



AtriCure is committed to **addressing**  
the global Afib epidemic

AtriCure

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 Nasdaq

**2018**  
ANNUAL REPORT

AtriCure



## 2018 HIGHLIGHTS

**AtriClip FLEX-V® Device**  
Product Launch



**Over \$200 Million in Revenue**  
Achieved Annual Growth of 15.4%



**Patient Enrollment Completed**  
Full Enrollment of Clinical Trial



**Public Stock Offering**  
Raised Over \$80 Million to Support Growth



**Worldwide Training**  
400+ Healthcare Professionals Trained



**620 Employees**  
Worldwide



## DEAR SHAREHOLDERS,

We had a strong 2018, as we continue our track record of strong, consistent revenue growth. Our many accomplishments position AtriCure for continued success. First and foremost, our technologies improved the lives of many thousands of patients globally in 2018, providing physicians several options for treating patients with the most serious forms of atrial fibrillation (Afib). As part of this, we sold more than 44,000 AtriClip® devices last year, bringing total sales to more than 170,000 and continuing the advancement of the AtriClip line as the most widely-used device for occluding the left atrial appendage. Other highlights include completing enrollment in the CONVERGE IDE clinical trial, training over 400 healthcare professionals worldwide, launching the AtriClip FLEX-V® device, and establishing a dedicated pain management team. We also raised over \$80 million, strengthening our balance sheet and creating financial flexibility. It was our sixth straight year of double-digit revenue growth, increasing total annual revenues 15 percent to \$202 million for the year.

We are maturing as a team and organization, positioning AtriCure to efficiently expand and grow over the next decade. Today we have more than 150 people in the field, robust training and education programs, and an adaptable infrastructure across our entire organization. The evolution of our team is reflected in our performance last year, underpinned by our continued commitment to education, clinical science and innovation as the cornerstones of our success.

Our mission is simple. We are passionately focused on reducing the global Afib epidemic and healing the lives of those affected. Our long-term growth strategy, developing a portfolio of products that expands our reach and impact worldwide, remains on track, and we are confident that our pipeline of new products, business development opportunities and continued focus on clinical trials and education set AtriCure up for long-term success.

### INNOVATION DRIVING COMPLETE PLATFORM DEVELOPMENT

During 2018, we continued to invest in and expand our product portfolio, with impactful progress across our platform. This is particularly evident from the steady, positive feedback we have received on our innovative approach to advancing products to meet clinical needs.

To highlight, we launched the AtriClip FLEX-V device within our Appendage Management franchise. This next generation open-chest AtriClip device leverages the same technology we developed for the AtriClip PRO-V® device. The AtriClip FLEX-V device offers a lower profile implant, an easier-to-use delivery system, and a trigger-release deployment mechanism — the first of its kind in the AtriClip platform. We are seeing everything from the AtriClip FLEX-V device being used in Open Concomitant cases – enabling more CABG procedures – to greater uptake of AtriClip PRO-V in the Convergent approach. We believe that the AtriClip FLEX-V device will help us grow adoption in open surgeries for many years to come, and the AtriClip PRO-V device will provide a significant step toward a comprehensive strategy for minimally invasive management of the left atrial appendage.

Another innovation highlight is the recently announced launch of the cryoICE® cryoSPHERE™ probe in the United States. The cryoSPHERE probe is the first device in the cryoICE platform solely dedicated to blocking pain by ablating peripheral nerves which temporarily prevents the nerves from transmitting pain signals. The block typically lasts several months while the nerve regenerates. Because of the nature of this therapy, physicians are adopting cryo nerve block therapy as a key part of their pain management strategies, offering a unique solution for patients undergoing cardiothoracic surgery. More than 80 cases have already been performed with the cryoSPHERE probe, and surgeons are noting remarkable improvement in post-operative recovery times, pain levels and patient satisfaction. In 2018, we established a small, dedicated thoracic team to support cryo nerve block therapy in select markets, and will expand this team during 2019.

We believe both of these new products have been additive to our product portfolio, and we expect our innovation and business development opportunities in 2019 will continue to expand our reach and impact on patients worldwide. This track record of innovation and evolving market dynamics are collectively driving our confidence in the diverse AtriCure platform and its long-term potential.

