval (i.e., the CE mark), if Acutus loses the CE mark for the ACM Console Product, the AcQMap Mapping Catheter or the AcQMap Patient Electrode Kits, then the Annual Purchase Targets for all such countries affected by the loss of the CE mark shall be reduced as reasonably necessary to account for the loss, as follows. In each calendar year in which the CE mark was not in effect for any part of such year, the Annual Purchase Target for the ACM Product for which the CE Mark was lost shall be reduced in the affected EU/EEA countries pro-rata based upon the duration of the loss a percentage of the duration of the calendar year. The Parties acknowledge that such loss is a serious obstacle to conduct sales in such affected countries of the Territory and may have negative effects beyond the actual time period during which or ACM Product for which no CE mark exists, however. Accordingly, Biotronik will have the right to provide an estimate for the impact on the sales on ACM Product beyond such adjustment and request an additional reduction of the Annual Purchase Targets. The Parties will discuss in good faith the impact of Acutus' loss of the CE mark, and each Party will attempt in good faith to reasonably resolve issues caused by the loss collaboratively with the other and to minimize adverse impact on ACM Product sales. For clarity, adjustments to Annual Purchase Targets beyond the automatic adjustment described in this paragraph above will be made solely as mutually agreed.

#### 2.4.2. Obligations of the Parties during the Ramp-Up Periods

- (a) Acutus shall provide sufficient therapy manager (i.e. mapper) training for Biotronik initial personnel to support and accelerate market adoption of the ACM Products in accordance with Section 3.11. Biotronik agrees that its personnel shall become the primary training resource for other Biotronik personnel as soon as practical subject to sufficient training by Acutus in accordance with Section 3.11.
- (b) Acutus and Biotronik shall set up shared service depots on a region by region basis as further agreed to and described in a separate agreement. For Europe the service depot will be set-up and operated by Acutus in Brussels as of the Effective Date.
- (c) Acutus and Biotronik shall discuss and separately agree on creating and developing centres of excellence, which shall include creating a centre of excellence in Berlin, for the purpose of promoting the ACM Products and the Bio Products. There shall be a centre of excellence at a hospital to be selected

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by the Parties for case observations, and a demo lab including one ACM Console Product that Acutus shall provide at no cost to be placed in Berlin. Biotronik shall keep the ACM Console Product in good working order, subject to sufficient training provided by Acutus. Acutus reserves the right to remove the ACM Console Product if it is not being used to promote ACM Products to support and accelerate market development consistent with Section 3.1(a).

- (d) Biotronik shall support Acutus' commercial team working closely with the Biotronik EP business development team to promote and support Biotronik's and Acutus' customers purchasing and using the ACM Products throughout the European Union.
- (e) To the extent agreed by the Parties in writing, Biotronik shall fund physician studies in the Biotronik Sphere of Commercialization and Acutus shall provide support as required.
- (f) Acutus agrees to hire sufficient personnel to provide training and logistical support to Biotronik for the Ramp-Up Periods in accordance with Section 3.11.
- (g) Biotronik agrees to hire or re-assign sufficient personnel to provide mapping, sales, technical and field support for the countries of the Territory; in each case consistent with Section 3.1(a).

### 2.5. Sales Outside the Territory

Biotronik will not, and will cause its Affiliates and Sub-Distributors not to, (i) conduct sales of or accept orders for ACM Products outside the Territory; or (ii) sell the ACM Products to any Third Party if Biotronik or its Affiliate knows or should know, in the exercise of good faith business judgement and without the need to investigate, that such sale will result in the distribution of any ACM Product outside of the Territory. In the case of each of (i) and (ii), Biotronik and its Affiliates remain free to passively sell ACM Products (i.e. responding to unsolicited requests from individual customers including delivery of ACM Products to such customers in the sense of para 51 of the Vertical-Guidelines (2010/C 130/01)) into all countries in the EU/EEA and Switzerland. While rights to distribute ACM Products in the Czech Republic are reserved to Acutus as of the Effective Date, the Parties will discuss, around the end of calendar year 2020, the extent to which Biotronik should receive exclusive rights in the Czech Republic. The Czech Republic will be added to the Territory solely to the extent mutually agreed.

# 2.6. Status of Biotronik

- (a) The relationship between Acutus and Biotronik will be that of independent contractors. Nothing contained in this Agreement will be construed to imply a joint venture or principal-agent relationship between the Parties.
- (b) Biotronik will act in its own name and for its own account. All financial obligations associated with the business of Biotronik are the sole responsibility of Biotronik.

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(c) Neither Party has nor will hold itself out as having any right, power or authority to create a contract or obligation, whether either expressed or implied, on behalf of, in the name of or binding on the other Party.

#### 2.7. Sub-Distributors

- (a) Biotronik may appoint third-party sub-distributors or agents in countries in the Territory other than those in the EEA/EU, UK and Switzerland (together the Sub-Distributors), such appointment to be made solely with the prior written consent of Acutus, which will not be unreasonably withheld, provided that Biotronik does not have a sales force in the country, the scope and duration of rights (including exclusivity) granted to Sub-Distributors does not exceed the scope or duration of rights granted to Biotronik under this Agreement and the agreements with Sub-Distributors are subject to the same rights of termination and conversion by Acutus as Biotronik's rights. Biotronik shall be responsible for the actions and inactions of its Affiliates and Sub-Distributors in connection with this Agreement as if such actions and inactions were by Biotronik. It shall be considered reasonable for Acutus to withhold consent based upon any good faith questions or concerns in Acutus' reasonable business judgement. For clarity, no MAA for an ACM Product will be owned or controlled by a Sub-Distributor except to the extent Acutus expressly indicates that the Sub-Distributor is authorized to own or control the MAA in such written approval by Acutus.
- (b) Biotronik will impose terms on its Sub-Distributors that are materially as protective of Acutus as the following terms in this Agreement:
  - (i) the terms in Sections 2.1(c), 2.2(d), 2.4.2(g), 2.5, 2.6, 3.1, 3.2, 3.3, 3.4, 3.6, 3.7, 3.8, 3.9, 3.10, <u>Annex 5.12</u> and Acutus' rights to make changes to, discontinue, and remove ACM Products;
  - (ii) subject to Acutus' obligations under Section 3.11, Biotronik will be solely responsible for ensuring Sub-Distributors have sufficient training;
  - (iii) the terms in Section 4, including those obligations of Biotronik regarding quality, regulatory and compliance and in the Quality Management Agreement;
  - (iv) the terms in Section 5.7(b) and the obligation not to modify ACM Products according to Section 5.8;
  - (v) no ACM Product shall display branding, labelling, or the like of any Sub-Distributor without the prior written approval of Acutus;
  - (vi) the warranty exclusions and remedy limitations in Section 5.13;
  - (vii) the terms in Sections 6, 7.3, 8, 9, 10, 11, and 13; and
  - (viii) Sections 12.1, 12.2 (excluding 12.2(d)), and Section 12.3.

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## 2.8. Resale Prices

Biotronik is free to determine the resale prices for the ACM Products.

#### 2.9. ACM Products

#### 2.9.1. Range of ACM Products

The ACM Products available for purchase from Acutus under this Agreement are specified in <u>Annex 2.1(a)</u>.

#### 2.9.2. ACM Products Changes

- (a) Biotronik may submit to Acutus non-confidential written proposals for changes to ACM Products and the Product Specifications. These proposals will be promptly reviewed in good faith and, if approved by Acutus, adopted by Acutus. Acutus will advise Biotronik in writing of acceptance or rejection of the proposed changes and additional costs and expenses involved with implementing accepted changes (if any). The Parties shall agree on the allocation of costs and expenses for such changes prior to the implementation of such changes to the ACM Products.
- (b) No later than the time at which Acutus first communicates with a Regulatory Authority or other Government Authority about a change or issue, but subject to Section 2.9.2(d) and in each case excluding changes to the extent implemented without prior approval or notice being required by a Regulatory Authority, Acutus will inform Biotronik in writing of any:
  - (i) intended design change that affects the form, fit or function of ACM Products;
  - (ii) intended change of clinical indication, contraindication or intended use of ACM Products;
  - (iii) intended changes that require a change of the Product Specification;
  - (iv) intended change of ACM Products that is visible to the user of ACM Products (including labelling and packaging); and
  - (v) any other intended changes, including to manufacturing or an ACM Product, that Acutus concludes will require a regulatory notice, submission or approval.
- (c) Unless changes to ACM Disposable Products notified to Biotronik pursuant to Section 2.9.2(b) are rejected by Biotronik in writing on reasonable grounds within thirty (30) days from receipt of notification, stating its reasons, these changes will be deemed accepted by Biotronik. If notified by Biotronik of rejection of a change in accordance with this Section 2.9.2(c), Acutus, subject to Section 2.9.2(d), will continue to provide the unchanged ACM Disposable

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Products until the earlier of (i) obtaining MAA for such changed ACM Disposable Products or (ii) eighteen (18) months after rejection by Biotronik, and in no event (other than as described in Section 2.9.2(d)) for a longer period of time then necessary to serve tenders; provided that Biotronik shall use diligent efforts to obtain an MAA for the updated ACM Product, and to transition each customer to the updated ACM Product, as soon as possible and in all cases such transition shall be completed within the such eighteen (18) month period.

- (d) Biotronik acknowledges and agrees that in the event Acutus, acting in good faith, considers it necessary to change an ACM Product on notice shorter than that set forth in Section 2.9.2(b) or 2.9.2(c) (i) due to unforeseeable material sourcing problems that Acutus has reasonable grounds to believe will create undue risk of safety or quality issues or of a violation of regulation or applicable law or other supply disruption, and/or (ii) due to unforeseeable changed regulatory requirements, then Acutus will nonetheless notify Biotronik in writing of the change and issue as early as reasonably possible, and in all cases no later than the time at which Acutus first communicates with a Regulatory Authority or other Government Authority about the change or issue. Acutus will discuss its reasons for such a change or issue reasonably with Biotronik and will provide to Biotronik the information set out in Section 2.9.2(b). Notwithstanding anything to the contrary, Acutus is under no obligation to provide ACM Products to Biotronik for which Acutus has notified Biotronik in accordance with this Section 2.9.2(d), or for which Acutus requires suspension under Section 8.4.2(c), for as long as the relevant change or issue is not resolved, and provided that Acutus uses commercially reasonable efforts to resolve the change or issue (or discontinues the ACM Product in light of the significance of the issue). In the event of such changes or issues, (i) the Parties will use good faith efforts to address and solve such situations in a mutually acceptable and reasonable manner, including good faith efforts to mitigate customer and partner impact, and (ii) Acutus will have the right to issue binding instructions to Biotronik regarding the ACM Products affected by such changes or issues that are reasonable in light of the issue(s).
- (e) Prior to implementing any change in ACM Product units supplied to Biotronik under this Agreement, Acutus shall provide Biotronik with the technical file for the applicable ACM Product reflective of such change.

#### 2.9.3. New Products

(a) Subject to agreement by the Parties on applicable terms under this Section 2.9.3(a), improvements and successor products of ACM Products, and new Acutus products, in each case that fall within the Field will be added to <u>Annex 2.1(a)</u>, provided their application lies within the Field (together the **New Products In The Field**). Acutus will promptly inform Biotronik of New Products In The Field and submit to Biotronik specifications of New Products In The Field. The Parties will in good faith negotiate in an effort to agree upon the terms applicable to the New Products In The Field which may include terms of

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the type set out under Sections 2.4 and 3.11. Notwithstanding anything to the contrary, neither Party will have any further obligation under this Agreement with regard to any New Product in the Field if the Parties fail to reach agreement on such terms within thirty (30) days.

- (b) Acutus will inform Biotronik of new or additional products of Acutus for electroporation (ablation devices and/or catheters), single shot PV-isolation systems with any energy source (cryo, radiofrequency, heat, or laser), and left atrial appendage occluder devices (the New Products Outside The Field). If either Party wishes to add any such New Products Outside The Field to <u>Annex 2.1(a)</u>, that Party will inform the other Party accordingly, and they will in good faith negotiate in an effort to agree upon the terms applicable to New Products Outside The Field should the Parties agree these should be included in this Agreement. Acutus will be under no obligation to agree to add New Products Outside The Field to <u>Annex 2.1(a)</u>, including if no agreement has been reached within thirty (30) days on the terms applicable to New Products Outside The Field.
- (c) Notwithstanding anything to the contrary, this Section 2.9.3 shall not apply (i) in the event of a Change of Control of or a Third Party otherwise becoming an Affiliate of Acutus, to require addition to this Agreement of any product not listed in <u>Annex 2.1(a)</u> at the time of the closing of the Change of Control or Third Party becoming an Affiliate of Acutus; and (ii) in the specific country of the Territory, to require the addition of any product for which the other Party or its Affiliate is distributing a Competing Product.

#### 2.9.4. Discontinued Products

- (a) Acutus reserves the right to discontinue ACM Products without replacement during the term of this Agreement, subject to Section 2.9.4(b) and provided an ACM Product will be considered "discontinued" only if Acutus no longer manufactures the relevant ACM Product (and no longer has the relevant ACM Product manufactured by a Third Party for sale or distribution in the Territory) (each a **Discontinued Product**).
- (b) Excluding changes pursuant to Section 2.9.2, if Acutus intends to discontinue an ACM Product, Acutus will notify Biotronik no less than (i) thirty-six (36) months in advance of the intended discontinuation for all ACM Console Product and AcQMap Mapping Catheter products and (ii) twelve (12) months in advance of the intended discontinuation for any other ACM Product, and the Parties will discuss in good faith a resolution for the discontinuation, which may (in the absence of issues of the type contemplated in Section 2.9.2(d)) include (i) a right for Biotronik to place a reasonable final Individual Purchase Order for the Discontinued Product in order to fulfil its obligations from tender business; (ii) transferring the manufacture of the Discontinued Product to a manufacturing site of Biotronik and allowing Biotronik to continue the manufacture under a license or after sale of the Intellectual Property Rights necessary to manufacture the Discontinued Product; or (iii) an

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adjustment to Annual Purchase Targets pursuant to Section 3.5(j). Acutus will, however, be under no obligation to accept any final Individual Purchase Order that seeks delivery beyond the period of time set forth in this Section 2.9.4(b) above (i.e., thirty-six (36) months for all ACM Console Product and AcQMap Mapping Catheter products and twelve (12) months for any other ACM Product), to transfer manufacture to Biotronik or any other party or to license or sell any Intellectual Property Rights to Biotronik or any other party.

#### 2.9.5. Removed Products

- (a) If Biotronik or any of its Affiliates (or a Sub-Distributor) distributes a Competing Product in any country in the Territory (irrespective of whether Biotronik or its Affiliates or the Sub-Distributor have developed such Competing Product, have acquired such Competing Product from a Third Party, or such Competing Product is otherwise distributed by Biotronik or its Affiliates or a Sub-Distributor), Acutus will have the right to remove any ACM Product with which the Competing Product competes from <u>Annex</u> 2.1(a) with effect for each of the countries within the Territory where the Competing Product is distributed (a **Removed Product**).
- (b) Acutus will inform Biotronik in writing of removal under Section 2.9.5(a). While Acutus will not be required to delay any removal, the Parties will negotiate in good faith in an effort to agree upon the consequences of such removal, which may include a transition period in which Biotronik retains non-exclusive rights if required to serve tenders and provide seamless customer support provided that Section 12.3.5 will apply by analogy if the Parties cannot reach agreement.
- (c) Upon removal of a Removed Product from <u>Annex 2.1(a)</u>, Biotronik will (and will cause its Affiliates and Sub-Distributors to), at no cost or expense to Acutus, assign and transfer all right, title and interest in and to any and all Marketing Authorization Approvals Biotronik or its Affiliate or their Sub-Distributor may own or hold for such Removed Products to Acutus or Acutus' Affiliate or designee, subject to applicable regulatory requirements.
- (d) For the avoidance of doubt, Acutus will have the right but not the obligation to distribute (and authorize Affiliates and third parties to distribute) Removed Products in each country in the Territory for which the Removed Product was removed, including countries where the relevant Competing Product is distributed.

#### 3. Sales Promotion

# 3.1. Principles Governing Sales Promotion

(a) Commencing with Marketing Authorization Approval for an ACM Product in the respective country in the Territory or, if the Marketing Authorization Approval exists in the respective country as of the Effective Date, commencing on the Effective Date, and with respect to the relevant ACM Products that do

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not require Marketing Authorization Approval for distribution, Biotronik and its Affiliates will use commercially reasonable effort to:

- (i) promote and increase the sales of that ACM Product in such country in the Territory; and
- (ii) maintain and enhance the reputation and acceptance of such ACM Product in such country in the Territory.
- (b) Biotronik will distribute the ACM Products in each country in the Territory and provide sales and customer training, product support and field clinical support, carry out price negotiations with customers, submit tender offers, and provide First Level Support that offers, *inter alia*, trouble shooting, subject to the provisions of this Agreement regarding Acutus' support of ACM Products to be provided to Biotronik, all consistent with Section 3.1(a).
- (c) Except as otherwise provided in this Section 3, and except to the extent the Parties have agreed to share costs under Section 2.4.1(a), Biotronik will bear all costs and expenses for Biotronik to comply with the obligations under this Section 3, including costs and expenses for sales promotion, marketing, advertising, workshops, sales meetings, seminars, conventions, or exhibitions.

# 3.2. Sales Organization

Biotronik will set up and maintain an adequate sales organization and First Level Support and Second Level Support, with all means and personnel necessary to ensure the fulfilment of its obligations under this Agreement for all ACM Products in each country in the Territory, all consistent with Section 3.1(a).

## 3.3. General Compliance

Without prejudice to any other obligations under this Agreement, Biotronik will comply with all legal and technical requirements that apply or have to be observed in any country in the Territory in respect to the distribution of the ACM Products, including rental units.

# 3.4. Annual Business Plan Session

- (a) In each September, or at such other time as mutually agreed to by the Parties, the Parties will together conduct an annual face-to-face business plan session, unless the Parties agree that such session can be conducted via teleconference (the Annual Business Plan Session). During the Annual Business Plan Session, the Parties will, without limitation and all consistent with Section 3.1(a):
  - (i) review Biotronik's performance in the past year, including sales promotion of ACM Products in each country throughout the Territory, as well as the Parties' expectations for the next calendar year;

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- (ii) discuss Biotronik's marketing program for the next calendar year;
- (iii) discuss and possibly renegotiate the Annual Purchase Targets pursuant to Section 3.5(b);
- (iv) discuss and possibly renegotiate the Prices pursuant to Section 5.9(c); and
- (v) review and discuss Affiliates and the Sub-Distributors performance, including with respect to the foregoing (except for pricing information, which may be redacted or omitted).
- (b) In addition, the Parties will review performance anytime on a Parties' reasonable request or at agreed times.

#### 3.5. Annual Purchase Targets

- (a) For the time after the end of the respective Ramp-Up Periods, the Parties will agree on country-specific annual purchase targets for each country in the Territory for each ACM Console Product and AcQMap Patient Electrode Kit (the Annual Purchase Targets). The Parties agree that starting from January 1, 2023 Annual Purchase Targets will apply for the AcQMap Mapping Catheters rather than the AcQMap Patient Electrode Kits. Annual Purchase Targets for each AcQMap Mapping Catheter will be determined based upon volumes of ACM Console Products, as more particularly set forth in <u>Annex 3.5</u>.
- (b) The Annual Purchase Targets will be established jointly by the Parties, consistent with Section 3.1(a), taking into account market conditions, cardiac mapping and ablation therapy development, the competitive environment, clinical acceptance of the ACM Products, reimbursement, and all other factors related to the ACM Products, including functionality, quality, and availability. A non-binding, preliminary example of country-specific Annual Purchase Targets for the ACM Console Product and the AcQMap Patient Electrode Kit is provided in <u>Annex 3.5</u>. If the Parties have not agreed on the Annual Purchase Targets for a given or several countries for the first year after the Ramp-Up Period, the Annual Purchase Targets for the countries and such ACM Products for such year will be those set forth in <u>Annex 3.5</u>.
- (c) At the Annual Planning Session prior the end of each calendar year, the Parties will annually renegotiate in good faith the Annual Purchase Targets for the next calendar year for each ACM Console Product, AcQMap Mapping Catheter and AcQMap Patient Electrode Kit, consistent with Section 3.1(a). If the Parties cannot agree to the Annual Purchase Targets for a given or several countries prior to the beginning of a calendar year, the Annual Purchase Targets for that year will be increased by [\*\*\*\*] for the ACM Console Product and the AcQMap Patient Electrode Kit in the Biotronik Sphere of Commercialization (but remain unchanged for the countries of the Joint Sphere of Commercialization), as compared to the Annual Purchase Targets to the preceding calendar year. Annual Purchase Targets for the AcQMap

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Mapping Catheter will be increased under this Section 3.5(c) only as a result of [\*\*\*\*] in the quantity of ACM Console Products (and not an [\*\*\*\*] increase in the "per ACM Console Product" quantity of AcQMap Mapping Catheters under <u>Annex 3.5</u>).

- (d) If any of the following occurs, then Biotronik shall have the right to notify, and initiate discussions with, Acutus in accordance with Section 3.5(j):
  - (i) Acutus ceases to provide ACM Products under Section 2.9.2(d);
  - (ii) ACM Products are discontinued under Section 2.9.4;
  - (iii) ACM Products are removed under Section 2.9.5;
  - (iv) ACM Products that Acutus is obligated to supply under this Agreement are not available for order by Biotronik from Acutus in accordance with this Agreement due to a material breach of this Agreement by Acutus; or
  - (v) ACM Products are otherwise not available for order for any reason that is unavoidable, unforeseeable, outside the reasonable control of Biotronik or Biotronik's Affiliates due to Acutus' material breach of this Agreement.
- (e) Biotronik will provide to Acutus no later than January 15<sup>th</sup> of each calendar year a report indicating for the respective ACM Console Products, AcQMap Mapping Catheters and the AcQMap Patient Electrode Kits the quantity of each such ACM Product sold to customers and to and by Sub-Distributors during the previous calendar year, broken down by quantity of each ACM Product distributed in each country.
- (f) Annual Purchase Targets are deemed to be met if, on a country-by-country basis, Biotronik has placed Individual Purchase Orders for at least the required quantity of the respective the ACM Console Product, AcQMap Mapping Catheter and the AcQMap Patient Electrode Kit (counted only until replaced by AcQMap Mapping Catheter under Section 3.5(a)) for the respective country of the Territory during the respective calendar year. Each rental unit of ACM Console Products will be counted only one time under this Agreement and will be counted only in the calendar year and country in which Biotronik first delivered the rental unit to an end user customer in the Territory. Units of ACM Console Product, AcQMap Electrode Kits, and AcQMap Mapping Catheters provided as a repair or replacement by Acutus under warranty or a service plan will not be counted as an additional unit, and demonstration units will not be counted, toward the Annual Purchase Targets.
- (g) If any of the following occurs, then Biotronik shall have the right to notify, and initiate discussions with, Acutus in accordance with Section 3.5(j):

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- ACM Console Products, AcQMap Mapping Catheters or AcQMap Patient Electrode Kits were not delivered within the Lead Time from receipt of the respective Individual Purchase Order pursuant to Section 5.3 as a result of a breach by Acutus of its obligations under this Agreement;
- (ii) ACM Console Products, AcQMap Mapping Catheters or the AcQMap Patient Electrode Kits were not delivered by Acutus in the calendar year(s) in which Acutus was obligated to deliver the ACM Products under Section 5.3(d) in breach of Acutus' obligations under this Agreement;
- (iii) ACM Console Products, AcQMap Mapping Catheters or AcQMap Patient Electrode Kits have been properly rejected in accordance with Section 5.5(c) and are not remedied by Acutus in accordance with this Agreement;
- (iv) Individual Purchase Orders have been cancelled in accordance with Section 5.6(c);
- (v) ACM Console Products, AcQMap Mapping Catheters or AcQMap Patient Electrode Kits have not all been free from defects in accordance with Section 5.13.1(a) and are not remedied by Acutus in accordance with this Agreement;
- (vi) Acutus has required Biotronik to suspend shipment of ACM Console Products, AcQMap Mapping Catheters or AcQMap Patient Electrode Kits under Section 7.3(e);
- (vii) Acutus has suspended or terminated ACM Console Products, AcQMap Mapping Catheters or AcQMap Patient Electrode Kits under Section 8.4.2(c);
- (viii) any other material breach by Acutus of its obligations in this Agreement have interfered with Biotronik's ability to sell ACM Console Products, AcQMap Mapping Catheters or AcQMap Patient Electrode Kits, including the obligations under Section 2.4.2, 3.11 and 3.12; or
- (ix) ACM Console Products, AcQMap Mapping Catheters or AcQMap Patient Electrode Kits have not been sold by Biotronik due to a Force Majeure event.
- (h) If, for any country in the Territory, Biotronik fails to meet the Annual Purchase Target for any of the ACM Console Product, AcQMap Mapping Catheters or the AcQMap Patient Electrode Kit in such country during each of any two (2) consecutive calendar years after the end of the respective Ramp-Up Period, the Parties will in good faith (i) review Biotronik's efforts to achieve acceptable market development in the relevant country and (ii) determine if a remediation plan to achieve acceptable market development is appropriate. Acutus will have the right to terminate Biotronik's exclusive or co-exclusive

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rights, as the case may be, in the relevant country and for all ACM Products, and thus convert the exclusive or co-exclusive distribution rights of Biotronik in the relevant country to non-exclusive distribution rights for all ACM Products, by providing written notice of such termination to Biotronik, on condition that the Parties have not agreed in writing on a remediation plan within thirty (30) days after the end of the second consecutive calendar year.

- (i) If, for any country in the Territory, Biotronik fails to meet the Annual Purchase Target for any of the ACM Console Products, AcQMap Mapping Catheters or the AcQMap Patient Electrode Kits in such country during each of any three (3) consecutive calendar years after the end of the respective Ramp-Up Period, Acutus shall have the right to terminate this Agreement for the relevant country in the Territory for all ACM Products, on condition that the Parties have not agreed on a remediation plan within thirty (30) days after the end of the third consecutive calendar year. The Parties will transition distribution of ACM Products to Acutus in accordance with the terms of this Agreement.
- (j) If an issue of the type described Section 3.5(d) or 3.5(g) occurs that is caused by a material breach by Acutus of its obligations under this Agreement and that Biotronik believes is materially adversely impacting the efforts of Biotronik to scale up sales, marketing or commercialization during the Ramp Up Period or to meet Annual Purchase Targets, then Biotronik will have the right to provide written notice to Acutus, reasonably describing the issue. The Parties will meet within thirty (30) days after such notice to Acutus to discuss the issue(s), the details of the impact on Biotronik, and the extent to which any Ramp-Up Period or Annual Sales Targets should be adjusted as a result of the issue. Biotronik will be responsible for substantiating the extent of the impact. Each Party will reasonably discuss and consider the information provided by Biotronik in evaluating whether or not the Annual Purchase Target should be reduced and each Party will attempt in good faith to identify a reasonable resolution of issues, provided that adjustments will be made solely as mutually agreed.

#### 3.6. Marketing

Biotronik will advertise and promote the ACM Products at its own cost and expense in each country throughout the Biotronik Sphere of Commercialization and in the Joint Sphere of Commercialization, consistent with Section 3.1(a), as follows:

- (a) Biotronik will clearly demonstrate in all its marketing and communication that it acts as an independent distributor of the ACM Products and does not act on behalf of Acutus.
- (b) Each Party will bear the marketing expenses it has incurred, unless agreed otherwise.
- (c) Biotronik will submit all documents concerning advertising, promotion of sales, public relations or product information that it intends to use in relation to the distribution of the ACM Products under this Agreement to Acutus for prior

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approval, which will not be unreasonably withheld or conditioned. Biotronik will make sure that all pricing information in such material is blackened prior to submission to Acutus. Acutus will approve or reject each such submission within thirty (30) Business Days, otherwise such submission will be deemed approved by Acutus.

- (d) Biotronik will independently participate in the main international congresses, fairs and industry events in the Field, and may independently participate in any other congresses, fairs and industry events. In each case the Parties will use commercially reasonable efforts to coordinate their participation and presence.
- (e) On Biotronik's reasonable request Acutus will participate in Biotronik's national or regional electrophysiology sales meetings in the Biotronik Sphere of Commercialization of the Territory. Acutus will bear its own costs and expenses (including for travel, food and accommodation) for participating in such sales meetings.

#### 3.7. Information to Acutus

- (a) Biotronik will keep Acutus informed about its activities as distributor of the ACM Products, about the number of sales of the ACM Products and about market conditions in each country in the Territory. Biotronik will provide reasonable responses to reasonable requests by Acutus for information.
- (b) Biotronik will use reasonable efforts to keep Acutus informed about significant changes in:
  - the laws and regulations that apply to obtaining any MAA (to the extent Biotronik is responsible for obtaining the MAA) or the sale of the ACM Products in the Territory (without limitation import regulations, labelling, technical specifications, and safety requirements) of which Biotronik becomes aware, and
  - (ii) the laws and regulations concerning Biotronik's activity (e.g. regarding any permits, MAAs that Biotronik is responsible for obtaining, or reporting or record keeping requirements associated with such MAAs) of which Biotronik becomes aware, as far as they are relevant for Acutus.

# 3.8. Stocks and Expired ACM Products

Biotronik will,

(a) at its own expense, perform stock keeping in accordance with the Quality Management Agreement and keep a balanced inventory of ACM Products in quantity and assortment sufficient to meet customer demand in each country in the Territory; and

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(b) not sell any ACM Products beyond the use-by-date indicated on the respective ACM Products.

## 3.9. Insurance

Each Party will secure and maintain in effect, during the term of this Agreement, comprehensive general liability insurance, underwritten by a reputable insurance carrier, in a form and with liability limits as are standard and customary for entities in the medical device industry in each country within the Territory, taking into account such Party's activities and indemnification obligations under this Agreement. Each Party will provide the other Party with written evidence of such insurance promptly on request.

#### 3.10. After-Sales Services

Subject to the terms and conditions of this Agreement that require Acutus to provide repair or replacement for ACM Products, including the applicable warranty terms, and conditional upon Biotronik having received sufficient training by Acutus pursuant to Sections 2.4.2 and 3.11, Biotronik will be responsible for providing First Level Support and Second Level Support for the ACM Products to customers to the extent set out in and in accordance with <u>Annex 5.12</u>.

# 3.11. Training

(a) Acutus will provide Biotronik at no cost to Biotronik with initial training support sufficient to enable Biotronik to train its own employees and representatives (and those of its Affiliates and any Sub-Distributors) regarding use of the ACM Products as necessary to enable Biotronik to perform its obligations under this Agreement, including distributing the ACM Products in accordance with this Agreement, servicing the ACM Products and developing customers into proficient ACM Products users. It is agreed that Acutus provides trainings to the initial Biotronik personnel in the same quality as for Acutus' own personnel. Subject to Biotronik making such personnel available for such activities, Acutus shall test, qualify and certify the successful trainings of the initial Biotronik personal in four sessions no later than (i) one hundred and twenty (120) days after the Effective Date for Europe, (ii) ninety (90) days after first receiving an MAA for an ACM Console Product in the Asia-Pacific region, (iii) ninety (90) days after first receiving an MAA for the ACM Console Product in Japan and (iv) ninety (90) days after first receiving an MAA for the ACM Console Product in Japan and (iv) ninety (90) days after first receiving an MAA for the ACM Console Product in south and Central America region. Biotronik will ensure that only personnel which has been trained, tested and approved in accordance with such initial trainings provided by Acutus, as may be updated by Acutus from time to time, shall work as service and training personnel in the field, on condition that Acutus is in compliance with this Section 3.11(a). The details of the training sufficient to meet Acutus' obligations shall be reasonably agreed by the Parties prior to Acutus commencing the training. Biotronik will bear all costs and expenses (for travel, food, accommodation

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etc.) of Biotronik and its employees in connection with their attendance to such initial training support.

(b) Any additional training will be subject to the Parties' agreement. Unless agreed otherwise in writing, all reasonable costs and expenses (for travel, food, accommodation etc.) of Acutus and its employees in connection with such additional training will be reimbursed by Biotronik subject to Biotronik's applicable reimbursement conditions. Biotronik will bear any costs and expenses of its employees in connection with such additional training.

## 3.12. Documentation and Specimens

- (a) Without prejudice to any of Acutus' other obligations under this Agreement, Acutus will provide Biotronik with a reasonable number of samples of the available documentation relating to the ACM Products reasonably needed (and requested) by Biotronik to carry out its obligations under this Agreement (such as marketing material, user manuals etc.). In particular, Acutus hereby grants Biotronik the rights to the brochures relating to the ACM Products, Clinical Data relating to the ACM Products that has been generated by or under the authority of Acutus to the extent necessary for Biotronik to obtain an MAA, advertising and selling information and promotional literature relating to the ACM Products, as reasonably requested by Biotronik and in control of Acutus, at no additional cost to Biotronik, as necessary for Biotronik to market and distribute the ACM Products and otherwise exercise its rights and perform its obligations under this Agreement; it being acknowledged that Biotronik shall be responsible for obtaining and generating information, materials and data not provided by Acutus if and to the extent such information is not necessary to be provided by Acutus as the legal manufacturer of the ACM Products.
- (b) Biotronik will, at its own costs and expense, translate any materials into local language and into Biotronik's branding with the private label product names, if applicable. Any use, disclosure or distribution of any brochures, Clinical Data, advertising and sales information and promotional literature produced by Biotronik will require approval by Acutus, which will not be unreasonably withheld or delayed. Acutus will approve or reject such materials submitted by Biotronik within thirty (30) Business Days, otherwise such submission will be deemed approved by Acutus.
- (c) Acutus will provide Biotronik with non-functional non-sterile specimens of each ACM Product to be used for promotional purposes at a price to be agreed by the Parties. Biotronik will not resell such specimens and will return them to Acutus if no longer needed.

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## 4. Quality, Regulatory and Compliance

#### 4.1. Quality Management

The Parties will enter into the Quality Management Agreement as attached as <u>Annex 4.1</u> on or before the Effective Date. The Quality Management Agreement will govern all communication and interaction between Acutus and Biotronik with regard to quality management, change management, regulatory compliance and reporting, preventive and corrective action including field safety corrective action. In case of any conflict between any provision of this Agreement and any provision of the Quality Management Agreement, the provision of the Quality Management Agreement will prevail.

#### 4.2. Marketing Authorization Approvals

#### 4.2.1. Principles Governing Marketing Authorization Approvals

- (a) Biotronik will, directly or through its Affiliates or Sub-Distributors (to the extent Acutus has authorized the Sub-Distributor in writing to hold the Marketing Authorization Approval in accordance with Section 2.7(a)), file, secure, own and hold at its own cost and expense all Marketing Authorization Approvals for the ACM Products in each country in the Territory, except for the CE approval. The CE approval will be owned, held and maintained by Acutus to allow Biotronik the distribution of ACM Products in the EU/EEA countries in the Territory under this Agreement.
- (b) Biotronik will own, directly or through its Affiliates or Sub-Distributors (to the extent Acutus has approved in advance in writing the Sub-Distributor to own the particular Marketing Authorization Approval in accordance with Section 2.7(a)) for purposes of applicable medical device regulations, any and all Marketing Authorization Approvals in each country in the Territory if Biotronik has, in full or in majority part (i.e. more than 50%), undertaken and paid for obtaining a given Marketing Authorization Approval; provided that notwithstanding anything to the contrary, Acutus shall, subject to applicable law, own and control all Clinical Data and other information in any Regulatory Materials, and such Clinical Data and information will be deemed to be the Confidential Information of Acutus (and not Biotronik) under this Agreement, regardless of who owns, holds or funded the MAA or the development of such data or information, provided that Biotronik may use such Clinical Data and information (and the copyrights and trade secrets of Acutus embodied therein) to the extent Biotronik deems it necessary to obtain and maintain the Marketing Authorization Approvals and to exercise its rights and perform its obligations to market and distribute ACM Products in the Territory under this Agreement. Biotronik hereby grants, and shall grant, Acutus a right (and access) to copy and reference all MAAs owned and held by Biotronik (or its Affiliates or Sub-Distributors) for ACM Products and all Clinical Data and information in such MAAs and other related Regulatory Materials, in each case including all copyrights and trade secrets embodied therein; provided

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that this obligation only apply to data and information developed by or under the authority of Biotronik that does not relate to any ACM Product.

- (c) Biotronik shall, to the extent necessary, conduct any Clinical Trials needed to obtain Marketing Authorization Approvals in each country in the Territory and hire and train staff to support such Clinical Trials. Upon request by Acutus, Biotronik shall keep Acutus informed of all activities and efforts associated with MAAs, including interactions and communications with Government Authorities, and shall give Acutus, upon Acutus specific request, the right to review and approve all material communications and material submissions in advance; provided, however, that Biotronik will be under no obligation to disclose Confidential Information to Acutus that does not pertain to any ACM Products or any of Biotronik's rights or obligations under this Agreement. Biotronik shall notify Acutus promptly upon receiving any MAA.
- (d) Biotronik shall file any periodic reporting, support other required maintenance mechanisms, and shall otherwise be solely responsible to maintain/retain Marketing Authorization Approvals in each country in the Territory, except for the CE marks that Acutus maintains for the EU/EEA countries in the Territory.
- (e) Biotronik shall within the first two (2) years of the Initial Term (unless such two year period is extended as described below),
  - (i) obtain all Marketing Authorization Approvals and registration materials for all countries in the Biotronik Sphere of Commercialization, but only to the extent not obtained or to be obtained by Acutus, and in the Joint Sphere of Commercialization, including approval of pricing if necessary; and
  - (ii) make a first commercial sale in a fully arms-length transaction to a non-Affiliate Third Party of each ACM Product in each country in the Territory including at least one ACM Console Product in each country in the Territory, provided that no rental ACM Console Product as contemplated in Section 2.3 shall be counted as a "first commercial sale".