### CLINICAL OPPORTUNITIES INCREASING ADDRESSABLE MARKET

On the clinical front, we are making robust progress on our programs. In 2018, we completed the enrollment of our CONVERGE IDE clinical trial, received IDE approval from the FDA to begin our ICE-Afib clinical trial, received approval from the FDA to resume enrollment of the DEEP AF IDE clinical trial to enroll 40 patients, enrolled 45 additional patients in CEASE AF, and enrolled our 80th patient in the FROST study. While we have many investments in gathering critical clinical data and improving our labeling and reimbursement profile globally, I would like to highlight two clinical trials: CONVERGE IDE and ICE-Afib.

The CONVERGE IDE clinical trial is the first of its kind, evaluating the Convergent approach against catheter ablation for patients who suffer from persistent Afib. We completed enrollment of 153 total patients in the second half of 2018, and now over 200 hospitals have completed Convergent procedures in the United States. Our next milestone will be completing one-year patient follow-ups in late 2019, followed by a submission to the FDA for pre-market approval of the AtriCure EPI-Sense® coagulation device for the treatment of persistent Afib using the Convergent approach.

As part of our commitment to developing clinical evidence, we are also investing in the ICE-Afib clinical trial. ICE-Afib will evaluate the safety and effectiveness of the cryoICE system for the treatment of persistent and long-standing persistent Afib during concomitant on-pump cardiac surgery. The trial is a prospective, multicenter, single-arm study of up to 150 patients at up to 20 U.S. centers, and our first patient enrolled in February 2019. The ICE-Afib trial is a unique opportunity to generate systematic clinical evidence on the safety and effectiveness of concomitant cryosurgery for the treatment of Afib patients undergoing structural heart surgery.

We believe that our investments in prospective clinical trials will bolster our position as a leading innovator in the market. We expect that upon the successful conclusion of these trials, we will be able to market our technologies and therapies as a comprehensive platform for a dramatically expanded group of physicians and patients.

## **EDUCATION PROGRAMS SPEARHEADING PHYSICIAN ADOPTION**

Training and education continues to be an important pillar of our growth strategy as we work to develop a vastly underpenetrated and underserved market. We have continued to drive adoption of surgical ablation in a concomitant setting through AtriCure-sponsored education programs, as well as collaborations with professional societies. In addition, evolving guidelines and emerging clinical data are driving behavior change. Surgical ablation is reducing Afib and improving the lives of patients. This fact is making an impact, driving steady demand for training and increasing adoption.

Over the course of 2018, we conducted a record number of training sessions in the United States and Europe. Programs were expanded, going beyond surgeons and electrophysiologists to include a higher mix of nurses, fellows and other healthcare professionals. We trained more than 400 physicians and healthcare providers worldwide, bringing the total to over 3,000 trained. We also significantly increased our cadaver labs at Maze IV courses to enable in-depth discussions and hands-on experiences. Further, our ablation training course recently received endorsement from the Society of Thoracic Surgeons (STS), which has spurred energized discussions and enthusiasm in the provider community.

We continue to believe that clinician data from leading medical institutions and societies, coupled with education and awareness, will ultimately improve patient care and support growing procedural volumes. The medical community is increasingly recognizing the clinical, safety and societal benefits of surgical ablation and the downside of non-treatment. We remain well positioned to both drive and take advantage of these market tailwinds. Uniting our robust clinical data and pipeline of products, we believe we are building a complete platform to serve the global Afib epidemic.

## **AN EXCITING PATH FORWARD: POISED FOR FUTURE EXPANSION**

As we enter 2019, we continue to focus on three pillars critical to our mission: innovation, clinical science and education. We are successfully building a portfolio of products with robust clinical data that expands our reach, benefits patients worldwide and creates shareholder value. We are looking forward to continued growth in 2019 and beyond, as we simultaneously strengthen our presence and enhance our comprehensive portfolio of surgical ablation and appendage management devices.

Finally, a thank you to all of my AtriCure colleagues. Their commitment in pursuit of AtriCure's mission led the way for the extraordinary achievements of 2018 and will allow us to look favorably upon the coming year and beyond. On behalf of the Board of Directors and my AtriCure colleagues, I thank you for your support of our company and our strategy for long-term growth. We look forward to sharing our successes with you.