The two year time period set forth above may be extended solely upon mutual agreement of the Parties upon Biotronik's reasonable request and backed by evidence in the event of certain extenuating circumstances outside of Biotronik's reasonable control; such as Regulatory Authority delays, study subject enrolment issues and events attributable to clinical site performance issues, in each case that were unforeseeable and are out of the ordinary; provided the Parties will discuss all such issues in good faith if Biotronik requests and each will reasonably consider the input and feedback of the other in deciding whether or not an extension or change is reasonable.

(f) Acutus will provide Biotronik with ACM Product information, testing documentation and Clinical Data, as well as any other information, in each

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case that can only be obtained from Acutus as the manufacturer and developer of the ACM Products, that is necessary to enable Biotronik to perform its obligations under this Agreement to obtain Marketing Authorization Approvals for ACM Products.

- (g) On an ongoing basis as promptly as is reasonable using efforts consistent with Section 3.1(a), Biotronik will obtain any additional Marketing Authorization Approvals and registrations in each country in the Territory, including approval of pricing, if necessary for future upgrades to the hardware or software of the ACM Products and provide translation support as needed (other than CE mark); unless Acutus has become responsible for obtaining and maintaining the MAA in accordance with the terms of this Agreement for the particular country and all existing MAAs for the country have been assigned and delivered to Acutus.
- (h) Notwithstanding the foregoing, if the applicable laws and regulations in any country require that any MAAs for any ACM Products are owned and/or held in the name of Acutus in order to enable Biotronik to exercise its rights under this Agreement for such ACM Products in such country, then such MAAs shall be owned and/or held in the name of Acutus.
- (i) Unless otherwise provided in this Agreement, Biotronik will use commercially reasonable efforts to seamlessly maintain in its own name and on its own expense any Marketing Authorization Approvals for the ACM Products in each country in the Territory to the extent necessary for Biotronik (and Acutus in the Joint Sphere of Commercialization) to distribute the ACM Products under this Agreement; unless Acutus has become responsible for obtaining and maintaining the MAA in accordance with the terms of this Agreement for the particular country and all existing MAAs for the country have been assigned and delivered to Acutus.
- (j) Biotronik will promptly (within five (5) Business Days) inform Acutus of any withdrawal or expiration without renewal of any Marketing Authorization Approvals in any country in the Territory.
- (k) If a clinical study or trial plan is required in order to obtain or maintain an MAA in a country in the Territory, the Parties will establish a plan that defines Biotronik's responsibilities with respect to such Clinical Trial, and the allocation of resources by Biotronik to the planning, execution and evaluation, and the target timeline to obtain the MAA (all at Biotronik's cost and expense); all subject to review and approval by Acutus; unless Acutus has become responsible for obtaining and maintaining the MAA in accordance with the terms of this Agreement for the particular country and all existing MAAs for the country have been assigned and delivered to Acutus.

## 4.2.2. Sale or Import without Marketing Authorization Approval

Biotronik will not sell or import any ACM Products into countries or regions without Marketing Authorization Approval if such Marketing Authorization Approval is

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required by applicable law. Acutus will have no responsibility for any such sales or imports.

### 4.3. Clinical Trial Coordination

- (a) Acutus will have the right to undertake Clinical Trials whether or not necessary to obtain Marketing Authorization Approvals, in relation to the ACM Products at any time and in any jurisdiction and territory; with the exception that Acutus will not, without the prior written consent of Biotronik not to be unreasonably withheld or delayed, perform Clinical Trials at clinical sites located in a country in the Biotronik Sphere of Commercialization in the Territory for purposes of obtaining a Marketing Authorization Approval in such country for those ACM Products for which Biotronik has exclusive distribution rights in such country. Units of ACM Console Products, AcQMap Mapping Catheters, and AcQMap Electrode Kits which are given by Acutus without charge to a Clinical Trial site in a country in the Territory will count toward satisfying Biotronik's respective Annual Purchase Target in such country. For the avoidance of doubt Acutus shall not charge for ACM Console Products, AcQMap Mapping Catheters, and AcQMap Electrode Kits provided by Acutus for such Clinical Trials. Additionally, Acutus retains the right to perform Clinical Trials at clinical sites located in such country for other purposes, however, provided that Acutus reasonably informs and coordinates with Biotronik. Similarly, Biotronik will inform (and obtain approval) of Acutus of Biotronik's Clinical Trial plans and Biotronik will coordinate and work with (and obtain approval of) Acutus on the design, execution, analysis, regulatory submission and publication of clinical studies by and under authority of Biotronik on the ACM Products and on the collection of clinical data required by applicable regulatory rules.
- (b) Unless agreed otherwise, Biotronik will bear full financial responsibility for these trials and all benefit resulting from such trials will accrue exclusively to Acutus, and all Clinical Data and information in Regulatory Materials (including copyrights and trade secrets embodied therein) will exclusively belong to Acutus; provided that Acutus will share such Clinical Data with Biotronik and Biotronik shall have the right to use such data (including such copyrights and trade secrets) as reasonably necessary to exercise its rights under this Agreement and to publish the results and/or summaries of results of all Clinical Trials, observational studies, and other studies, including the protocols of all such Clinical Trials, after obtaining the prior written approval of Acutus, which approval shall not be unreasonably conditioned, withheld, or delayed.
- (c) Biotronik may inform Acutus of non-confidential ideas of customers concerning clinical studies and/or investigations and collection of Clinical Data related to the ACM Products or New Products. Acutus will have the right but not the obligation to support and fund the study or data collection, in which case any and all rights in the Clinical Data will exclusively belong to Acutus. If Acutus decides not to exploit such customer ideas, Biotronik will have the

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right to further develop such ideas and to conduct a Clinical Trial; in all cases solely upon Acutus' prior written consent not to be withheld unreasonably.

### 4.4. Government Reimbursement

Biotronik will, at its own cost and expense, develop and implement a plan for securing reimbursement for ACM Products in the Biotronik Sphere of Commercialization. In countries of the Joint Sphere of Commercialization of the Territory where Acutus has not developed or implemented and has no intention to develop or implement a plan for securing reimbursement for ACM Products, Biotronik may, at its own cost and expense, develop and implement a plan for securing reimbursement. In both cases, Acutus will reasonably support Biotronik in any such plan, including providing Biotronik with the information required in order to receive reimbursement approval.

#### 5. Sales to Biotronik

#### 5.1. Terms of Sale

All sales and rental of ACM Products and Service Contracts under <u>Annex 5.12</u> by Acutus to Biotronik will be pursuant to the terms and conditions of this Agreement. No other terms of either Party will apply, even if referenced or contained in an order, acknowledgement, acceptance or otherwise.

#### 5.2. Forecasts

- (a) Each calendar month, no later than by the fifth (5<sup>th</sup>) Business Day, Biotronik will provide Acutus with a rolling forecast for the immediately succeeding twelve (12) months period (i.e., commencing with the following calendar month). This forecast will be provided in writing and will specify the anticipated purchases for each ACM Product (and for the ACM Console Products the anticipated rental units, in accordance with Section 5.2(c)) for delivery to Biotronik in each calendar month covered by the forecast. A first forecast will be provided prior to signing on the Effective Date.
- (b) For each forecast, the volumes of ACM Products forecasted for:
  - (i) the forecast for the immediately succeeding two (2) calendar months, i.e., months one (1) and two (2) covered by the respective forecast, will be binding;
  - (ii) the forecast for the two (2) calendar months following that period, i.e., months three (3) and four (4) covered by the respective forecast, will each not vary more by than twenty percent (20 %) from the volumes forecasted for the respective calendar month in the last forecast; and
  - (iii) the forecast for the two (2) calendar months following that period, i.e., months five (5) and six (6) covered by the respective forecast, will each not vary by more than fifty percent (50 %) from the amounts forecasted for the respective calendar month in the last forecast.

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(c) For the forecasts for ACM Console Products to be delivered by Acutus in the first six (6) calendar months after the Effective Date, Biotronik will be entitled to specify the total number of Console Product units only, without having to specify the number Product units which are rental units and the number of units which are purchase units.

# 5.3. Order Process

- (a) Biotronik will order the ACM Products and Service Contracts as contemplated in <u>Annex 5.12</u> from Acutus by issuing Individual Purchase Orders in writing to Acutus. The terms and conditions of this Agreement, including Section 13.8 and <u>Annex 5.12</u>, will apply to all supplies of ACM Products to and Service Contracts with Biotronik even if the Individual Purchase Order does not specifically refer to this Agreement.
- (b) Individual Purchase Orders will be in English. Biotronik will be entitled to use its standard purchase order form to place Individual Purchase Orders, provided that the terms and conditions of this Agreement will control and no different, conflicting, or additional terms on Biotronik's purchase order, Acutus' acknowledgement, invoice, or similar document will apply. All additional and different terms on any document issued by either Party are hereby rejected and objected to. Each Individual Purchase Order will comply with the terms and conditions of this Agreement and will, in particular, contain the following information:
  - (i) name and part number of each ACM Product ordered;
  - (ii) the quantity of each ACM Product ordered;
  - (iii) the requested delivery date, considering the Lead Times for each ACM Product;
  - (iv) for ACM Console Product units that Biotronik desires to rent, clearly designate such units as (specifying the quantity of) rental units;
  - (v) any other instructions and terms (consistent with this Agreement) as may be appropriate under the circumstances.
- (c) Biotronik will send the Individual Purchase Order to the address listed in this Agreement or to any other address communicated by Acutus to Biotronik from time to time. An Individual Purchase Order will be binding on Biotronik on receipt of that Individual Purchase Order by Acutus.
- (d) Acutus will accept or refuse Individual Purchase Orders in writing within five (5) Business Days of receipt. Acutus will accept Individual Purchase Orders that comply with the applicable Lead Times and with the volumes forecasted pursuant to Section 5.2, provided that the respective forecast complies with Section 5.2. Acutus will only be bound upon acceptance of an Individual Purchase Order. Acutus will use commercially reasonable efforts to accept

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Individual Purchase Order to the extent they reasonably exceed the applicable forecast. Any Individual Purchase Order that is not refused within five (5) Business Days of receipt will be deemed accepted.

- (e) In case of discrepancies between order and acceptance, Acutus' acceptance will prevail, unless (i) the acceptance is not in accordance with this Agreement or (ii) Acutus' acceptance modifies the order in accordance with the terms of this Agreement and Biotronik immediately objects in writing to the modifications. For the avoidance of doubt, Acutus will be entitled, in particular, to adjust delivery dates in order to comply with Lead Times and to adjust quantities to typical packaging quantities or avoid splitting of production lots, provided the quantity to be delivered must not deviate more than five percent (5 %) from the ordered quantity for each ACM Product.
- (f) Each Party may request changes of the delivery terms of an Individual Purchase Order, including the cancellation or rescheduling of an Individual Purchase Order. Any such requested change is subject to written agreement by the Parties. For the avoidance of doubt, only the final Individual Purchase Order, i.e. after any such changes, will be considered as ordered for all purposes of the Annual Purchase Targets.

## 5.4. Delivery Terms

- (a) The ACM Products will be delivered suitably packed for shipment in Acutus' standard shipping cartons marked for shipment.
- (b) Acutus will deliver the ACM Products according to FCA (Incoterms 2020) at Acutus' facility in Carlsbad, CA, USA (or to any other pickup location specified by Acutus provided that Acutus shall notify Biotronik in writing reasonably in advance prior to such change of location) to a carrier designated by Biotronik; it being acknowledged that Acutus may designate different pickup points for different ACM Products, even if such ACM Products have been ordered in one.
- (c) Biotronik will obtain all export licenses and other governmental approvals required, if any. Biotronik will obtain all import licenses, if any, and will comply with any legislation or regulations governing the importation of the ordered ACM Products into the country of destination.
- (d) The Parties will discuss and may agree on the conditions under which Acutus would deliver the ACM Console Products directly to specific locations in some countries (e.g. Japan) of the Biotronik Sphere of Commercialization or Joint Sphere of Commercialization.

## 5.5. Receipt of the Deliveries

(a) Biotronik will take delivery of the ACM Products even in case of partial deliveries provided that all additional transportation costs and expense due to partial deliveries will be borne by Acutus and that the Lead Times are complied with regardless of such partial deliveries.

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- (b) Biotronik will inspect each delivery of ACM Products. Biotronik will give written notice within twenty (20) Business Days of the day of receipt by Biotronik of the respective ACM Products from the respective carrier of any:
  - (i) shortage or overage;
  - (ii) apparent defect or damage to any ACM Products or non-conformity with the Product Specifications or the Individual Purchase Order.

However, Biotronik will not be required to open sealed boxes or sterile packaging that would make the ACM Products unusable, or to perform any testing that might destroy ACM Products.

- (c) Biotronik will have the right to reject any delivered ACM Products if the use-by-dating indicated on the individual ACM Products did not, on the date of actual delivery by Acutus to the carrier pursuant to Section 5.4, correspond (i) for ACM Products with a Shelf Life Period of more than twelve (12) months, to a period greater than or equal to the Shelf Life Period less two (2) months, and (ii) for ACM Products with a Shelf Life Period of twelve (12) months or less, to a period greater than or equal Shelf Life Period less one (1) month. Biotronik will reject such ACM Products in writing provided to Acutus within twenty (20) Business Days of the day of receipt by Biotronik of the respective ACM Products from the respective carrier. If ACM Products are not rejected pursuant to this Section 5.3(c), they are deemed accepted with respect to their use-by date, quantities and absence of apparent defects or damage. Acutus has no responsibility if the use-by date does not meet such requirement as a result of delays to the extent attributable to the carrier or Biotronik.
- (d) Biotronik will not accept a visibly damaged delivery from the carrier without reservation. Furthermore, Biotronik will properly document the damages and the circumstances in order to preserve the Parties' rights against the carrier and any insurance.

## 5.6. Late Delivery

- (a) Acutus will notify Biotronik promptly of expected delays of the ordered ACM Products, in whole or in part, stating the reasons for and the estimated duration of the delay and proposed remediation measures.
- (b) Acutus will be deemed to be in default if it fails to deliver the ordered ACM Products of an Individual Purchase Order at the delivery date (or within the agreed delivery date range) which Acutus is obligated to meet under Section 5.3(d), provided such failure is not caused in full or in part by any event under Biotronik's control.
- (c) After twenty-five (25) Business Days of default, Biotronik may cancel the respective Individual Purchase Order, in full or in part, except for ACM Products already delivered, without liability of Biotronik to Acutus.

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## 5.7. Packaging and Labelling

- (a) Acutus will supply the ACM Products ready for sale in accordance with the Product Specifications. Acutus will, at its own cost and expense, provide the ACM Products with instructions for use and labelling in accordance with the Product Specifications.
- (b) If for any country of the Territory the instructions for use are required in a different language, Biotronik will arrange for translation at its own cost and expense and Acutus will review and release the translation in accordance with the provisions of its quality management system at its own cost and expense prior to the distribution in accordance with Sections 3.6 and 3.12.
- (c) The Parties acknowledge that the ACM Accessory Products and ACM Disposable Products will be distributed by Biotronik with the Biotronik private label on the outer box (but the Acutus branding still on the disposable or accessory itself and not obscured). Upon Biotronik's request, the Parties will promptly discuss and agree upon the private label specifications for such ACM Products boxes. Subject to an agreement by the Parties, Acutus will adapt packaging (including any box labels, pouch labels, instructions for use) of the respective ACM Products boxes (excluding any relabelling of the products themselves) to provide a Biotronik "look-and-feel" on the packaging by applying colours, Biotronik's Trademarks, labels, labelling styles and other visual elements of Biotronik's branding to the ACM Product boxes, subject to regulatory requirements in the respective countries and provided that Acutus will act and will be labelled as the Manufacturer of Record of these ACM Products. Notwithstanding the foregoing, the packaging of the ACM Console Product (and the console itself) shall maintain the Acutus original packaging and branding, including its external packaging and branding and any branding in any user interface. Biotronik will provide Acutus its design requirements for the packaging, marking and labelling of the respective ACM Products and, subject to Acutus' approval, the respective design requirements will be integrated in the Product Specifications.

#### 5.8. No Modifications to the ACM Products

Biotronik will not make any modification or alteration to the ACM Products as delivered by Acutus, including their packaging, their labelling or any product description without Acutus' prior written approval. Notwithstanding the foregoing, Biotronik may affix on all ACM Products a label stating that the ACM Products are distributed by Biotronik, provided that such labels do not obscure in any way Acutus' name, labelling, or branding for or on the ACM Products.

# 5.9. Prices

(a) The ACM Products are sold by Acutus to Biotronik at the prices according to the price list in force at the time when the Individual Purchase Order is sent to Acutus by Biotronik (the **Prices**). Notwithstanding such Prices, Acutus and Biotronik will use the "CENEMEA pricing" for the initial transfer price for all

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shipment of ACM Product, subject to reconciliation in accordance with Section 5.9(f).

- (b) The price list applicable on the Effective Date of this Agreement is attached as <u>Annex 5.9</u>.
- (c) The Prices set forth in <u>Annex 5.9</u> will be firm until 31 December 2020. The Parties will renegotiate in good faith the Prices annually for the following calendar year not later than by 30 September, for the first time until 30 September 2020 for the year 2021, considering, *inter alia*, manufacturing yield improvements and other applicable manufacturing cost reductions of Acutus or its contract manufacturers. As a result of successful negotiations, an amended price list will be agreed and will become <u>Annex 5.9</u>. Such amended price list will become effective as of 1 January of the calendar year following agreement on the amended prices and will apply to all Individual Purchase Orders received by Acutus after the effective date of the Price change. If no agreement is reached, the Prices of the preceding year will continue to apply.
- (d) Except where expressly stated otherwise, all prices are quoted exclusive of VAT, and custom tariffs and duties applicable from the time of transfer of ownership (FCA, Incoterms 2020), which will all be borne by Biotronik. Biotronik will pay all taxes or other charges associated with the supply to Biotronik, distribution and delivery of the ordered ACM Products, including insurance costs, sales, use, exercise, value-added and similar taxes and customs, duties or governmental impositions. Any tax or duty Acutus is required to collect or pay upon delivery of the ACM Products will be paid by Biotronik and will be due and payable to Acutus upon being invoiced.
- (e) For the avoidance of doubt, Biotronik shall not be obligated to pay Acutus a Price for ACM Console Product components or sub-assemblies or disposable ACM Products that Acutus provides to Biotronik for warranty repair or replacement purposes that are covered by Acutus' Warranty expressly set forth in Section 5.13.1 of this Agreement.
- (f) Because ACM Product pricing for sales of ACM Product by Acutus to Biotronik is to be determined based upon the region to which the ACM Product is shipped by Biotronik, and because the Parties will not know the region to which a particular ACM Product unit will be shipped by Biotronik at the time of shipment by Acutus, Biotronik will provide a monthly shipping report to Acutus for each calendar month no later than the 2nd Business Day of the following calendar month. Each such shipping report shall indicate the region in which the end user or sub-distributor is located for each ACM Product that has been shipped to an end user or sub-distributor. Within three (3) Business Days after the end of each calendar quarter, the Parties will reconcile payments by Biotronik to Acutus under Section 5.9(a) as follows: (i) to the extent that Biotronik has overpaid Acutus for the ACM Product shipped by Biotronik in the calendar quarter because CENEMEA pricing was used as the initial transfer price under Section 5.9(a), then Acutus will credit the

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overpayment to other payments owed by Biotronik to Acutus under this Agreement; and (ii) to the extent that Biotronik has underpaid Acutus for the ACM Product shipped by Biotronik in the calendar quarter because CENEMEA pricing was used as the initial transfer price under Section 5.9(a), then Acutus will have the right to invoice Biotronik for the amount of the underpayment. Biotronik shall pay within forty-five (45) calendar days from receipt of invoice.