Sincerely,



Michael H. Carrel  
President and Chief Executive Officer

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

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**ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2018

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 000-51470

**AtriCure  
AtriCure, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**

State or other jurisdiction of  
incorporation or organization

**34-1940305**

(I.R.S. Employer  
Identification Number)

**7555 Innovation Way, Mason, OH**

(Address of principal executive offices)

**45040**

(Zip Code)

**Registrant's telephone number including area code: (513) 755-4100**

**Securities Registered Pursuant to Section 12(b) of the Act:**

Title of each class  
**Common Stock, \$.001 Par Value Per Share**

Name of each exchange on which registered  
**NASDAQ Global Market**

**Securities Registered Pursuant to Section 12(g) of the Act:**

**None**

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large Accelerated Filer  Accelerated Filer  Non-Accelerated Filer  Smaller Reporting Company  Emerging Growth Company

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

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

The aggregate market value of the voting Common Stock held by non-affiliates of the registrant, based upon the closing sale price of the Common Stock on June 30, 2018, as reported on the NASDAQ Global Market, was \$911.1 million.

As of February 22, 2019, there were 38,605,737 shares of Common Stock, \$.001 par value per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Items 10, 11, 12, 13 and 14 of Part III of this Form 10-K incorporate information by reference from the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K.

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## PART I

*This Form 10-K, including the sections titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors,” contains forward-looking statements regarding our future performance. All forward-looking information is inherently uncertain and actual results may differ materially from assumptions, estimates or expectations reflected or contained in the forward-looking statements as a result of various factors, including those set forth under “Risk Factors” and elsewhere in this Form 10-K. Forward-looking statements address our expected future business, financial performance, financial condition and results of operations, and often contain words such as “intends,” “estimates,” “anticipates,” “hopes,” “projects,” “plans,” “expects,” “seek,” “believes,” “see,” “should,” “will,” “would,” “target,” and similar expressions and the negative versions thereof. Such statements are based only upon current expectations of AtriCure. Any forward-looking statement speaks only as of the date made. Reliance should not be placed on forward-looking statements because they involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to differ materially from those expressed or implied. Forward-looking statements include statements that address activities, events, circumstances or developments that AtriCure expects, believes or anticipates will or may occur in the future. Forward-looking statements are based on AtriCure’s experience and perception of current conditions, trends, expected future developments and other factors it believes are appropriate under the circumstances and are subject to numerous risks and uncertainties, many of which are beyond AtriCure’s control. With respect to the forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. These forward-looking statements speak only as of the date of this Form 10-K. We undertake no, and hereby disclaim any and all, obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise unless required by law.*

*(Dollar and share amounts referenced in this Part I are in thousands.)*

### ITEM 1. BUSINESS

#### Overview

We are a leading innovator in treatments for atrial fibrillation (Afib) and left atrial appendage (LAA) management. Afib affects approximately 1% of the population in the United States. It is the most common cardiac arrhythmia, or irregular heartbeat, encountered in clinical practice and accounts for more doctor visits and hospital days than any other cardiac arrhythmia. When a patient is in Afib, abnormal electrical impulses cause the atria, or upper chambers of the heart, to fibrillate, or beat rapidly, irregularly, and in an uncoordinated fashion. As a result, blood in the atria may be in stasis, increasing the risk that a blood clot will form and cause a stroke or other serious complications. In patients with Afib, a significant percentage of those clots can form inside of the LAA. Symptoms of Afib may include heart palpitations, dizziness, fatigue and shortness of breath, and these symptoms may be debilitating and life threatening in some cases. Patients often progress from being in Afib intermittently to being in Afib continuously. Afib often occurs in conjunction with other cardiovascular diseases, including hypertension, congestive heart failure, left ventricular dysfunction, coronary artery disease and valvular disease.

Our products are used by physicians during both open-heart and minimally invasive surgical procedures, either in conjunction with heart surgery for other conditions (“concomitant” to such a procedure), or on a standalone basis. We have several product lines for the ablation of cardiac tissue, including our Isolator<sup>®</sup> Synergy<sup>™</sup> Ablation System, the first and only surgical device approved by the United States Food and Drug Administration (FDA) for the treatment of persistent and long-standing persistent forms of Afib in patients undergoing certain open concomitant procedures. We also offer a variety of minimally invasive ablation devices and access tools to facilitate less invasive cardiac and thoracic surgery. Our cryoICE<sup>®</sup> cryosurgery product line offers a variety of cryoablation devices for use in multiple types of cardiothoracic surgery. Our AtriClip<sup>®</sup> LAA Exclusion System is a device specifically designed to occlude the heart’s left atrial appendage.

We believe that we are currently the market leader in the surgical treatment of Afib. Our Isolator Synergy System is approved by FDA for the treatment of persistent and long-standing persistent Afib concomitant to other open-heart surgical procedures. All of our other ablation devices are cleared for sale in the United States under FDA 510(k) clearances, including our other RF and cryoablation products, which are indicated for the ablation of cardiac tissue and/or the treatment of cardiac arrhythmias. In addition, certain of our cryoablation probes are cleared for managing pain by temporarily ablating peripheral nerves. Our AtriClip products are 510(k)-cleared with an indication for the occlusion of the heart’s LAA, performed under direct visualization and in conjunction with other cardiac surgical procedures. Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope or other appropriate viewing technologies. We also offer reusable surgical instruments typically used in cardiac valve replacement or repair. Our Isolator Synergy clamps, Isolator Synergy pens, Coolrail<sup>®</sup> linear pen, cryosurgery devices, certain products of the AtriClip LAA Exclusion System, COBRA Fusion<sup>®</sup> Ablation System, Numeris<sup>™</sup> System and the Epi-Sense<sup>®</sup> Guided Coagulation System with VisiTrax<sup>®</sup> technology bear the CE mark and may be commercially distributed throughout the member states of the European Union and other countries that comply with or mirror the Medical Device Directive. We anticipate that substantially all of our revenue for the foreseeable future will relate to products we currently sell, or are in the process of developing.

We sell our products to medical centers through our direct sales force in the United States and in certain international markets, such as Germany, France, the United Kingdom and the Benelux region. We also sell our products to distributors who in turn sell our products to medical centers in other international markets. Our business is primarily transacted in U.S. Dollars with the exception of transactions with our European customers, which are transacted in Euros or British Pounds.

## Market Overview

Afib is the most commonly diagnosed sustained cardiac arrhythmia, and affects more than 30 million people worldwide, including more than five million in the United States. It is estimated that the incidence of Afib doubles with each decade of an adult's life. At age 40, remaining lifetime risk for Afib is 26% for men and 23% for women. Afib is an under-diagnosed condition due in large part to the fact that patients with Afib often have mild or no symptoms, and their Afib is only diagnosed when they seek treatment for an associated condition, such as a structural heart disease or stroke. We believe that increasing awareness of Afib and improved diagnostic screening will result in an increased number of patients diagnosed with Afib. Recently, there have been several new diagnostic technologies introduced in the United States that allow for less invasive screening options, which should assist patients with more compliant and proactive identification of Afib. Also, since the prevalence of Afib increases with age, there will likely be an increase in the number of diagnosed Afib patients in the United States as the population ages. We believe that the same trends in the United States apply globally, as in many geographies the incidence of Afib is increasing as the population ages.

Afib is a condition that doctors often find difficult to treat and, historically, there has been no widely accepted long-term cure for Afib. This difficulty is exacerbated with more serious forms of Afib, which are typically classified as "persistent" and "long-standing persistent" Afib. Doctors typically begin treating Afib with pharmaceuticals, which are often ineffective, not well-tolerated and may be associated with serious side effects, including the risk of bleeding. Patients who cannot effectively be treated with pharmaceuticals may be candidates to undergo catheter-based ablation procedures to treat their Afib. To perform a catheter ablation, an electrophysiologist inserts a flexible catheter into the interior of the heart, typically through the femoral vein in the groin. There are currently no catheter ablation technologies indicated for the treatment of persistent or long-standing persistent Afib. Implantable devices, such as pacemakers and defibrillators, are sometimes used to reduce the frequency and symptoms of Afib, although they are not designed to treat the underlying disease. In the past, an open-heart surgical procedure known as the "cut and sew Maze" was used to treat Afib. While the cut and sew Maze was highly effective, this procedure has not been widely adopted because it is technically challenging, highly invasive and involves long recovery times. Over the past two decades, technology advancements have made surgical ablation more effective, repeatable and available to cardiac surgeons around the world. Recent societal guideline changes from the Society of Thoracic Surgeons (STS) and Heart Rhythm Society (HRS) have increased the class of recommendation for concomitant surgical ablation to Class I, meaning that it is a "recommended" treatment, no longer just "reasonable", for patients who have structural heart disease and Afib. These societal guidelines are reflective of the scientific evidence suggesting that surgical ablation is safe and effective for all structural heart patients who also have Afib.