## 5.10. Payment Conditions

- (a) Acutus will issue an invoice for each delivery, including partial deliveries. Acutus will submit the invoice on or after the respective pick-up date.
- (b) All payments will be made by Biotronik in U.S. Dollars (USD) in immediately available funds by wire transfer to the bank account designated by Acutus in the respective invoice or otherwise in writing, within forty-five (45) calendar days from receipt of invoice. If Biotronik does not pay the invoiced amount in full within the payment deadline, Biotronik will be deemed to be in default, and default interest of five percent (5 %) per year will apply on the outstanding amount. In addition, if outstanding invoices and default interest in an amount set forth above, to the extent not disputed in good faith by Biotronik, are not paid within thirty (30) days after Acutus' notice of payment default, Acutus will have the right to hold back any deliveries to Biotronik.

## 5.11. Refurbishment Service

- (a) Acutus offers refurbishment services for the ACM Console Product. Biotronik shall have the right to return such ACM Console Product units to Acutus and Acutus will perform its standard cleaning, inspection, testing, and analysis, solely in accordance with Acutus' current standard refurbishment practices, to verify performance of the ACM Console Product within factory specifications. Acutus shall use its expertise and commercially reasonable efforts to refinish (for example repolish or rebrush) such returned ACM Console Products to make them look as new as possible, solely to the extent included in Acutus' current standard refurbishment practices. Acutus will return such refurbished ACM Console Products to Biotronik in a timely manner. Acutus will not be required to refurbish or repair any ACM Product units that do not qualify for refurbishment or repair under Acutus' then current standard practices. Acutus has the right update its refurbishment practices at any time to reflect updates and changes in Acutus' standard practices.
- (b) Acutus shall perform such refurbishment services at the fixed price of [\*\*\*\*] per ACM Console Product unit. Biotronik shall bear all related freight and any applicable taxes, with regard to inbound to Acutus or an Acutus field service depot and outbound back to a desired Biotronik location. In the event replacement parts are required, such replacement parts are not included in the refurbishment. Accordingly, Acutus shall provide a list of such required parts and a quotation for the costs of such replacement parts to Biotronik (unless covered by the Warranty or a Service Contract). Only after

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written approval of any such additional costs by Biotronik, Acutus may proceed with any necessary repair work. Acutus acknowledges and agrees that no additional labour costs beyond the fixed price of [\*\*\*\*] per ACM Console Product shall be charged by Acutus to Biotronik for the refurbishment.

(c) The Warranty and the Warranty Period of ACM Console Product units refurbished pursuant to this Section 5.11 shall not be extended or changed as a result of any refurbishment. For example, if the ACM Console Product unit is out of warranty when sent for refurbishment, the ACM Product shall remain out of warranty during and after any refurbishment, except for the extended warranty provided by Acutus on repaired or replaced components under Section 5.13.2.

#### 5.12. Service for ACM Console Products

Acutus agrees to make available the services, including parts and labor, to the extent Acutus is obligated to do so under <u>Annex 5.12</u> to this Agreement. Any amendment of <u>Annex 5.12</u> is effective based upon notice by Acutus to Biotronik as set forth in <u>Annex 5.12</u>. Acutus has the right to amend <u>Annex 5.12</u> to reflect updates and changes in Acutus' standard practices; it being understood that any changes that are inconsistent with the terms set forth in the body of this Agreement or with Acutus' standard practices under the same circumstances will not be accepted. Acutus agrees to reasonably consider comments and feedback from Biotronik regarding any changes by Acutus to <u>Annex 5.12</u> that Biotronik believes may adversely impact sales, customer perception or satisfaction, or the like; it being acknowledged that Acutus intends to maintain reasonably competitive service terms in <u>Annex 5.12</u>.

## 5.13. Warranty

## 5.13.1. In General

- (a) Acutus warrants to Biotronik that the ACM Products will be, at the time of delivery by Acutus to Biotronik's carrier, free and clear from Defects (the **Warranty**).
- (b) The Warranty does not apply:
  - (i) to ACM Products that have been modified after delivery without prior written approval of Acutus, it being understood and agreed that the removal, alteration or defacing of any serial number will be deemed to be a modification in the sense of this Section 5.13.1(b)(i);
  - (ii) to defects not existing at the time of delivery by Acutus to Biotronik's carrier, for example defects caused by the handling after pick-up, by normal wear and tear or otherwise due to the normal aging of the ACM Products;
  - (iii) to consumable parts of or for the ACM Products, such as batteries;

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- (c) any issues caused by Misuse, abuse, improper handling or storage, contamination, damage, out of specification environmental conditions, or the like.
- (d) Except for this Warranty set forth in this Section 5.13.1 above, no representation or warranty whatsoever, express or implied, is made by or on behalf of Acutus, and all other representations and warranties are hereby expressly excluded and disclaimed.
- (e) This Section 5.13 as well as Sections 8.4.2 will apply by analogy to defects of title in the ACM Products (*Rechtsgewahrleistung*).

# 5.13.2. Warranty Period

The Warranty period will, for non-sterile ACM Products, be twelve (12) months after invoicing date and will, for sterile ACM Products, correspond to the use-by-dating indicated on the individual ACM Products (the **Warranty Period**). The Warranty Period for repaired or replaced ACM Console Products, and repaired or replaced components in ACM Console Products, that have been supplied by Acutus shall be the longer of ninety (90) days from the date Acutus ships the repair or replacement or the remaining Warranty Period for the original ACM Console Product. For clarity, any extension beyond the original Warranty Period as a result of such ninety (90) day minimum shall be only for the repaired and replaced components. Responsibility for exchanging and replacing components in ACM Console Products will be determined in accordance with <u>Annex 5.12</u>. Repair and replacement components and ACM Console Products supplied by Acutus may be refurbished and reworked units, in Acutus' discretion.

## 5.13.3. Warranty Process

- (a) <u>Complaints; RAs; Returns</u>. If Biotronik believes that an ACM Product, or a component of an ACM Product, that is within its Warranty Period needs to be returned to or replaced by Acutus because the ACM Product or component does not comply with the Warranty, Biotronik must notify Acutus thereof by sending a Complaint to Acutus during the Warranty Period in accordance with <u>Annex 5.12</u>. Biotronik must also obtain an RA and return claimed Defective ACM Products and components to Acutus during the Warranty Period in accordance with <u>Annex 5.12</u>.
- (b) Biotronik must notify Acutus Immediately in writing upon Biotronik becoming aware of any behaviour or issues with an ACM Product that may present a safety issue or upon receiving any submission to, or a decision or order rendered by any Governmental Authority, which is reasonably likely to result in a Complaint. Complaints must be delivered to Acutus sufficiently early during the Warranty Period for Acutus to have reasonable opportunity to, at its option, (i) respond to or (ii) require Biotronik to respond to such submission, or (iii) submit a timely appeal or other challenge against such decision or order.

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(c) Failure to submit a proper Complaint within the Warranty Period will exclude Acutus' liability for remedying a Defect under Warranty except to the extent Section 5.13.5(b) provides an extension of time and provided that additional coverage can be obtained by Biotronik for customers by purchasing Service Contracts from Acutus as contemplated in <u>Annex 5.12</u>. Without limiting the other terms of this Agreement, the Parties expressly waive Biotronik's duty to immediately notify Acutus pursuant to, and the application of article 201 CO.

#### 5.13.4. On-Site Assessment, Third Party Assessment and Proceedings

- (a) Acutus reserves the right to require that an ACM Product for which a Complaint has been submitted (whether for the entire ACM Product or a component) be made available to Acutus on-site at customer, Sub-Distributor, or Biotronik facilities in a manner sufficient to enable Acutus to perform onsite diagnosis, troubleshooting and information gathering that Acutus determines is appropriate or desired in advance of Acutus issuing an RA number. ACM Product must be made available to Acutus for such assessment within ten (10) Business Days (or such longer period as Acutus may agree) after Acutus' request for such assessment. Acutus is not required to perform on-site activities.
- (b) If Acutus rejects a Complaint or if Acutus replaces or repairs an ACM Product or component for which a Complaint has been filed with a reservation that Acutus does not accept the respective Complaint, each Party will have the right but not the obligation to request a Third Party analysis through a mutually agreed neutral Third Party acting as expert (the **Third Party Analysis**). The findings of such Third Party Analysis will be duly considered by each Party, but will not be final or binding in terms of an expert or arbitrator opinion. The costs and expenses for the Third Party Analysis, each Party will be borne by the Party who requested the Third Party Analysis or, if both Parties requested the Third Party Analysis, each Party will bear half of the costs and expenses for the Third Party Analysis.
- (c) If the Parties do not resolve the Complaint, each Party will be entitled to initiate proceedings pursuant to Section 13.8, subject to Sections 5.13.5 and 5.13.6.

#### 5.13.5. Remedies

(a) In case that an ACM Product or component that have been returned to Acutus in accordance with <u>Annex 5.12</u> have failed to comply with the Warranty during the Warranty Period, Acutus will, at its option, replace or repair the Defective ACM Product or component or provide a credit to Biotronik for the purchase price paid for the ACM Product. Under no circumstances shall Acutus be required to provide a refund. Without limiting Acutus' obligation to indemnify under Section 7.2 for personal injury caused by a Defect in Acutus' software in an ACM Console Product, all breaches of Warranty due to, and other Defects in, software, firmware and code in any ACM Product shall be

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remedied solely in accordance with Acutus' obligations described in <u>Annex 5.12</u>. Except to the extent otherwise required by applicable law, this Section 5.13.5(a) and Section 7.2(a) sets forth the sole remedy, and exclusive liability, of Acutus for any failure to meet a Warranty (and for all Defects, errors and issues in or with any ACM Product).

- (b) After an ACM Product or component has been returned to Acutus in accordance with <u>Annex 5.12</u> and if Acutus has determined that there has been a failure of an ACM Product to comply with the Warranty, the repaired or replacement for the Defective ACM Product or component will, at the option and cost and expense of Acutus be supplied to Biotronik by Acutus. Unless concluding that the ACM Product or component have failed to comply with the Warranty, Acutus will, at the option of Biotronik, either return the ACM Product or component to Biotronik or destroy the ACM Product or component (in each case as specified by Biotronik within ten (10) Business Days of Acutus notifying Biotronik of the result of its Warranty assessment).
- (c) Except for the Warranty and limited remedies in this Section 5.13, the ACM Products are provided "AS IS," "AS-AVAILABLE" and "WITH ALL FAULTS." Acutus hereby disclaims any and all other warranties and conditions, whether express, implied, or statutory, and any warranties that may arise from course of dealing, course of performance or usage of trade. No oral or written information or advice given by Acutus or its representatives shall create any additional warranty. Biotronik shall not make or pass on any representation or warranty or commitment on behalf of Acutus to any customer, Sub-Distributor or other party.

## 5.13.6. Time Limitations (Verjahrung) and Forfeiture (Verwirkung) of Claims

- (a) All Complaints will become time-barred and forfeited upon the lapse of the Warranty Period, even if the breach of Warranty is discovered after that lapse. However Acutus shall grant Biotronik a period often (10) Business Days following the expiration of the applicable Warranty Period, to submit to Acutus only those Complaints that were submitted to Biotronik by end users and Sub-Distributors within the applicable Warranty Period and Biotronik may obtain additional protection against Defects by purchasing Service Contracts under <u>Annex 5.12</u>.
- (b) Subject to the other terms of this Agreement, including <u>Annex 5.12</u>, it is hereby understood and agreed that if a Complaint is properly delivered to Acutus within the Warranty Period, the relevant Complaint may be resolved after lapse of the Warranty Period, provided that the Complaint will be time-barred and forfeited should Biotronik fail to initiate arbitration proceedings against Acutus in accordance with Section 13.8 within ninety (90) days following expiry of the Warranty Period.

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#### 5.13.7. Firmware and Other Code

For each ACM Console Product unit purchased from Acutus under this Agreement, Biotronik must maintain at all times a Service Contract for the Software installed on the ACM Console Product; provided that Updates under <u>Annex 5.12</u> will be provided without charge (as if a Service Contract was in place) during the Warranty Period for the particular ACM Console Product unit.

#### 6. Liability

To the extent permitted by law, neither Party nor any of its Affiliates will be liable to the other Party for breach of this Agreement to the extent causing loss of present or prospective profits, revenue, or savings; loss of present or prospective sales; loss of use; loss of data; or cost of substitute goods or services in each case suffered by the other Party or any of its Affiliates as a result of such breach. This limitation of liability will not apply to (i) a breach of Section 10 and (ii) the unauthorized exploitation of the other Party's Intellectual Property Rights. This limitation of liability will apply to the indemnification pursuant to Section 7 and whether or not either Party is aware or has been advised of the possibility of such damages.

## 7. Indemnification

## 7.1. Indemnification of Acutus by Biotronik

Biotronik will hold harmless and indemnify Acutus from all non-Affiliate third-party claims against Acutus, including for reasonable legal expenses associated with such claims, which are the result of (i) Biotronik's negligence, illegal conduct or wilful misconduct, (ii) any unauthorized modification of or failure to maintain any ACM Product (e.g., any rental product), or (iii) any representations, warranties, or commitments beyond the warranty and limited remedies provided by Acutus in Section 5.13 (or failure to limit remedies as set forth in this Agreement); in the case of each of (i) and (ii) only, except to the extent such claims are the result of Acutus' or any Acutus Affiliate's negligence, illegal conduct, wilful misconduct or breach of this Agreement and in each case which are based on a final judgment or settlement agreement, provided Acutus complied with all obligations under Section 7.3.

# 7.2. Indemnification of Biotronik by Acutus

(a) Acutus will hold harmless and indemnify Biotronik from all non-Affiliate third-party claims against Biotronik, including for reasonable legal expenses associated with such claims, which are the result of Acutus' negligence, wilful misconduct or illegal conduct or for physical injury or death in connection with the use of the ACM Products to the extent the injury or death is caused by a Defect in the ACM Product that existed at the time of supply by Acutus, or Acutus otherwise has responsibility for the injury or death in accordance with statutory product liability provisions; in each case except to the extent such claims are the result of Biotronik's negligence, illegal conduct, wilful

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misconduct or breach of this Agreement and in each case which are based on a final judgment or settlement agreement, provided Biotronik complied with all obligations under Section 7.3. Acutus will have no responsibility or liability under this Section 7.2(a) as a result of any injury or death that occurs as a result of any failure by Biotronik to follow Acutus' instructions in accordance with this Agreement to suspend or discontinue distribution of or recall any ACM Product. Rather, Biotronik will be responsible for indemnifying Acutus for such injury or death under Section 7.1. Additionally, Acutus is not responsible under this Section 7.2(a) based upon any representations, warranties, or commitments beyond the Warranty and limited remedies provided by Acutus in Section 5.13 (or failure to limit remedies as set forth in this Agreement); or for any modification, alteration, or Misuse of an ACM Product by Biotronik, its Affiliate, Sub-Distributor, or any customer of Biotronik or such an Affiliate or Sub-Distributor.

(b) Acutus will hold harmless and indemnify Biotronik from any non-Affiliate third-party claims against Biotronik, including for reasonable legal expenses associated with such claims, claiming that the ACM Products infringe or misappropriate third-party Intellectual Property Rights, as a result of the distribution or use (to the extent the use is described in the Product Specification) of the ACM Products by Biotronik in the Territory; in each case which are based on a final judgment or settlement agreement, provided Biotronik complied with all obligations under Section 7.3. Acutus will have no responsibility or liability under this Section 7.2(b) as a result of (i) any infringement that occurs after Acutus requests that use or distribution of the ACM Product that is the target of the claim be discontinued or suspended in accordance with Section 8.4.2(c), (ii) any use or distribution of ACM Products in the manner not intended or of any Software other than the most recent version and release, or (iii) any unauthorized modification of any ACM Product or any combination with any product or technology not supplied by Acutus unless the infringement occurred in the absence of the modification or combination.

## 7.3. Third-party claims

- (a) If a Party (the **Indemnitee**) believes that the other Party (the **Indemnitor**) is responsible for defending and indemnifying the Indemnitee under this Section 7 above, the Indemnitee will promptly but in no event more than five (5) Business Days from the date it becomes aware of the good-faith Third Party claim notify the Indemnitor in writing of the third-party claim, describing the claim in reasonable detail, provided that failure to give notice as provided in this Section 7.3(a) will not relieve the Indemnitor of its indemnification obligation under this Agreement except to the extent such Indemnitor is actually and materially prejudiced as a result of such failure.
- (b) Neither the Indemnitee nor the Indemnitor will make any admission of liability in respect of any third-party claim without the prior written consent of the

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other Party, and the Indemnitee will use reasonable efforts to mitigate losses arising from such third-party claim.

- (c) The Indemnitor will have the exclusive right to conduct and control defence, negotiations and settlement of claims for which the Indemnitor is responsible under this Section 7 and will assume, conduct and control the defence and settlement of any suit or action against the Indemnitee using counsel selected by the Indemnitor. The Indemnitee will, at the Indemnitor's expense, cooperate and cause its Affiliates and agents to cooperate as reasonably requested by Indemnitor in the defence and settlement of the third-party claim.
- (d) The Indemnitor will not be responsible for any costs, expenses or settlement agreement incurred or made without the prior written consent of Indemnitor, which will not be unreasonably withheld or delayed. The Indemnitor will not have authority to bind the Indemnitee except to a settlement in which the sole relief to be provided is for monetary damages that are paid in full by the Indemnitor and any other commitments by the Indemnitor that do not adversely impact the Indemnitee.
- (e) If Acutus becomes aware of a good faith third-party product liability claim relating to an ACM Product, Acutus will have the right, acting reasonably and in good faith, to require Biotronik to suspend further sales of such ACM Product, provided that Acutus uses commercially reasonable efforts, in addition to Acutus' indemnification obligations hereunder, to replace or modify the affected ACM Product so that it becomes conforming to all applicable requirements hereunder in all respects while giving equivalent performance and without undue delay or interruption of sales. Notwithstanding anything to the contrary, if Acutus requires suspension of ACM Product sales under this Section 7.3(e) due to a breach by Acutus of its obligations under this Agreement or the Quality Management Agreement, and if as a result of such breach ACM Product that have been previously delivered to Biotronik and that remain in Biotronik's inventory are not suitable to be sold (or that are being rented by Biotronik are not suitable to continue to be rented), then (i) in accordance with this Section and to the extent Acutus has not otherwise required such return, Biotronik shall have the right to return to Acutus, at Acutus' cost and expense, (aa) all sterile ACM Products immediately and (bb) all ACM Products not supplied by Acutus in sterile form, within three (3) months after receipt of the notification of suspension by Biotronik, and (ii) in accordance with this Section, Biotronik shall have the right to cease the rental payments after return of all rental units and terminate with immediate effect the rental program for each affected ACM Console Product.