Of the patients undergoing open-heart surgery globally on an annual basis, we estimate that over 250,000 are potential candidates for surgical ablation using our products. Today, we estimate that approximately 25-35% of those candidates are being treated, but we believe many are not treated properly or fully. Of the population diagnosed with Afib, a large percentage of patients are symptomatic and do not respond to pharmacological therapy. Additionally, there is a large population of patients who have no other underlying cardiac disease but who suffer from serious forms of Afib. Many of these patients fail traditional therapies, and thus we believe could benefit from a minimally invasive or multi-disciplinary ("hybrid") Afib treatment using our products.

In addition, Afib is thought to be responsible for approximately 15% to 20% of the estimated 800,000 strokes that occur annually in the United States. According to the American Heart Association, the risk of stroke is five times higher in people with Afib. Studies have also suggested that 90% of clots that cause strokes in patients who have Afib originate from within the LAA. Afib accounts for billions of dollars in hospitalization-related and office visit costs in the United States each year. Indirect costs, such as the management of Afib-related strokes, are believed to be significant. Because of the risk of stroke and the significant cost burden on the healthcare system, more and more surgeons are routinely addressing the LAA, both in patients who have Afib, but also in those who do not have Afib but may be at increased risk of developing the disease in the future. We believe that our AtriClip system is safer, more effective and easier to use than other products and techniques for occluding the LAA. Therefore, we believe that the market for the AtriClip system represents a significant growth opportunity.

Cardiothoracic surgery involving an incision through the ribcage, typically referred to as thoracotomy access, can often times result in post-operative pain and longer hospital recovery times as patients refrain from mobilizing their chest near the incision site. Most cardiothoracic surgeons will employ a multi-modal pain management protocol that includes global and local pain management techniques. Global techniques include epidural delivery of medication directly around the spinal cord, intravenous, or oral delivery of opioid and non-opioid pain medications. Local, more focused, techniques include syringe injections between vertebrae and cryo nerve block, the use of cryo-energy to temporarily ablate peripheral nerves. Cryo nerve block can be delivered using our cryoICE CRYO2 probe, one of the same probes used to treat cardiac arrhythmias, as well as our cryoICE cryoSPHERE™ probe, which is specifically designed for cryo nerve block. Depending on the degree of invasiveness of the cardiothoracic surgery, physicians and their nursing staff will take advantage of multiple modes of pain management. It is estimated that each year roughly 150,000 cardiothoracic procedures are performed in the United States through thoracotomy access. Hospital recovery times can vary from two to eight days

depending on the procedure, operative complications associated with the procedure, pain management protocol, and other factors. In recent years, opioids have come under heavy scrutiny due to their potential for long-term dependency, overdose and possible death. The Center for Disease Control has reported over 42,000 deaths involving opioids in the United States in a single year, and both federal and local governments in the United States have proposed and implemented new regulations to curb the opioid overdose epidemic. It is also estimated that one in seven cardiothoracic surgical patients develops an unhealthy post-procedural addiction to prescription narcotics, making alternative, non-opioid pain management modalities, such as cryo nerve block, increasingly important.

## The AtriCure Solution and Products

We believe the surgical and catheter-based ablation devices currently marketed by our competition are not ideal for safely, rapidly and reliably creating lesions that completely and permanently block the abnormal electrical impulses that cause Afib, particularly for patients with more chronic forms of Afib or patients who have failed single or multiple catheter ablations. Our products, including our Isolator Synergy System, enable cardiothoracic surgeons to mimic the cut and sew Maze procedure with a faster, less invasive and less technically challenging approach. We have completed, and continue to invest in, clinical studies for the use of our ablation products to treat Afib. Leading cardiothoracic surgeons and electrophysiologists, including those who serve or who have served as consultants to us, have published results of initial clinical studies utilizing our Isolator Synergy System. The results of these studies have assessed efficacy, ease of use and safety endpoints.

We offer product lines for cardiac tissue ablation, left atrial appendage management and temporary pain management.