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# 8. Intellectual Property

### 8.1. Principle

- (a) Except for the licenses granted by a Party to the other in this Agreement, each Party and its Affiliates will retain all right, title and interest in and to its and their respective Intellectual Property Rights.
- (b) Intellectual Property Rights for works or inventions to the extent created or conceived solely by either Party will be owned exclusively to the Party creating or conceiving such Intellectual Property Rights; and Intellectual Property Rights for works or inventions to the extent created or conceived jointly by both Parties will be owned jointly to the Parties, and neither Party shall have the duty to account or obtain the consent of the other Party to exploit or license any jointly owned Intellectual Property Rights notwithstanding any contrary provisions of applicable law in any country.

## 8.2. Use of Acutus Intellectual Property Rights by Biotronik

## 8.2.1. Firmware and Other Code

- (a) Acutus hereby grants to Biotronik (and to the customer to whom Biotronik rented or sold an ACM Console Product) the right to use, in object code form only, the software and firmware installed by Acutus on the ACM Console Product, and Updates and Upgrades properly installed by Biotronik on the ACM Console Product unit, all solely in the same form as installed or authorized by Acutus, as follows. All use shall be solely through the ACM Console Product user interface as contemplated in the user manual for the ACM Console Product and solely on the particular ACM Console Product unit on which it was installed by Acutus or Biotronik, as contemplated above. For clarity, Updates shall be installed on an ACM Console Product unit only during the Warranty Period or Service Term for the particular ACM Console Product unit and Upgrades shall be installed only on the ACM Console Product units authorized by Acutus in writing and for which appropriate fees have been paid.
- (b) Notwithstanding anything to the contrary, all copies of any firmware, software, or code included in any ACM Product is licensed, and not sold, by Acutus. Acutus shall retain title to all copies (including ownership of all copyrights and other Intellectual Property Rights pertaining thereto), subject only to the license expressly granted to Biotronik in Section 8.2.1(a). The Software shall not be copied, modified, or otherwise distributed without the prior written consent of Acutus.
- (c) Copies of Software contain and reflect valuable trade secrets of Acutus. Except to the extent such restrictions are prohibited by applicable law, Biotronik shall not (and shall not authorize or enable any party to) disassemble, interrogate, decompile, reverse engineer, or otherwise seek to obtain or learn the trade secrets reflected or embodied in any Software, other than trade secrets otherwise disclosed by Acutus to the extent necessary to

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enable Biotronik's personnel to provide the training and service to customers in accordance with Sections 3.10 and 3.11 of this Agreement.

# 8.2.2. Other Acutus IP

- (a) For the term of this Agreement and subject to its terms and conditions, Acutus hereby grants Biotronik a limited, non-exclusive, non-assignable (except as set forth in Section 13.7) and royalty-free license to use the Acutus Trademarks for the sole purpose of identifying and distributing the ACM Products purchased by Biotronik from Acutus pursuant to this Agreement. For the avoidance of doubt, no license to use the Acutus Trademarks on or in connection with any products other than the ACM Products purchased from Acutus is being granted hereunder. This Section 8.2 does not limit any rights expressly granted in the Agreement.
- (b) Biotronik will have the right to grant sublicenses to its Sub-Distributors to use the Acutus Trademarks, provided that the scope of rights granted to Sub-Distributors does not exceed the scope of rights granted to Biotronik under this Agreement.
- (c) Biotronik will not register, and hereby represents it has not registered, any trademark or similar rights that are identical or confusingly similar to the Acutus Trademarks or to those used or registered by Acutus.
- (d) The use of the Acutus Trademarks by Biotronik will inure to the benefit of Acutus. To the extent necessary or desirable to preserve rights or remedies with regard to the Acutus Trademarks in a country of the Territory, Biotronik will execute and file a registered user agreement in such country that is acceptable to Acutus. Acutus will pay any registration fee, provided that Biotronik shall remain responsible for determining whether a registered user agreement is needed in the particular country in the Territory.

### 8.3. Use of Biotronik Intellectual Property Rights by Acutus

- (a) For the term of and subject to this Agreement, Biotronik hereby grants Acutus a limited, non-exclusive, non-assignable (except as set forth in Section 13.7), non-sublicensable and royalty-free license to use the Biotronik Trademarks for the sole purpose of manufacturing, packaging and delivering ACM Products in accordance with this Agreement, in particular ACM Products distributed under the Biotronik private label pursuant Section 5.7(c). For the avoidance of doubt, no license to use the Biotronik Trademarks or any other Intellectual Property Rights of Biotronik on or in connection with any products other than ACM Products is granted hereunder.
- (b) Acutus will not register, and hereby represents it has not registered, any trademark or similar rights that are identical or confusingly similar to the Biotronik Trademarks or to those used or registered by Biotronik.

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(c) The use of the Biotronik Trademarks by Acutus will inure to the benefit of Biotronik. To the extent necessary to preserve Biotronik's rights or remedies with regard to the Biotronik Trademarks in a country in the Territory, Acutus will execute and file a registered user agreement in such country that is acceptable to Biotronik. Biotronik will pay any registration fee, provided that Acutus shall remain responsible for determining whether a registered user agreement is needed in the particular country outside the Territory.

## 8.4. Infringements

## 8.4.1. Infringements of Acutus Intellectual Property Rights

Biotronik will Immediately notify Acutus of any actual or potential infringement of Intellectual Property Rights of Acutus that comes to Biotronik's attention. Biotronik will reasonably assist Acutus at Acutus' request and at Acutus' sole cost and expense in any action against such infringements. For the avoidance of doubt, Acutus will have no obligation to take such action.

## 8.4.2. Infringements of Third-Party Intellectual Property Rights

- (a) Biotronik will Immediately notify Acutus of any alleged infringement of third-party Intellectual Property Rights by the ACM Products that comes to Biotronik's attention.
- (b) Acutus will:
  - (i) have the right to conduct negotiations with the Third Party;
  - (ii) assume, conduct and control the defence and settlement of any suit or action for infringement against or resulting from an ACM Product provided that Acutus will not be responsible for any costs, expenses or settlement agreements incurred without the prior written consent of Acutus; and
  - (iii) have the right to issue binding instructions to Biotronik regarding continued sales of the ACM Products affected by such claims as more particularly contemplated in Section 8.4.2(c).
- (c) If Acutus becomes aware of a good faith third-party claim relating to an infringement or misappropriation of Intellectual Property Rights relating to an ACM Product affected by such third-party claim, Acutus, acting reasonably and in good faith, has the right to require Biotronik to suspend further sales of such ACM Product, provided that Acutus shall use commercially reasonable efforts, in addition to Acutus' indemnification obligations hereunder: (i) to obtain for Biotronik the right to continue distributing the affected ACM Product, or (ii) replace or modify the affected ACM Product so that it becomes non-infringing while giving equivalent performance and without undue delay or interruption of sales; provided that Acutus shall have the right to terminate

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or suspend Biotronik's right to continue to distribute the affected ACM Product to the extent Acutus determines is appropriate in its reasonable business judgment as a result of the infringement risk. Failure by Acutus to obtain the right to continued distribution or replacing or modifying the affected ACM Product so that it becomes non-infringing within three (3) months from receipt by Acutus of notice under Section 8.4.2(a) or, if no notice was given under Section 8.4.2(a), from receipt by Biotronik of the notification of suspension under this Section 8.4.2(c), will be deemed termination of the affected ACM Product. Notwithstanding anything to the contrary, to the extent Acutus requires Biotronik to suspend or terminate sales of any ACM Product under this Section, such occurrence shall not be considered a breach of this Agreement by Acutus, and Biotronik shall also have the right (if Acutus has not already required such return) to return to Acutus at Acutus' cost and expense all ACM Products terminated by Acutus under this Section 8.4.2(c). Notwithstanding anything to the contrary, the sole remedy, and Acutus' sole responsibility, as a result of any infringement by an ACM Product are adjustments to Biotronik's minimums under Section 3.5(j) and Acutus' obligation to indemnify Biotronik in accordance with Section 7.2(b).

## 9. Force Majeure

- (a) If a Party is prevented from performing its obligations under this Agreement as a result of any unforeseeable contingency beyond its reasonable control (a Force Majeure), including any unforeseeable, out of the ordinary actions of Governmental Authorities, war, terrorism, hostilities between nations, riots, strikes, lockouts, sabotage, shortages in supplies (but only to the extent such shortages are not caused and their effects could not reasonably have been mitigated by the nonperforming Party), energy shortages, fire, floods, epidemics, pandemics, and acts of nature, the Party so affected will not be responsible to the other Party for any delay or failure of performance of its obligations hereunder, for so long as Force Majeure prevents such performance; provided that the non-performing Party notifies the other Party in writing Immediately upon the occurrence of the Force Majeure as set forth in 9(b) below and the Parties discuss how to mitigate and eliminate the effects of the Force Majeure. Except to the extent otherwise agreed by the Parties in writing pursuant to such discussions, a Party shall have the right to terminate this Agreement by providing written notice of termination to the non-performing Party if a Force Majeure impacts such non-performing Party for a period of longer than ninety (90) days. This clause shall not excuse a failure to make payments.
- (b) In the event of Force Majeure, the Party immediately affected thereby will give Immediate written notice to the other Party specifying the Force Majeure and the intended or taken mitigating measures, and will use commercially reasonable efforts to resume performance of its obligations.

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## 10. Confidentiality

# **10.1.** Handling of the Confidential Information

During the term of this Agreement and for a period of ten (10) years thereafter, each Party will:

- (a) keep Confidential Information of the other Party or the other Party's Affiliates confidential, not make it available to third parties and protect it from unauthorized access, unauthorized disclosure and unauthorized use;
- (b) use Confidential Information of the other Party or the other Party's Affiliates for the performance of its obligations or exercise of its rights under this Agreement only;
- (c) only make available the Confidential Information of the other Party or the other Party's Affiliates to its own employees and consultants as well as to the employees and consultants of its Affiliates or Sub-Distributors and to its Affiliates or Sub-Distributors (approved in accordance with Section 2.7(a)) themselves, provided that these:
  - (i) require knowledge of the Confidential Information for the performance of the receiving Party's obligations under this Agreement;
  - (ii) have been informed about the confidentiality of such Confidential Information; and
  - (iii) are bound to keep such Confidential Information confidential in a manner consistent with the receiving Party's obligation under this Agreement;
- (d) inform the other Party if Confidential Information of that Party or that Party's Affiliates becomes known without authorization or is inappropriately used and take reasonable measures in order to prevent improper distribution and use of such Confidential Information;
- (e) upon request and at the option of the disclosing Party, upon expiry of this Agreement at the latest, return the Confidential Information received from the disclosing Party to that Party, and destroy or delete all copies of Confidential Information and confirm this in writing to such Party. The following will be excluded from these obligations:
  - (i) the secure retention of copies of Confidential Information, to the extent retention is required by law, guidelines from professional or self-regulating organizations or an order of a Governmental Authority or a self-regulating organization;
  - (ii) back-up copies in accordance with customary business practice and by means of an automated, secured data back-up system.

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(f) For clarity, Biotronik's rights above to use and disclose exclude the right to do so for the benefit any product that is not an ACM Product or for any product that is a Competing Product relative to any ACM Product.

# 10.2. Exceptions

- (a) If a Party is obliged to disclose Confidential Information received from the other Party by law or by order of a Governmental Authority or a self-regulating organization, the following will apply:
  - (i) the disclosure will be limited to the necessary extent;
  - (ii) the receiving Party will inform the disclosing Party to the extent permitted prior to the disclosure, will coordinate the next steps with the disclosing Party in order to guarantee that Confidential Information received from the other Party is kept confidential to the greatest extent possible.
- (b) If a Party is obliged to disclose Confidential Information received from the other Party to internal or external auditors due to compliance regulations, such disclosure is to be limited to the necessary extent and the provisions of Section 10.2(a) will apply by analogy.

## 11. Data Protection

- (a) The Parties represent that, regarding any operation or set of operations which is performed upon information relating to identified or identifiable natural persons in relation with this Agreement (Personal Data), each Party determines the purposes and means of the processing of Personal Data individually (Sole Controller) in accordance with the data protection laws applicable to the processing of Personal Data by a Party (Data Protection Legislation). Each Party individually must determine whether it has the lawful basis for any processing of Personal Data and will comply with its obligations under applicable Data Processing Legislation. Each Party will share Personal Data with the other Party if necessary for purposes of this Agreement or for fulfilment of statutory functions, provided such sharing is lawful. Each Party will process Personal Data received from or pertaining to the employees of the other Party and the other Party's Affiliates, agents, auxiliaries and contractors only for purposes of this Agreement or for fulfilment of statutory functions.
- (b) The Parties will ensure that Personal Data is limited to what is necessary in relation to the purposes they are processed by applying data minimisation techniques where possible such as reducing or replacing personal identifiers or aggregating data. Each Party will respond to enquiries from data subjects and supervisory authorities concerning its processing of Personal Data within a reasonable time. Requests concerning the other Party's processing of

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Personal Data will be forwarded to the other Party without delay. Each Party will appoint a contact person authorized to receive such forwarded requests.

(c) If the transfer or disclosure of Personal Data by a Party to recipients in the receiving Party's jurisdiction is restricted under the Data Protection Legislation, the Parties will, on either Party's request, take appropriate measures as may be required or permitted by the Data Protection Legislation for the lawful transfer of Personal Data to the receiving Party, including, in particular, the Set II controller—controller clauses set forth in the European Commission Decision 2004/915/EC, dated 27 December 2004—in which the Commission approved an alternative set of model clauses for transfers from data controllers in the EEA to data controllers outside the EEA, which are hereby incorporated by reference.

## 12. Term and Termination of this Agreement

# 12.1. Term

- (a) This Agreement will come into effect on the Effective Date and will continue for a period of seven (7) years (the **Initial Term**).
- (b) The Parties will agree in writing until the fifth (5th) anniversary of the Effective Date whether or not this Agreement is to be extended beyond the Initial Term. If the Parties agree on an extension, this Agreement will continue after the Initial Term for an additional three (3)-year period (a **Prolongation Term**). In each Prolongation Term, the Parties will conduct good faith negotiations on whether or not the Agreement will be extended for a successive Prolongation Term (i.e., an additional three (3) year period) and will seek to determine whether or not there will be prolongation (if applicable) no later than one (1) year prior to the expiration of the then current Prolongation Term. If the Parties do not agree to extend this Agreement beyond the Initial Term or the then current Prolongation Term, it will terminate on expiry of such Initial Term or Prolongation Term.

#### 12.2. Termination for Good Cause

(a) Each Party will have the right to terminate this Agreement with immediate effect by written notice for good cause (*aus wichtigem Grund*), provided that the other Party has failed to cure such good cause within thirty (30) days of being informed by the terminating Party in writing of the good cause, unless such cure can reasonably be excluded. Good cause is deemed to mean any material failure to comply with any term of this Agreement or the Quality Management Agreement. Good cause includes any event caused or controlled by one Party that makes continuation of this Agreement unconscionable for the other Party due to the adverse effect of such event on the business and/or the reputation of the other Party, and includes any material breach of Section 2.5 (Sales Outside the Territory), Section 4.2.2 (Sale or Import without Marketing Authorization Approval), Section 5.8 (No Modifications to the ACM Products), and Section 10 (Confidentiality). For the avoidance of doubt, a

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Party enforcing the obligations under this Agreement will not constitute good cause entitling the other Party to terminate the Agreement.

- (b) Each Party will have the right to terminate this Agreement with immediate effect by written notice in case of insolvency, moratorium, receivership or liquidation with regard to the other Party, or any similar circumstances that are likely to substantially affect the other Party's ability to carry out that Party's material obligations under this Agreement, provided that the Party that is subject to the insolvency, moratorium, receivership, liquidation, or similar circumstances has failed to provide adequate assurances of continued performance within thirty (30) days of the terminating Party requesting such assurances in writing, unless it can reasonably be excluded that the other party will provide such assurances. In the case of insolvency, moratorium, receivership or liquidation of any Sub-Distributor, or any similar circumstances that are likely to substantially affect the Sub-Distributor's ability to carry out its material obligations under this Agreement, Biotronik shall notify Acutus in writing of such circumstance and Biotronik shall terminate the Sub-Distributor upon request by Acutus.
- (c) Acutus will have the right to terminate this Agreement for all countries or on a country-by-country basis by giving written notice of termination to Biotronik specifying in the notice that it is being provided by Acutus pursuant to this Section 12.2(c):
  - (i) in the event of a Change of Control of Biotronik that closes during the Initial Term, with termination of this Agreement to be effective on the earlier of (i) the third (3<sup>rd</sup>) anniversary of the closing date of the respective Change of Control, or (ii) the end of the Initial Term. In the event of a Change of Control of Biotronik that closes during a Prolongation Term, unless this Agreement has already been terminated or expires earlier pursuant to its terms, Acutus will have the right to terminate this Agreement with termination to be effective on the earlier of (i) the third (3<sup>rd</sup>) anniversary of the closing date of the respective Change of Control, or (ii) the end of the then-current Prolongation Term. All notices of termination pursuant to this Section 12.2(c)(i) must be given no later than six (6) months after the closing date of the respective Change of Control.
  - (ii) in the event of a Change of Control of Acutus that closes during the Initial Term, with termination of this Agreement to be effective on the earlier of (i) the third (3<sup>rd</sup>) anniversary of the closing date of the respective Change of Control, or (ii) the end of the Initial Term. In the event of a Change of Control of Acutus that closes during a Prolongation Term, unless this Agreement has already been terminated for any other reason or expires earlier pursuant its terms, Acutus will have the right to terminate this Agreement with termination to be effective on the earlier of (i) the third (3<sup>rd</sup>) anniversary of the closing date of the respective Change of Control, or (ii) the end of the then-current Prolongation Term.

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All notices of termination pursuant to this Section 12.2(c)(ii) must be given no later than six (6) months after the closing date of the respective Change of Control.

- (iii) In the event of a Change of Control of a Sub-Distributor, Acutus has the right to withdraw its approval of the Sub-Distributor by providing written notice of such withdrawal to Biotronik. Biotronik agrees that no ACM Product will be distributed by any such Sub-Distributor more than twelve (12) months after Acutus provides such notice.
- (d) Biotronik will have the right to terminate this Agreement by giving written notice of termination to Acutus:
  - (i) For a country in the Territory in the event that the exclusive distribution rights granted by Acutus to Biotronik in Section 2.1 of this Agreement are converted to non-exclusive distribution rights in such country under Section 3.5(h), with termination by Biotronik to be effective immediately (except subject to transition in accordance with Sections 12.2(d)(iii) and 12.3.3(c) below). All notices of termination pursuant to this Section 12.2(d)(i) must be given no later than six (6) months after Biotronik first has notice of the conversion to non-exclusive under Section 3.5(h).
  - (ii) For all countries or on a country by country basis in the event of a Change of Control of Acutus where the Acquiring Party of Acutus is a Competing Company, with effect as of thirty (30) days after such notice by Biotronik, provided that such notice must be given by Biotronik to Acutus no later than ninety (90) days after the closing date of the Change of Control. If Biotronik gives notice of termination under this Section 12.2(d)(ii), Biotronik's distribution rights will become non-exclusive in all countries in the Territory on the date of such notice unless Acutus specifies a different date within the ninety (90) day period after the date of such notice, which Acutus may do on a country by country basis.
  - (iii) Biotronik shall diligently, and in a manner that minimizes adverse impact on ACM Product sales and relationships, transition distribution of ACM Products to Acutus for all countries in the Territory during the six month period following the date of Biotronik's or Acutus' notice (unless Acutus specifies a shorter transition period).

# 12.3. Effects of Termination

#### 12.3.1. Surviving Obligations

The following Sections will survive termination or expiry of this Agreement (including as imposed on Sub-Distributors in accordance with Section 2.7(b), if applicable): Section 2.9.5(c) (until any applicable assignment has been completed), Section 3.3 (for ACM Products that have been distributed under this Agreement), Section 3.5(e) (a

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final report covering all ACM Product sales under this Agreement, including any after termination or expiration), Section 3.7(a) (until all ACM Product distribution has ended), Section 3.10 (After-Sales Services), Section 4.1 (Quality Management), Section 5.9(f), Section 5.10, Section 5.13 (Warranty), Section 6 (Liability), Section 7 (Indemnification), Section 9, Section 10 (Confidentiality), Section 11, Section 12.3 (Effects of Termination), and Section 13. Biotronik's responsibility for Affiliates and Sub-Distributors, as stated in Section 2.7(a), shall survive any termination or expiration of this Agreement. The restrictions and obligations on Biotronik in <u>Annex 2.3</u> shall survive until Acutus has taken possession or control of all ACM Console Product rental units; all of which must be returned by Biotronik to Acutus upon any termination or expiration of this Agreement. All loaner ACM Console Product units, including all ACM Console Product units in any service depot or center of excellence, must be returned to Acutus upon any termination or expiration of this Agreement. The following Sections of <u>Annex 5.12</u> shall survive: 5, 6, 8, and 10. All sublicenses granted by Biotronik to any Sub-Distributors shall terminate upon any termination or expiration of this Agreement. All other provisions of this Agreement shall terminate, and have no further force or effect, upon any termination or expiration of this Agreement.

#### 12.3.2. Right to Convert Exclusive Distribution to Non-Exclusive Distribution

Subject to Section 12.3.7, and without limiting any other rights or remedies of Acutus, in case of a Change of Control of Acutus, the Acquiring Party(s) of Acutus shall have the right to convert any exclusive and co-exclusive distribution rights granted to Biotronik under Section 2.1 of this Agreement to non-exclusive distribution right commencing on the two (2) year anniversary of the closing date of the Change of Control, provided that the Acquiring Party(s) of Acutus shall provide written notice to Biotronik within six (6) months after the closing date of the Change of Control of the extent to which the rights under this Section 12.3.2 shall be executed. This Section does not limit Biotronik's right to execute its termination rights under Section 12.2(d) as a result of such Change of Control of Acutus or Acutus' rights under Section 12.3.2 on a country by country basis.

## 12.3.3. Right to Represent the ACM Products

- (a) On the effective date of any termination or expiry of this Agreement and after the Sell-Off Period, the right of Biotronik to represent and sell the ACM Products ends.
- (b) On the effective date of termination or expiry of this Agreement and after the Sell-Off Period, Biotronik will avoid any remarks and the use of any materials or equipment giving rise to the impression that it continues to be an appointed distributor for sales of or authorized to provide service, maintenance or support for any ACM Products.

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(c) In the event of any termination or expiration of this Agreement (as a whole or in any country), Biotronik shall cooperate reasonably with Acutus, for a period of up to six (6) months after any termination or expiration, in order to transition distribution of the ACM Products back to Acutus or its designee smoothly and without adverse impact to ongoing distribution of the ACM Products and relationships. To the extent Biotronik continues sales under Section 12.3.5 after such six (6) month period, Biotronik shall continue such collaboration and efforts to effect a smooth transition so long as Biotronik continues such sales. Biotronik shall cause all Sub-Distributors to cooperate in the same manner if a Sub-Distributor is terminated.

## 12.3.4. Intellectual Property

On the effective date of termination or expiry of this Agreement and after the Sell-Off Period, each Party's rights to use the other Party's Intellectual Property Rights pursuant to this Agreement cease; except that Acutus' rights to use any Intellectual Property Rights of Biotronik in or to any Regulatory Materials or Clinical Data shall survive.

# 12.3.5. ACM Products in Stock

- (a) Acutus will have the right but not the obligation to repurchase from Biotronik a part of or all ACM Products that Biotronik and its Affiliates have in stock as of the effective date of termination or expiry of this Agreement and that Biotronik has purchased from Acutus, at the net price originally paid by Biotronik (FCA Berlin, Incoterms 2020), except to the extent ACM Products have already been sold to Third Party customers as of the date of receipt by Biotronik of Acutus' notice of intent to repurchase stock or to the extent Biotronik is obligated to fulfil its existing contractual or tender obligations, as provided in Section 12.3.5(b) below. Acutus may exercise its option according to this Section 12.3.5(a) in writing no later than on the effective date of the termination of this Agreement or, if this Agreement is terminated with immediate effect, within one (1) month after the effective date of termination. Biotronik will, on Acutus' request, inform Acutus of the ACM Products in Biotronik's and its Affiliates' stock. Acutus has the right to exercise its rights under this Section 12.3.5 on a country by country basis with regard to ACM Products in stock in the respective country if Biotronik's rights are terminating for less than the entire Territory.
- (b) If Acutus exercises its option according to Section 12.3.5(a), Acutus will for a period of twenty-four (24) months after the effective date of the termination permit Biotronik to:
  - (i) fulfil contractual obligations to Third Parties that Biotronik entered into before notice of termination, and
  - (ii) serve tenders for which Biotronik has submitted offers to Third Parties before notice of termination,

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provided that, on Acutus' reasonable request, Biotronik produces documentary evidence that the requirements of (i) and (ii) are fulfilled. For this purpose Acutus will allow Biotronik to keep existing ACM Products in stock, and Acutus will sell additional ACM Products to Biotronik during such twenty four (24) month period under the terms and conditions of this Agreement as in force at the time Biotronik's request under this Section 12.3.5(b) is provided to Acutus. Notwithstanding anything to the contrary, under no circumstances shall any ACM Product be sold by or under authority of Biotronik (i) after any expiration of this Agreement; and (ii) more than twenty (24) months after any termination of this Agreement.

- (c) If Biotronik keeps existing ACM Products in stock or has purchased additional ACM Products in order to serve tenders according to Section 12.3.5(b)(ii) and Biotronik has not won such tender, Biotronik will inform Acutus within ten (10) days of the final decision relating to such tender, and Acutus will have the right but not the obligation to repurchase from Biotronik some or all of the ACM Products that Biotronik has in stock or has bought from Acutus in view of such tender at the net price originally paid by Biotronik. Acutus may exercise its option according to this Section 12.3.5(c) in writing within thirty (30) days of Biotronik informing Acutus of the final decision relating to such tender.
- (d) If Acutus chooses not to exercise its option pursuant to 12.3.5(a), Biotronik will have the right for a period of twelve (12) months starting from the effective date of termination, in accordance with this Agreement, to sell the remaining ACM Products purchased from Acutus (the **Sell-Off Period**). After the Sell-Off Period, Acutus will for a period of twelve (12) months permit Biotronik to:
  - (i) fulfil contractual obligations that Biotronik has entered into before notice of termination, and
  - (ii) serve tenders for which Biotronik has submitted offers before notice of termination,

provided that, on Acutus' reasonable request, Biotronik produces documentary evidence that the requirements of (i) and (ii) are fulfilled. For this purpose, Acutus will sell additional ACM Products to Biotronik at the terms and conditions of this Agreement. Thereafter, Biotronik will not be authorized to sell ACM Products. Biotronik will inform Acutus of any remaining ACM Products purchase from Acutus, and Acutus will have the right to take these ACM Products back at no cost to Biotronik. Otherwise, Biotronik will destroy them as waste.

## 12.3.6. Marketing Authorization Approvals

(a) If, upon the effective date of termination or expiry of this Agreement and after the Sell-Off Period, Biotronik, its Affiliate, or any Sub-Distributor owns or holds any Marketing Authorization Approvals for any ACM Products in any country of the Territory, Biotronik, the Affiliate and Sub-Distributor will at no

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cost or expense to Acutus, assign and transfer all right, title and interest in and to any and all such Marketing Authorization Approvals to Acutus, subject to applicable regulatory requirements.

- (b) If an assignment or transfer of a Marketing Authorization Approval according to Section 12.3.6(a) is not possible, then Biotronik, the Affiliate and Sub-Distributor shall take such action to the extent allowed by applicable law to enable Acutus to otherwise benefit from the respective Marketing Authorization Approval after the effective date of termination or expiry of this Agreement to the extent reasonably possible, including providing copies of all MAA's, Clinical Data, and Regulatory Materials as well as rights of reference.
- (c) In case of the conversion of the appointment of Biotronik as an exclusive or co-exclusive distributor to a non-exclusive distributor, or such rights are terminated, Acutus and its distributors shall be allowed distribution of ACM Products in the specific country of the Territory and Biotronik shall facilitate such distribution under the existing or modified MAA as expeditiously as reasonably possible and feasible in accordance with regulatory requirements. Biotronik shall ensure that all Sub-Distributor rights terminate and convert to non-exclusive or co-exclusive to the same extent as Biotronik's rights so terminate or convert.

## 12.3.7. Compensation in case of Change of Control and Termination

(a) For clarity, all terms and conditions in Section 12.3.7(b) shall terminate, and have no further force or effect, after any expiration of this Agreement unless the respective Change of Control closed during the term of this Agreement. Similarly, Section 12.3.7(b) and all obligations to make any Compensation Payment shall terminate, and have no further force or effect, to the extent this Agreement is terminated for any reason other than termination by Acutus providing written notice of termination to Biotronik under Section 12.2(c)(ii) as a result of a Change of Control of Acutus. In particular, no Compensation Payment shall be due or payable (i) upon or as a result of valid termination of this Agreement (or Biotronik's distribution rights) in accordance with its terms and conditions for any reason (including under Section 12.2(d)) other than a termination by Acutus under Section 12.2(c)(ii) as a result of a Change of Control of, or any change in, an ACM Product under this Agreement in accordance with its terms; or (iv) upon or as a result of any conversion of exclusive rights to co-exclusive or non-exclusive. Under no circumstances shall more than one Compensation Payment be paid under this Section 12.3.7. For clarity, the Country Specific Compensation Payment for a country shall be zero if Biotronik's distribution rights in that country expire or if Biotronik's distribution rights in that country are terminated for any reason other than Acutus providing written notice stating that Acutus is terminating Biotronik's in such country under Section 12.2(c)(ii).

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## 12.3.8. No Indemnity

Subject to and safe for the Compensation Payment under Section 12.3.7 of this Agreement, Biotronik agrees that the terms of this Agreement enable Biotronik to recover equitable benefits from its investments in the marketing of the ACM Products, and that the position of Biotronik is not similar to that of an agent. Accordingly, Biotronik will, subject to and safe for the Compensation Payment to be paid to Biotronik under Section 12.3.7 of this Agreement, not be entitled to an indemnity for goodwill or similar compensation, or any other damages or compensation, in case of any termination or expiration of this Agreement, even if Biotronik has significantly developed Acutus' business in the Territory and Acutus continues to derive substantial benefits from the business generated by Biotronik after the date of termination or expiration; including if such termination is a termination under 12.2(d).

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## 13. Miscellaneous

### 13.1. No Set-Off

Each Party waives its right to set off any claim made by the other Party against it under or in connection with this Agreement against a claim that it has itself against the other Party.

## 13.2. Entire Agreement and Annexes

- (a) This Agreement including all Annexes, which are an integral part of this Agreement, and the Quality Management Agreement, and those portions of the License and Distribution Agreement (if any) which are incorporated by reference, constitutes the complete agreement between the Parties regarding its subject matter and supersedes all other prior and contemporaneous oral and/or written agreements, representations and/or communications, concerning the subject matter hereof.
- (b) To the extent of any conflict between any provision of the body of this Agreement and any provision of an Annex, the provision of the body of this Agreement will prevail, provided that appropriate measures according to Section 11 will prevail over conflicting provisions of the body of this Agreement.

#### 13.3. Written Notices

Any written notice with regard to this Agreement will be delivered by mail, e-mail or fax to Acutus:

Acutus Medical, Inc. 2210 Faraday Ave Suite 100 Carlsbad 92008, California U.S.A. Attn.: [ ] Phone: [ ] Email: [ ] Biotronik:

Biotronik SE & Co. KG Woermannkehre 1 12359 Berlin Germany

 Attn.:
 [
 ]

 Phone:
 [
 ]

 Email:
 [
 ]

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Each change of address will be communicated to the other Party in the same way.

#### 13.4. Severability

If any provision of this Agreement is held to be unenforceable or invalid, then that provision is to be construed either by modifying it to the minimum extent necessary to make it enforceable and valid (if permitted by law) or disregarding it (if not). If an unenforceable or invalid provision is modified or disregarded in accordance with this Section 13.4, the rest of the Agreement is to remain in effect as written, and the unenforceable and invalid provision is to remain as written in any circumstances other than those in which the provision is held to be unenforceable and invalid; provided that such continuation of the Agreement, with the modified and/or disregarded provision, is not materially inconsistent with the original intent of the Parties in entering into this Agreement. This rule applies by analogy to contractual omissions, intended or unintended.

## 13.5. Amendments

Any amendment or supplementation of this Agreement will require a written document executed by both Parties. The written form requirement may be dispensed only in writing.

## 13.6. No Waiver

Failure by either Party to take any action or assert any right hereunder will not be deemed to be a waiver of such right in the event of the continuation or repetition of the circumstances giving rise to such right, except if expressly agreed otherwise.

#### 13.7. Assignment

- (a) Except as provided in Section 13.7(b), neither Party may assign or otherwise transfer this Agreement or its rights or obligations under this Agreement, in whole or in part, to any Third Party except with the prior written consent of the other Party.
- (b) Each Party has the right to assign this Agreement to any of its Affiliates. In the event of a Change of Control with respect to a Party, such Party has the right to assign this Agreement to the Third Party that acquires control of such Party or an affiliate of such Third Party, subject to Section 13.7(c) below.
- (c) If Acutus or Biotronik undergoes a Change of Control during the Initial Term of the Agreement, the Party undergoing the Change of Control (or its successor or permitted assign) shall be bound in all respects to the terms and conditions of this Agreement for a period of the shorter of (a) the 3 year anniversary of the closing of the Change of Control, or (b) the remaining period of the Initial Term of the Agreement. If Biotronik or Acutus undergoes a Change of Control during a Prolongation Term, the Party undergoing the Change of Control (or its successor or permitted assign) shall be bound in all respects to the terms and conditions of Agreement for the shorter of (a) the remaining duration of

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the Prolongation Term or (b) 3 year anniversary of the closing of the Change of Control.

#### **13.8.** Applicable Law and Jurisdiction

- (a) This Agreement will be governed by the substantive laws of Switzerland, to the exclusion of the UN Convention on Contracts for International Sale of Goods (CISG) of 11 April 1980.
- (b) In the event of any dispute arising out of or in relation to this Agreement, the Parties will refer the dispute to senior executive officers and such senior executive officers will attempt in good faith to resolve such dispute. If the Parties are unable to resolve a given dispute according to this Section 13.8(b) within thirty (30) days of referring such dispute to senior executive officers, if it cannot reasonably be expected that the dispute will resolved according to this Section 13.8(b) within thirty (30) days and in case of urgency, any such dispute will be resolved pursuant to Section 13.8(c).
- (c) Any dispute, controversy or claim arising out of or in relation to this Agreement and all purchases and deliveries within the framework of this Agreement, including the validity, invalidity, breach, or termination thereof, as well as pre-contractual and extra-contractual related issues, will be resolved by arbitration in accordance with the Swiss Rules of International Arbitration of the Swiss Chambers' Arbitration Institution in force on the date on which the Notice of Arbitration is submitted in accordance with these Rules. The number of arbitrators will be three (3). The seat of the arbitration will be Zurich. The arbitral proceedings and all pleadings, filings, written evidence, decisions and other relevant documents shall be in English and any written evidence in a language other than English shall be submitted with an English translation. All and any awards will be final and binding on the Parties, but subject to any rights of appeal and rights of revision from all and any awards insofar allowed under applicable law. All and any awards may be entered as final judgment in any court of competent jurisdiction as necessary to enforce the award.

\* \* \* \* \*

(THE NEXT PAGE IS THE SIGNATURE PAGE)

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## Signatures

# BIOTRONIK SE & CO. KG

11 May 2020

11 May 2020

Berlin,

Place, date

Berlin,

Place, date

Acutus

Carlsbad, California May 10, 2020

Place, date

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/s/ Dr. Daniel Bühler By: Dr. Daniel Bühler Title: Managing Director

/s/ Dr. Ralf Lieb By: Dr. Ralf Lieb Title: Managing Director

/s/ Vince Burgess By: Vince Burgess Title: Chief Executive Officer

### Annex 1(a) – Definitions

ACM Accessory Product means those products listed in <u>Annex 2.1(a)</u> that are designated as an "accessory".

ACM Console Product means the product listed in <u>Annex 2.1(a)</u> as the "ACM Mapping System", as updated by Acutus from time to time in accordance with this Agreement.

**ACM Disposable Product** means those products listed in <u>Annex 2.1(a)</u> that are designated as "disposable". ACM Disposable Product includes the AcQMap Mapping Catheter and the AcQMap Patient Electrode Kit.

ACM Products means the ACM Console Products, the ACM Disposable Products, and the ACM Accessory Products, in each case listed in <u>Annex</u> <u>2.1(a)</u>.

Acutus Trademark means any trademark, trade name, trade dress, service mark, logo or similar mark, whether or not registered or registerable, of Acutus or its Affiliates.