Products for cardiac tissue ablation are characterized as either (1) those that heat tissue using Radio Frequency (RF) energy to create the tissue effects or (2) those that cool tissue using cryo-thermal heat transfer to create the tissue effects:

- 1.) **Radio Frequency Ablation Devices.** Our RF products fall into four platforms each consisting of disposable handpieces which connect to compact RF power generation sources that we generally place with our direct customers and sell to our distributors. Our RF devices primarily consist of the following products:
  - **Isolator Synergy and Isolator Synergy Access® Clamps.** Our Isolator Synergy System represents our primary product line and currently generates the majority of our RF ablation-related revenue. Physicians use the Isolator Synergy System and related RF devices in both open and minimally invasive procedures. All of our clamps are single-use disposables and have jaws that close in a parallel fashion. We sell multiple configurations of our Isolator Synergy clamps with the primary difference being the form of the clamping jaws. The parallel closure compresses tissue and evacuates the blood and fluids from the energy pathway in order to make the ablation more effective.
  - **EPI-Sense Guided Coagulation System with VisiTrax Technology.** The EPI-Sense Guided Coagulation System with VisiTrax technology utilizes monopolar energy for the coagulation of tissue. The Epi-Sense device is a single-use disposable which is also capable of intra-operative cardiac signal sensing and recording when connected to an external recording device.
  - **Multifunctional Pens and Linear Ablation Devices.** These devices are single-use disposable RF products that come in multiple configurations which have different contact lengths and are powered by the Isolator Synergy Ablation and Sensing Unit RF generator. The MAX and Max Linear Pen devices enable surgeons to evaluate cardiac arrhythmias, perform temporary cardiac pacing, sensing and stimulation and ablate cardiac tissue with the same device. Surgeons are able to readily toggle back and forth between these functions. The Coolrail device enables the user to make longer linear lines of ablation. Surgeons generally use one or more of our pen and linear devices in combination with Isolator Synergy clamps.
  - **COBRA Fusion Surgical Ablation System.** The COBRA Fusion Surgical Ablation System's Versapolar technology combines bipolar temperature-controlled RF energy with monopolar energy. The COBRA Fusion devices are single-use disposable devices which incorporate a unique suction design that draws tissue in to assure stable contact and optimizes ablation performance.
- 2.) **cryoICE Cryoablation System.** The cryoICE cryoablation system consists of the cryoICE BOX generator along with a range of cryoICE probes and is used to ablate cardiac tissue. The single-use disposable probes come in a variety of configurations, with the primary differences being the flexibility, length and form of the distal end.

Products for left atrial appendage management:

**AtriClip System.** The AtriClip System includes an implantable device (AtriClip) coupled to a single-use disposable applicator. The AtriClip is designed to occlude the left atrial appendage by mechanically clamping the appendage from the outside of the heart, eliminating blood flow between the left atrial appendage and the atrium while avoiding contact with circulating blood. We believe that the AtriClip system is potentially safer, more effective and easier to use than other available products and techniques for permanently occluding the left atrial appendage. The AtriClip device comes in a variety of lengths allowing the user to select a configuration specific to the patient and in two geometries (rectangular and "V" shape). The applicators come in multiple forms tailored to specific procedural needs and with different deployment mechanisms. The AtriClip System includes various combinations of AtriClips and applicators.

Products for temporary pain management:

**cryoICE Cryoablation System.** The cryoICE cryoablation system for temporary pain block consists of the cryoICE Box generator along with a single-use disposable probe, the cryoICE CRYO2 probe or the cryoICE cryoSPHERE probe. The primary differences between these cryoablation probes is the form of the distal end. This system is used to apply cryo-energy to targeted intercostal peripheral nerves in the ribcage in order to temporarily relieve pain. This technique, called cryo nerve block, is applied intra-operatively by the cardiothoracic surgeon and results in temporary pain relief for up to 90 days after the procedure. Sensation typically returns to the affected region of the chest after this period. Studies are ongoing to characterize the effects of cryo nerve block and further refine the procedure.

In addition to the above product lines we also sell enabling technologies including our Lumitip™ dissectors, the Fusion Magnetic Retriever System and a line of reusable cardiac surgery (valve) instruments. The Lumitip dissector is used by surgeons to separate tissues to provide access to key anatomical structures that are targeted for ablation. The Fusion Magnetic Retriever System™ allows access around key anatomical structures and facilitates positioning of the Cobra Fusion Surgical Ablation System™. Cardiac surgery instruments are used during certain surgical procedures for repair or replacement of heart valves.

### **Current Afib Treatment Alternatives**

Physicians usually begin treating Afib patients with a variety of drugs intended to prevent blood clots, control heart rate or restore the heart to normal sinus rhythm. If a patient's Afib cannot be adequately controlled with drug therapy, doctors may perform one of several open-heart or minimally-invasive procedures that vary depending on the severity of the Afib symptoms and whether or not the patient suffers from other forms of heart disease.