AcQMap Mapping Catheter means the product listed in <u>Annex 2.1(a)</u> as the "AcQMap 3D Imaging and Mapping Catheter", as updated by Acutus from time to time in accordance with this Agreement.

**AcQMap Patient Electrode Kit** means the electrode patches to connect the patient with the ACM Console Product as defined in the respective Product Specification, as amended from time to time in accordance with this Agreement.

Acquiring Party shall have the meaning as defined in the Change of Control definition.

Affiliate means, with respect to any person or entity specified, any other person or entity that Controls or is Controlled by or is under common Control with the person or entity specified. For the purpose of this Agreement, **Control** means direct or indirect beneficial ownership by any person or entity of more than fifty percent (50%) of shares of stock entitled to vote for the election of directors in the case of a corporation, or more than fifty percent (50%) of the corresponding equity interest in the case of any other type of legal entity or status as a general partner in any partnership, in each case sufficient to, directly or indirectly through one or more intermediaries, control the board of directors or equivalent governing body of a corporation or other entity and cause the direction of the management and policies of the corporation or other entity.

Agreement means this distribution agreement including all of its Annexes.

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**Aggregate Country Specific Compensation Payments** means the sum of all Country Specific Compensation Payments for all countries in the Territory (without duplication) that have been terminated by Acutus under Section 12.2(c)(ii) (and not under another Section of this Agreement).

**Annex** means an annex attached to this Agreement on the Effective Date, as such annexes are updated from time to time solely in accordance with this Agreement.

Annual Business Plan Session has the meaning defined in Section 3.4.

Annual Purchase Targets has the meaning defined in Section 3.5(a).

**Bio Products** has the meanings set forth in the written agreement between the Parties, titled "Global Alliance for Biotronik Product Distribution Agreement," having an effective date of May 8, 2020.

**Biotronik Sphere of Commercialization** means only those countries that are defined in <u>Annex 2.1</u> as being included in the "Biotronik Sphere of Commercialization."

**Biotronik Trademark** means any trademark, trade name, trade dress, service mark, logo or similar mark, whether or not registered or registerable, of Biotronik or its Affiliates.

**Business Day** means every calendar day except (i) Saturdays and Sundays, (ii) public holidays in Berlin, Germany or San Diego, California, USA, and (iii) 24 and 31 December.

Change of Control means, with respect to a Party, any of the following events:

- (a) a Third Party becomes the beneficial owner, directly or indirectly, of more than sixty-seven percent (67%) of the total voting power of the capital stock then outstanding of such Party normally entitled to vote in elections of directors;
- (b) a Party conveys, transfers, leases or assigns all or substantially all of its business and assets to any Third Party, whether resulting from merger, acquisition, consolidation, or otherwise.

For purposes of this definition of "Change of Control" only, references to (A) "beneficial ownership" (and other correlative terms) means beneficial ownership as defined in Rule 13d-3 under the Exchange Act, and (B) "group" means group as defined in the Exchange Act and the rules of the SEC thereunder as in effect on the date hereof. The Third Party or other corporation or entity which effects a Change of Control with respect to a Party

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shall be referred to as the "Acquiring Party". Notwithstanding the foregoing, in no event shall a sale of capital stock for the purpose of financing Acutus, Biotronik, and/or their Affiliate, including to underwriters of a public offering of the capital stock of Acutus, Biotronik, and/or their Affiliate, constitute a Change of Control.

**Clinical Data** means all data, information, and documentation (each in draft or complete form) generated by conducting and/or analyzing a Clinical Trial (whether or not completed) hereunder, in whatever form, whether stored as hard copy or in electronic form, including raw data to the extent legally permissible, study data, all study reports, case reports, filings, monitor reports, notices, books, records, informed consent forms, other files (or parts thereof), or any information related thereto.

**Clinical Trial** means a human clinical study conducted on human subjects that is designed to (a) establish that a medical device is reasonably safe for continued testing; (b) investigate the safety and efficacy of the medical device for its intended use, and to define warnings, precautions, and adverse reactions that may be associated with the medical device in the manner to be prescribed; or (c) support Marketing Authorization Approval or label expansion of such medical device.

Closing Date means the closing date of a Change of Control of Acutus.

CO means the Swiss Code of Obligations (OR).

### Compensation Payment means: [\*\*\*\*]

**Competing Product** means, with respect to an ACM Product, a product with the same or substantially the same indication as such ACM Product, including having the ability for on-label use in similar procedures, provided that such product can reasonably be considered to directly compete with such ACM Product. For the avoidance of doubt, non-electrophysiology products of Biotronik and its Affiliates will not be considered Competing Products.

**Competing Company** means the entities listed in <u>Annex 2.5</u> and their respective Affiliates, and the successors and assigns at any time during the term of this Agreement to all or substantially all of the business and assets of such entities listed in <u>Annex 2.5</u>, including of their Affiliates.

**Complaint** has the meaning set forth in <u>Annex 5.12</u>.

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**Confidential Information** of a Party or that Party's Affiliates means any and all information, regardless of its form and the type of disclosure (in particular documents, data files, charts, sketches, plans, e-mails, and oral information), which:

- (a) such Party or an Affiliate of such Party's makes directly or indirectly available to the other Party in connection with this Agreement or has already made available prior to the conclusion of this Agreement under obligations of confidentiality; and
- (b) has been identified as "confidential" or which is confidential by nature (in particular financial data, sales figures, know-how, and customer lists).

Information made available by either Party or an Affiliate will not be deemed Confidential Information in the event:

- (c) it was or has become publicly known without the receiving Party being involved in breach of its obligations or otherwise being responsible for it;
- (d) the receiving Party has created or obtained the information itself independently of the disclosure by the disclosing Party, whether prior to or after such disclosure by the disclosing Party, provided that the receiving Party may assume in good faith that no confidentiality obligations have been breached thereby and that it may use and/or disclose this information; or
- (e) the disclosing Party has explicitly excluded from the confidentiality obligations in writing.

Control has the meaning set forth in the definition of Affiliate above.

Country Specific Compensation Payment means, [\*\*\*\*]

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[\*\*\*\*]

Data Protection Legislation has the meaning defined in Section 11(a).

**Defect** has the meaning set forth in <u>Annex 5.12</u>.

**Downside Multiplier** means, [\*\*\*\*]

[\*\*\*\*]

Net Proceeds	Downside Multiplier
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

Effective Date means the date of execution of this Agreement by both Parties.

**EU Model Clauses** means the standardized contractual clauses issued or **approved** by the EU Commission or other competent EU authorities during the Agreement for the transfer of Personal Data to third country recipients.

**Field** means atrial and ventricular catheter-based heart rhythm diagnostics and radiofrequency point-by-point cardiac ablation with 3D imaging and mapping. For the avoidance of doubt, the following product categories are included in the Field: Diagnostic, steerable, introducer and transseptal catheters, high-power-short-duration (SW adaptation and/or ablation device hardware adaptation and/or catheter improvement), ECG recording systems, irrigation pumps, esophageal temperature probes, deviators, and transseptal access tools. For the avoidance of doubt, and without limitation, the following product categories are considered to be outside of the Field: Products for electroporation (ablation devices and/or catheters), single shot PV-isolation

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systems with any energy source (cryo, radiofrequency, heat, or laser), and left atrial appendage occluder devices.

First Level Support has the meaning set forth in <u>Annex 5.12</u>.

**Force Majeure** has the meaning defined in Section 9(a).

Hardware has the meaning set forth in <u>Annex 5.12</u>.

**Governmental Authority** means any court, agency, department, authority, or other instrumentality of any multi-national, national, state, county, city, province, or other political subdivision.

**Immediately** means, with respect to any obligation of a Party hereunder to act in a certain manner upon the occurrence of any event, as soon as possible upon becoming aware of such event and without delay, and in any case within one (1) Business Day.

Incremental Multiplier means, [\*\*\*\*]

Calendar Vear in which Closing Date Occurs	Incremental Multiplier
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

**Indemnitee** has the meaning defined in Section 7.3(a).

**Indemnitor** has the meaning defined in Section 7.3(a).

Individual Purchase Order means any purchase order placed by Biotronik with Acutus for ACM Products.

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Initial Term has the meaning defined in Section 12.1(a).

**Intellectual Property Rights** means all and any intellectual property rights, including any copyrights, utility model rights, design rights, patent rights, trademark rights, topography rights, trade secret rights, know-how rights, rights in databases as well as any other proprietary rights, in all cases whether or not registered or registerable.

**Joint Sphere of Commercialization** means the Hong Kong Special Administrative Region of the People's Republic of China, as it exists on the Effective Date, excluding any and all other portions of China and excluding Taiwan. For clarity, references in the Agreement to "country" will be deemed to include this Hong Kong Special Administrative Region.

**Lead Time** means six (6) calendar weeks for the ACM Console Product and four (4) calendar weeks for any other ACM Product. In case of FCA (Incoterms 2020), the Lead Time will be calculated from the date of the respective Individual Purchase Order receipt by Acutus to the date the purchased ACM Products are ready to be picked up from the pick-up point designated by Acutus, provided that if the last day of the Lead Time is not a Business Day, the Lead Time will end on the following Business Day.

**License and Distribution Agreement** means the agreement titled "License and Distribution Agreement," entered into between the Parties and VascoMed GmbH, having an effective date of June 28, 2019.

**Manufacturer of Record** shall mean the natural or legal person responsible for the design, manufacture, packaging and labelling of a medical device before it is placed on the market, regardless of whether these operations are carried out by that person or on his behalf by a Third Party.

**Marketing Authorization Approval** or **MAA** means, with respect to a product in any country or jurisdiction, any approval, registration, license, or authorization from a Regulatory Authority or other Governmental Authority in that country or jurisdiction that is necessary to offer for sale, market, and sell such product in such country or jurisdiction.

Misuse has the meaning set forth in <u>Annex 5.12</u>.

**Net Proceeds** means, with respect to a Change of Control of Acutus, the total aggregate amount of the purchase price paid by the Acquiring Party to, and actually received by, Acutus or its stockholders (in their capacity as stockholders of Acutus) from such Acquiring Party as consideration for the Change of Control of Acutus. For clarity, Net Proceeds includes cash; the value of marketable securities; the present value of loans by a Third Party to Acutus that are actually assumed by the Acquiring Party (to the extent the aggregate amount of such loans exceed the cash and cash equivalents of Acutus);

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and excludes all other consideration, such as contingent consideration and all consideration that is not expressly made part of the purchase price at the closing of the Change of Control for Acutus stock or assets in such Change of Control of Acutus, all as set forth in the definitive agreements that effects such Change of Control of Acutus.

**Net Sales** means the purchase price (and rental fees) actually invoiced by Acutus to, and received by Acutus from, Biotronik for sales of ACM Products (and rental of ACM Console Product) by Acutus directly to Biotronik, excluding or reduced by reasonable and customary exclusions and deductions to the amount invoiced, such as: (i) trade, cash and quantity credits, discounts, refunds or rebates; (ii) amounts for claims, allowances or credits for returns, retroactive price reductions, charge-backs or destroyed goods; (iii) packaging, handling fees and prepaid freight, sales taxes, duties and other governmental charges (including value added tax); and (iv) past due account receivable balances.

New Products means the New Products in the Field and the New Products Outside The Field.

New Products In The Field has the meaning defined in Section 2.9.3(a).

New Products Outside The Field has the meaning defined in Section 2.9.3(b).

Personal Data has the meaning defined in Section 11(a).

**Price** has the meaning defined in Section 5.9(a).

**Product Specification** means, with respect to a ACM Products, any and all requirements to the respective ACM Products, including technical, physical, chemical, environmental, labelling, packaging and supplementary requirements as exclusively described in respective product specification as included in <u>Annex 2.1(a)</u>.

**Prolongation Term** has the meaning defined in Section 12.1(b).

Quality Management Agreement or QMA means the agreement attached to this Agreement in <u>Annex 4.1</u>.

Ramp-Up Period has the meaning set forth in Section 2.4.1(b) and further specified on a country-by-country basis in Annex 2.1.

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Regulatory Authority means any Governmental Authority responsible for granting Marketing Authorization Approval for a product the Territory.

**Regulatory Materials** means all filings and supporting documents submitted to (or retained for purposes of satisfying requirements of) any Regulatory Authority relating to any ACM Product, and all data contained therein, including, without limitation, advertising and promotion documents, adverse event files, complaint files and manufacturing records.

Removed Product has the meaning defined in Section 2.9.5(a).

**RA** has the meaning set forth in <u>Annex 5.12</u>.

**Section** means a section of this Agreement.

Second Level Support has the meaning set forth in <u>Annex 5.12</u>.

Sell-Off Period has the meaning defined in Section 12.3.5(d).

Service Contract has the meaning set forth in <u>Annex 5.12</u>.

**Service Term** has the meaning set forth in <u>Annex 5.12</u>.

Shelf-Life Period means, with respect to sterile ACM Products, their maximum approved shelf life.

Software has the meaning set forth in <u>Annex 5.12</u>.

**Sub-Distributor** has the meaning defined in Section 2.7(a).

Territory means the Biotronik Sphere of Commercialization and the Joint Sphere of Commercially, all as more particularly defined in <u>Annex 2.1</u>.

Third Party means a party other than Acutus, Biotronik and the Affiliates of each.

Third Party Analysis has the meaning defined in Section 5.13.4(b).

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**Trailing Twelve Month Capture Period** means, with respect to each country in the Territory, the twelve (12) calendar month period immediately preceding the calendar month in which Biotronik's rights terminate in such country as a result of a termination by Acutus under Section 12.2(c)(ii).

**Transfer Price Multiplier** means, [\*\*\*\*]

Country	Transfer Price Multiplier
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

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[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

**Update** shall have the meaning specified in <u>Annex 5.12</u>.

**Upgrade** shall have the meaning specified in <u>Annex 5.12</u>.

**Warranty** has the meaning defined in Section 5.13.1(a).

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### Annex 2.1 – Territory and Ramp-Up Period

The **Territory** shall mean collectively the countries of the Biotronik Sphere of Commercialization and the Joint Sphere of Commercialization, excluding all other countries and jurisdictions.

### A) Countries of the Acutus Sphere of Commercialization

All countries and jurisdictions of the world not included in the Biotronik Sphere of Commercialization, and not included in the Joint Sphere of Commercialization, each as defined below shall belong to the Acutus Sphere of Commercialization.

### B) Countries of the Biotronik Sphere of Commercialization in the Territory and Ramp-Up Periods for such countries

Biotronik Sphere of Commercialization means and is limited to the following countries. The Ramp Periods specified in the table below will apply respectively:

Country	
Germany	12 months
Austria	12 months
Hungary	12 months
Poland	12 months
Slovakia	12 months
Russia	12 months
United Arab Emirates	12 months
Saudi Arabia	12 months
South Africa	12 months
Switzerland	24 months
Japan	24 months
Australia and New Zealand	24 months
Singapore	24 months

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South Korea	24 months
Malaysia	24 months
Vietnam	24 months
Thailand	24 months
Taiwan	24 months
Brazil	12 months
Argentina	24 months
Mexico	24 months

# C) Countries of the Joint Sphere of Commercialization in the Territory

The countries of the Joint Sphere of Commercialization of the Territory will comprise of the following countries:

Hong Kong

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24 months

# Annex 2.1(a) – ACM Products

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# Annex 2.1(b) – EEA/EU Countries

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# Annex 2.5 – Competing Companies

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# Annex 3.5 – Annual Purchase Targets

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# Annex 4.1 – Quality Management Agreement

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## Annex 5.9 – Price List

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# Annex 5.12 – Service Terms and Conditions

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#### ACUTUS MEDICAL, INC.

### CONSULTING AGREEMENT

This Consulting Agreement (this "*Agreement*") is made and entered into as of **1/4/2019** (the "*Effective Date*") by and between Acutus Medical, Inc., a Delaware corporation with its principal place of business at Faraday Avenue, Suite 100, San Diego, CA 92008 (the "*Company*"), and Elia Health Sciences, Inc., with a principal place of business/residence at [\*\*\*\*] ("*Consultant*") (each herein referred to individually as a "Party," or collectively as the "*Parties*").

The Company desires to retain Consultant as an independent contractor to perform consulting services for the Company, and Consultant is willing to perform such services, on the terms described below. In consideration of the mutual promises contained herein, the Parties agree as follows:

#### 1. Services and Compensation

Consultant shall perform the services described in **Exhibit A** (the "*Services*") for the Company (or its designee,) and the Company agrees to pay Consultant the compensation described in **Exhibit A** for Consultant's performance of the Services.

#### 2. Applicability to Past Activities

Company and Consultant acknowledge that Consultant may have performed work, activities, services or made efforts on behalf of or for the benefit of Company, or related to the current or prospective business of Company in anticipation of Consultant's involvement with Company, that would have been "Services" if performed during the term of this Agreement, for a period of time prior to the date of this Agreement (the "*Prior Consulting Period*"). Accordingly, Consultant agrees that if and to the extent that, during the Prior Consulting Period: (i) Consultant received access to any information from or on behalf of Company that would have been "Confidential Information" (as defined below) if Consultant received access to such information during the term of this Agreement; or (ii) Consultant conceived, created, authored, invented, developed or reduced to practice any item (including any intellectual property rights with respect thereto) on behalf of or for the benefit of Company that would have been an "Invention" (as defined below) if conceived, created, authored, invented, developed or reduced to practice any item (including any intellectual property rights with respect thereto) on behalf of or for the benefit of Company that would have been an "Invention" (as defined below) if conceived, created, authored, invented, developed or reduced to practice during the term of this Agreement; then any such information shall be deemed "Confidential Information" hereunder and any such item shall be deemed an "Invention" hereunder, and this Agreement shall apply to such activities, information or item as if disclosed, conceived, created, authored, invented, developed or reduced to practice during the term of this Agreement.

### 3. Confidentiality

A. **Definition of Confidential Information.** "**Confidential Information**" means any non-public information that relates to the actual or anticipated business and/or products, research or development of the Company, its affiliates or subsidiaries or to the Company's, its affiliates' or subsidiaries' technical data, trade secrets, or know-how, including, but not limited to, research, product plans, or other information regarding the Company's, its affiliates' or subsidiaries' products or services and markets therefor, customer lists and customers (including, but not limited to, customers of the Company whom Consultant became acquainted during the term of this Agreement), software, developments, inventions, processes, formulas, technology, designs, drawings, engineering, hardware configuration information, marketing, finances, and other business information disclosed by the Company, its affiliates or subsidiaries, either directly or indirectly, in writing, orally or by drawings or inspection of premises, parts, equipment or other property of Company, its affiliates or subsidiaries.

Notwithstanding the foregoing, Confidential Information shall not include any such information which Consultant can establish (i) was publicly known or made generally available prior to the time of disclosure to Consultant; (ii) becomes publicly known or made generally available after disclosure to Consultant through no wrongful action or inaction of Consultant; (iii) is in the rightful possession of Consultant, without confidentiality obligations, at the time of disclosure as shown by Consultant's then- contemporaneous written records; or (iv) is subsequently developed by Consultant without reliance upon the Company's Confidential Information, as supported by written records or other competent evidence kept in the ordinary course of business.

B. *Nonuse and Nondisclosure*. During and after the term of this Agreement, Consultant will hold in the strictest confidence, and take all reasonable precautions to prevent any unauthorized use or disclosure of Confidential Information, and Consultant will not (i) use the Confidential Information for any purpose whatsoever other than as necessary for the performance of the Services on behalf of the Company, or (ii) disclose the Confidential Information to any third party without the prior written consent of an authorized representative of Company. Consultant may disclose Confidential Information to the extent compelled by applicable law; *provided however*, prior to such disclosure, Consultant shall provide prior written notice to Company and seek a protective order or such similar confidential protection as may be available under applicable law. Consultant agrees that no ownership of Confidential Information is conveyed to the Consultant. Without limiting the foregoing, Consultant shall not use or disclose any Company property, intellectual property rights, trade secrets or other proprietary know-how of the Company to invent, author, make, develop, design, or otherwise enable others to invent, author, make, develop, or design identical or substantially similar designs as those developed under this Agreement for any third party. Consultant may disclose the existence of this Agreement and the fact that Consultant is providing services to the Company; *provided*, *however*, that Consultant shall not disclose the material or commercial terms of this Agreement (other than with Consultant's accountants, tax preparers or attorneys) without the consent of the Company. Consultant agrees that Consultant's obligations under this Section 3.B shall continue after the termination of this Agreement.

C. **Other Client Confidential Information.** Consultant agrees that Consultant will not improperly use, disclose, or induce the Company to use any proprietary information or trade secrets of any former or concurrent employer of Consultant or other person or entity with which Consultant has an obligation to keep in confidence. Consultant also agrees that Consultant will not bring onto the Company's premises or transfer onto the Company's technology systems any unpublished document, proprietary information, or trade secrets belonging to any third party unless disclosure to, and use by, the Company has been consented to in writing by such third party.

D. *Third Party Confidential Information*. Consultant recognizes that the Company has received and in the future will receive from third parties their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. Consultant agrees, to the extent that the Company's confidentiality obligations based on the circumstances of disclosure or the nature of the subject matter itself, that at all times during the term of this Agreement and thereafter, Consultant owes the Company and such third parties a duty to hold all such confidential or proprietary information in the strictest confidence and not to use it or to disclose it to any person, firm, corporation, or other third party except as necessary in carrying out the Services for the Company consistent with the Company's agreement with such third party.

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#### 4. Ownership

A. Assignment of Inventions. Consultant agrees that all right, title, mid interest in and to any copyrightable material, notes, records, drawings, designs, inventions, improvements, developments, discoveries and trade secrets conceived, discovered, authored, invented, developed or reduced to practice by Consultant, solely or in collaboration with others, during the term of this Agreement and arising directly and solely out of, or in connection with, performing the Services under this Agreement and any copyrights, patents, trade secrets, mask work rights or other intellectual property rights relating to the foregoing (collectively, "Inventions"), are the sole properly of the Company. Consultant also agrees to promptly make full written disclosure to the Company of any Inventions and to deliver and assign (or cause to be assigned) and hereby irrevocably assigns folly to the Company all right, title and interest in and to the Inventions.

B. *Pre-Existing Materials.* Subject to Section 4.A, Consultant agrees that if, in the course of performing the Services, Consultant incorporates into any Invention or utilizes in the performance of the Services any pre-existing invention, discovery, original works of authorship, development, improvements, trade secret, concept, or other proprietary information or intellectual property right owned by Consultant ("*Prior Inventions*"), (i) Consultant will provide the Company with prior written notice and (ii) the Company is hereby granted a nonexclusive, royalty-free, perpetual, in-evocable, transferable, worldwide license (with the right to grant and authorize sublicenses) to make, have made, use, import, offer for sale, sell, reproduce, distribute, modify, adapt, prepare derivative works of, display, perform, and otherwise exploit such Prior Inventions, without restriction, including, without limitation, as part of or in connection with such Invention, and to practice any method related thereto. Consultant will not knowingly incorporate any invention, improvement, development, concept, discovery, work of authorship or other proprietary information owned by any third party into any Invention without Company's prior written permission. Company understands that Consultant makes to warranties or representations of any kind regarding any services provided by Consultant, or any invention, improvement, development, concept, discovery, work of authorship or other proprietary information disclosed to Company during the term hereof.

C. *Moral Rights.* Any assignment to the Company of Inventions includes all rights of attribution, paternity, integrity, modification, disclosure and withdrawal, and any other rights throughout the world that may be known as or referred to as "moral rights," "artist's rights," "droit moral," or the like (collectively, "*Moral Rights*"). To the extent that Moral Rights cannot be assigned under applicable law, Consultant hereby waives and agrees not to enforce any and all Moral Rights, including, without limitation, any limitation on subsequent modification, to the extent permitted under applicable law.

D. *Maintenance of Records.* Consultant agrees to keep and maintain adequate, current, accurate, and authentic written records of all Inventions made by Consultant (solely or jointly with others) during the term of this Agreement, and for a period of three (3) years thereafter. The records will be in the form of notes, sketches, drawing s, electronic files, reports, or any other format that is customary in the industry and/or otherwise specified by the Company. Such records are and remain the sole properly of the Company at all times and upon Company's request, Consultant shall deliver (or cause to be delivered) the same.

E. *Further Assurances.* Consultant agrees to provide the Company, or its designee, at the Company's expense, with reasonable assistance in securing the Company's rights in Inventions in any and all countries, including the disclosure to the Company of all pertinent information and data with respect thereto, the execution of all applications, specifications, oaths, assignments and all other instruments that the Company may deem necessary in order to apply for, register, obtain, maintain, defend, and enforce such rights, and in order to deliver, assign and convey to the Company, its successors, assigns and nominees the sole and exclusive right, title, and interest in and to all Inventions and testifying in a suit or other proceeding relating to such Inventions. Consultant further agrees that Consultant's obligations under this Section 4.E shall continue after the termination of this Agreement.

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F. Attorney-in-Fact. Consultant agrees that, if the Company is unable because of Consultant's unavailability, dissolution, mental or physical incapacity, or for any other reason, to secure Consultant's signature with respect to any Inventions, including, without limitation, for the purpose of applying for or pursuing any application for any United States or foreign patents or mask work or copyright registrations covering the Inventions assigned to the Company in Section 4.A, then Consultant hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Consultant's agent and attorney-in-fact, to act for and on Consultant's behalf to execute and file any papers and oaths and to do all other lawfully permitted acts with respect to such Inventions to further the prosecution and issuance of patents, copyright and mask work registrations with the same legal force and effect as if executed by Consultant. This power of attorney shall be deemed coupled with an interest, and shall be irrevocable.

#### 5. Conflicting Obligations

A. A Consultant represents and warrants that Consultant has no agreements, relationships, or commitments to any other person or entity that conflict with the provisions of this Agreement, Consultant's obligations to the Company under this Agreement, and/or Consultant's ability to perform the Services. Consultant will not enter into any such conflicting agreement during the term of this Agreement.

B. Consultant shall require all Consultant's employees, contractors, or other third- parties performing Services under this Agreement to execute a confidential information and assignment agreement in a form no less restrictive than this Agreement, and promptly provide a copy of each such executed agreement to the Company. Consultant's violation of this Article 5 will be considered a material breach under Section 8.B.

C. Consultant represents and warrants that Consultant, and, to Consultant's knowledge, its officers, directors, employees, and agents acting on its behalf, if applicable, have complied in all material respects with any and all applicable law, statute, order, decree, consent decree, judgment, rule, regulation, ordinance or other pronouncement having the effect of law whether in the United States, any foreign country, or any domestic or foreign state, county, city or other political subdivision or of any governmental entity, and other governmental requirements, including, but not limited to, federal, state, local and foreign laws, ordinances, rules, regulations and other requirements (collectively, "**Laws**") to which Consultant may be subject to and which relate to the subject matter of this Agreement, including Consultant's provision of Services under this Agreement, and no claims have been filed against Consultant alleging a violation of any such Laws and Consultant has not received any notice asserting that it is not so in compliance.

#### 6. Return of Company Materials

Upon the termination of this Agreement, or upon Company's earlier request, Consultant will immediately deliver to the Company, and will not keep in Consultant's possession, recreate, or deliver to anyone else, any and all Company property, including, but not limited to, Confidential Information, tangible embodiments of the Inventions, all devices and equipment belonging to the Company, all electronically-stored information and passwords to access such property, those records maintained pursuant to Section 4.D and any reproductions of any of the foregoing items that Consultant may have in Consultant's possession or control.

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### 7. Reports

Consultant agrees that Consultant will keep the Company advised as to Consultant's progress in performing the Services under this Agreement. Consultant further agrees that Consultant will, as reasonably requested by the Company, prepare written reports with respect to such progress. The Company and Consultant agree that the reasonable time expended in preparing such written reports will be considered time devoted to the performance of the Services.

#### 8. Term and Termination

A. *Term.* The term of this Agreement will begin on the Effective Date of this Agreement and will continue until the earlier of (i) final completion of the Services or (ii) termination as provided in Section 8.B.

B. *Termination.* Except as otherwise provided in Exhibit A-l, either party may terminate this Agreement upon giving the other thirty (30) days prior written notice of such termination pursuant to Section 13.G of this Agreement. Either Party may terminate this Agreement immediately and without prior notice if the other party is in breach of any material provision of this Agreement.

C. Survival. Upon any termination, all rights and duties of the Company and Consultant toward each other shall cease except:

(1) The Company will pay, within thirty (30) days after the effective date of termination, all undisputed amounts owing to Consultant for Services completed prior to the termination date and related reimbursable expenses, if any, submitted in accordance with the Company's policies and in accordance with the provisions of Article 1 of this Agreement; and

(2) Article 3 (Confidentiality), Article 4 (Ownership), Section 5.B (Conflicting Obligations), Article 6 (Return of Company Materials), Article 8 (Term and Termination), Article 9 (Independent Contractor Relationship), Article 10 (Indemnification), Article 11 (Noninterference), Article 12 (Limitation of Liability), and Article 13 (Miscellaneous) will survive termination or expiration of this Agreement in accordance with their terms.

#### 9. Independent Contractor Relationship

It is the express intention of the Company and Consultant that Consultant perform the Services as an independent contractor to the Company. Nothing in this Agreement shall in any way be construed to constitute Consultant as an agent, employee or representative of the Company. Without limiting the generality of the foregoing, Consultant is not authorized to bind the Company to any liability or obligation or to represent that Consultant has any such authority. Consultant agrees to furnish (or reimburse the Company for) all tools and materials necessary to accomplish this Agreement and shall incur all expenses associated with performance, except as expressly provided in **Exhibit A**. Consultant acknowledges and agrees that Consultant is obligated to report as income all compensation received by Consultant pursuant to this Agreement.

### **10. Indemnification**

Each Party agrees to indemnify and hold harmless the other party and the other party's affiliates and their directors, officers and employees from and against all taxes, losses, damages, liabilities, costs and expenses, including attorneys' fees and other legal expenses, arising directly or indirectly from or in connection with (i) any negligent, reckless or intentionally wrongful act of the indemnifying party or the indemnifying party's assistants, employees, contractors or agents, and (ii) any breach by the indemnifying party or the indemnifying party's assistants, employees, contractors or agents of any of the covenants contained in this Agreement.

### 11. Nonsolicitation

To the fullest extent permitted under applicable law, from the date of this Agreement until six (6) months after the termination of this Agreement for any reason (the "*Restricted Period*"), Consultant will not, without the Company's prior written consent, directly or indirectly, solicit any of the Company's employees to leave their employment, or attempt to solicit employees of the Company, either for Consultant or for any other person or entity. Consultant agrees that nothing in this Article 11 shall affect Consultant's continuing obligations under this Agreement during and after this six (6) month period, including, without limitation, Consultant's obligations under Article 3.

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### 12. Limitation of Liability

IN NO EVENT SHALL EITHER PARTY BE LIABLE TO OTHER PARTY OR TO ANY OTHER THIRD PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES, OR DAMAGES FOR LOST PROFITS OR LOSS OF BUSINESS, HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHER THEORY OF LIABILITY, REGARDLESS OF WHETHER COMPANY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND NOTWITHSTANDING THE FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY. IN NO EVENT SHALL COMPANY'S LIABILITY ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT EXCEED THE AMOUNTS PAID BY COMPANY TO CONSULTANT UNDER THIS AGREEMENT FOR THE SERVICES, DELIVERABLES OR INVENTION GIVING RISE TO SUCH LIABILITY. IN NO EVENT SHALL CONSULTANT'S LIABILITY ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT EXCEED THE AMOUNTS RECEIVED BY CONSULTANT FROM THE COMPANY UNDER THIS AGREEMENT FOR THE SERVICES, DELIVERABLES OR INVENTION GIVING RISE TO SUCH LIABILITY.

### 13. Miscellaneous

A. *Governing Law; Consent to Personal Jurisdiction.* This Agreement shall be governed by the laws of the State of California, without regard to the conflicts of law provisions of any jurisdiction. To the extent that any lawsuit is permitted under this Agreement, the Parties hereby expressly consent to the personal and exclusive jurisdiction and venue of the state and federal courts located in California.

B. *Assignability.* This Agreement will be binding upon Consultant's assigns, administrators, and other legal representatives, and will be for the benefit of the Company, its successors, and its assigns. There are no intended third-party beneficiaries to this Agreement, except as expressly stated. Except as may otherwise be provided in this Agreement, Consultant may not sell, assign or delegate any rights or obligations under this Agreement. Notwithstanding anything to the contrary herein, Company may assign this Agreement and its rights and obligations under this Agreement to any successor to all or substantially all of Company's relevant assets, whether by merger, consolidation, reorganization, reincorporation, sale of assets or stock, or otherwise.

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C. *Entire Agreement.* This Agreement constitutes the entire agreement and understanding between the Parties with respect to the subject matter herein and supersedes all prior written and oral agreements, discussions, or representations between the Parties. Consultant represents and warrants that it is not relying on any statement or representation not contained in this Agreement. To the extent any terms set forth in any exhibit or schedule conflict with the terms set forth in this Agreement, the terms of this Agreement shall control unless otherwise expressly agreed by the Parties in such exhibit or schedule.

D. Headings. Headings are used in this Agreement for reference only and shall not be considered when interpreting this Agreement.

E. *Severability*. If a court or other body of competent jurisdiction finds, or the Parties mutually believe, any provision of this Agreement, or portion thereof, to be invalid or unenforceable, such provision will be enforced to the maximum extent permissible so as to affect the intent of the Parties, and the remainder of this Agreement will continue in full force and effect.

F. *Modification, Waiver*. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in a writing signed by the Parties. Waiver by the Company of a breach of any provision of this Agreement will not operate as a waiver of any other or subsequent breach.

G. *Notices.* Any notice or other communication required or permitted by this Agreement to be given to a Party shall be in writing and shall be deemed given (i) if delivered personally or by commercial messenger or courier service, (ii) when sent by confirmed facsimile, or (iii) if mailed by U.S. registered or certified mail (return receipt requested), to the Party at the Party's address written below or at such other address as the Party may have previously specified by like notice. If by mail, delivery shall be deemed effective three business days after mailing in accordance with this Section 14.G.

(1) If to the Company, to:

2210 Faraday Avenue, Suite 100 Carlsbad, CA 92008 Attention: Vince Burges – President / CEO

(2) If to Consultant, to the address for notice on the signature page to this Agreement or, if no such address is provided, to the last address of Consultant provided by Consultant to the Company, with copy of each notice provided to Seyamack Kouretchian, Coast Law Group, LLP, [\*\*\*\*]

H. *Attorneys' Fees.* In any court action at law or equity that is brought by one of the Parties to this Agreement to enforce or interpret the provisions of this Agreement, the prevailing Party will be entitled to reasonable attorneys' fees, in addition to any other relief to which that Party may be entitled.

I. *Signatures.* Th.is Agreement may be signed in two counterparts, each of which shall be deemed au original, with the same force and effectiveness as though executed in a single document.

(signature page follows)

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IN WITNESS WHEREOF, the Parties hereto have executed this Consulting Agreement as of the date first written above.

## ELIAS HEALTH SCIENCES, INC.

# By: /s/ Peter Elia Name: Peter Elia

Name: Peter Elia Title: Date: 1/4/2019

Address for Notice:

ACUTUS MEDICAL, INC.

By:	/s/ Gary Doherty
Name:	Gary Doherty
Title:	CFO
Date:	1/4/2019

Acutus Medical, Inc. - Consulting Agreement

# EXHIBIT A-1 SERVICES AND COMPENSATION

I. Contact. Consultant's principal Company contact:

Name: <u>Vince Burgess</u> Title: <u>CEO</u> Email: [<u>\*\*\*\*</u>] Phone: [<u>\*\*\*\*</u>]

2. Services. The Services shall consist of the following:

- Market Development Consultant
  - Peer-to-peer physician engagement, including planning and execution
  - Guidance, strategic planning, and implementation for site selection and pricing !
  - Establish national accounts and contracts
  - Product features and performance requirements
  - Other activities, as mutually agreed, including those typically required when introducing an advanced/new technology to at medical specialty.
- The Company and the Consultant agree that, unless Company and Consultant mutually agree to earlier termination, the Services shall be for a minimum of 3 months. If such notice is given before the minimum 3-month period ends, unless Consultant otherwise agrees, termination will not be effective until the end of the minimum 3 month period. For the avoidance of doubt, the effect of this provision is to provide Consultant with a total of at least 3 months compensation for Services, unless Company and Consultant mutually agree to earlier termination or unless there is a breach of a material term of the Agreement.
- Compensation.

A. The Company will pay Consultant \$31,250 per month at a fixed rate for the duration of the consultancy.

B. The Company will reimburse Consultant, in accordance with Company policy, for all reasonable expenses incurred by Consultant in performing the Services pursuant to this Agreement, if Consultant receives written consent from an authorized agent of the Company prior to incurring such expenses and submits receipts for such expenses to the Company in accordance with Company policy.

C. Subject to board approval, the Company will agree to grant 15,000 options to purchase Common Stock at the then current fair market value (as established by the board based on an active 409a valuation) for each month of paid Service. In the event Service is terminated, Consultant will have 12 months to exercise any options granted.

Monthly or every two weeks, Consultant shall submit to the Company a written invoice for Services and expenses. Company shall pay any such undisputed invoices within 15 days of receipt. The Company shall promptly give Consultant notice of any unapproved invoices or disputed amounts

## CONSULTANT

By:	/s/ Peter Elia
Name:	Peter Elia
Title:	
Date:	1/4/19

## ACUTUS MEDICAL, INC.

By:	/s/ Gary Doherty
Name:	Gary Doherty
Title:	CFO
Date:	1/4/2019