Alternative treatments to open-heart and minimally invasive procedures include:

- *Drugs.* Pharmaceutical options called anti-arrhythmics are available to treat Afib. Depending on a patient's severity of the disease and heart condition, physicians typically administer these medications in a hospital setting with continuous monitoring. If the patient goes back into a normal rhythm, the physician will often prescribe a similar anti-arrhythmic drug to try to prevent a recurrence of Afib. The effectiveness of drug therapy varies based on the patient population and the drug being prescribed, among other factors. Often, pharmaceuticals to thin the blood (anti-coagulants) are prescribed due to the increased risk of stroke for patients who also have Afib.
- *Implantable Devices.* Implantable devices, such as defibrillators and pacemakers, can be effective in reducing the symptoms of Afib episodes, but neither device is intended to treat Afib. Patients may continue to experience the adverse effects of Afib as well as some of the symptoms and complications, including dizziness, fatigue, palpitations and stroke because the Afib continues.
- *Catheter Ablation.* Catheter ablation is a procedure that is typically performed by an electrophysiologist. The ablations are made from the inside of the heart using a flexible catheter. The heart is reached via a blood vessel, most commonly through the femoral vein. In proportion to the prevalence of Afib, only a small number of catheter-based Afib treatments are performed each year in the United States.

We do not promote our products specifically for Afib treatment in the United States, except for the Isolator Synergy System, which may be promoted according to its FDA-approved indication for patients with persistent and long-standing persistent Afib undergoing certain open concomitant procedures. During elective open-heart surgical procedures, such as bypass or valve surgery, cardiothoracic surgeons use our ablation systems to treat patients with a pre-existing history of Afib. Surgeons use our products to perform cardiac procedures that may vary depending on the length of time a patient has been diagnosed with Afib and whether the patient's Afib is intermittent, known as paroxysmal, or more continuous (non-paroxysmal), which is typically further classified as persistent, long-standing persistent or permanent. Patients who have been diagnosed with Afib for a longer duration and have non-paroxysmal forms of Afib generally receive more extensive ablation procedures than patients who have been diagnosed with Afib for a shorter duration or who have paroxysmal Afib. Additionally, during an open-heart procedure, physicians may use our AtriClip system to occlude the left atrial appendage.

For those patients with Afib who do not require a concomitant open-heart surgical procedure, surgeons have used our products for minimally invasive Afib treatment procedures. These procedures have generally been performed through minimally invasive incisions without the need to place patients on a heart-lung bypass machine. We do not currently have any products with FDA-approved indications for the standalone treatment of Afib.

Certain physicians are combining various minimally invasive stand-alone epicardial ablation procedures (surgical ablation on the outside of the heart) with endocardial ablation and mapping techniques (catheter ablation from the inside of the heart). These combination procedures are often referred to as "hybrid" or "multi-disciplinary" approaches, in that both surgical ablation and catheter ablations are performed. Sometimes, both procedures are performed on the same day or in the same hospital stay, where other times they are performed days or weeks apart. Patient health condition, physician preference, hospital logistics and procedural room availability influence the decision whether to perform hybrid ablations in a single or a staged setting. Physicians are reporting that they are performing these procedures utilizing certain of our products to primarily treat patients who have non-paroxysmal forms of Afib.



## Business Strategy

We are passionately focused on reducing the global Afib epidemic and healing the lives of those affected. Our strategy is to expand the treatment options for patients who suffer from Afib or have a high risk of stroke through the continued development of our technologies and expansion of our product offerings, global commercial expansion and clinical science investments. The key elements of our strategy include:

***New Product Innovation.*** Our product development pipeline includes projects which extend and improve our existing products, as well as research and development projects for new technologies. We plan to continue to develop new and innovative products, including those that allow us to enter new market opportunities or expand our growth in existing markets.

***Invest in Clinical Science and Build Physician and Societal Relationships.*** We continue to invest in landmark clinical trials to validate the long-term results of procedures using our products and to support applications to regulatory agencies for expanded indications. We also make clinical research grants to support our product development efforts.

We have formed consulting relationships with cardiothoracic surgeons, cardiologists, electrophysiologists and thoracic surgeons who work with us to evaluate and develop our products. Additionally, we have formed advisory boards made up of key opinion leaders in multiple specialties to oversee our training and clinical programs. We are also building these relationships to provide insight regarding treatment trends, input on future product direction and education for providers involved in treating the disease.

We are partnering with leading surgical and cardiology societies to increase the awareness of Afib treatment options. In the past two years, both the Society for Thoracic Surgeons and the Heart Rhythm Society have released new guidelines on the surgical treatment of Afib in both open-heart and minimally-invasive settings.

***Provide Training and Education.*** We have recruited and trained sales and physician education professionals to effectively communicate to our customers the unique features and benefits of our technologies as they relate to their indications for use. Our highly trained professionals meet with physicians at institutions around the world to provide education and technical training on the features, benefits and safe-and-effective use of our products. With the approval of our Isolator Synergy System for the treatment of non-paroxysmal Afib, we instituted a program to train providers on the use of the Isolator Synergy System to treat persistent and long-standing persistent Afib in patients undergoing open-heart surgery. We believe this training and education program has increased awareness about the surgical treatment of Afib during open-heart procedures, and we will continue to make investments to serve our physician customers. As a result of the educational process, we believe that awareness of our technologies is growing and will result in the increased use of our products.

***Expand Adoption of Our Minimally Invasive Products.*** We believe that the catalysts for expanded adoption of our minimally invasive products include procedural advancements, such as the hybrid or multi-disciplinary procedure, and the publication of peer-reviewed articles, which we believe will help validate the successful, long-term use of our products for patients with Afib. We believe that ongoing research activities, including prospective clinical trials, new procedural techniques and anticipated presentations and publications will create an increased demand for our minimally invasive products.

***Evaluate Acquisition Opportunities.*** We expect to continue to be opportunistic with respect to acquisitions which make strategic and financial sense.

## Clinical Trials

In the United States, a significant risk device requires the prior submission of an application for an Investigational Device Exemption (IDE) to FDA for approval before initiating a clinical trial. Clinical trials are required to support a pre-market approval (PMA) and are sometimes required for 510(k) clearance. Some trials require a feasibility study followed by a pivotal trial. An IDE supplement is a means of obtaining approval to initiate a pivotal trial following the conclusion of a feasibility trial. We are conducting several clinical trials to validate the long-term results of procedures using our products and to support applications to regulatory agencies for expanded indications. In addition, we also conduct various studies to gather clinical data regarding our products. Key trials and studies are:

***CONVERGE.*** We are conducting the CONVERGE IDE clinical trial to evaluate the safety and efficacy of the EPi-Sense Guided Coagulation System with VisiTrax technology to treat symptomatic persistent Afib patients who are refractory or intolerant to at least one Class I and/or III anti-arrhythmic drug. The trial provides for enrollment of up to 153 patients at 27 domestic medical centers and three international medical centers. Enrollment began in 2014 and was completed in August 2018. The study protocol requires patient follow-up for twelve months post procedure for the primary effectiveness endpoint assessment and long-term follow-up through five years.



**ATLAS.** The ATLAS study is a non-IDE randomized pilot study evaluating outcomes of patients with risk factors for developing postoperative Afib as well as risk of bleeding on oral anticoagulation. There are two types of patients subject to this study: those with a postoperative Afib diagnosis and receiving prophylactic exclusion of the left atrial appendage with the AtriClip device concomitant to cardiac surgery and those with a postoperative Afib diagnosis who are medically managed. Enrollment began in February 2016 and ended in March 2018. We are analyzing preliminary data obtained from this trial.

**FROST.** We are conducting a cryo nerve block study, which is a non-IDE randomized pilot study evaluating intraoperative intercostal cryoanalgesia. The study involves treatment arm patients who receive intercostal cryoanalgesia in conjunction with standard post-operative pain management and control arm patients who receive standard post-operative pain management only. The study provides for enrollment of up to 100 patients at five medical centers. Enrollment began in June 2016 and remains ongoing.

**DEEP AF Pivotal Study.** The DEEP AF IDE pivotal trial evaluates the safety and efficacy of the Isolator Synergy System when used in a staged approach where a minimally invasive surgical ablation procedure is first performed and the patient undergoes the intracardiac catheter procedure approximately 90-120 days later. The trial was paused during 2016-2017 due to our work to mitigate the risk related to esophageal injury during the procedure. We are committed to patient safety, and we worked collaboratively with FDA and obtained approval to resume enrollment in the trial in 2018. We currently have FDA approval to enroll 40 patients, and we plan to seek approval of additional patients pending FDA's review of additional data.

**CEASE AF.** We are also pursuing a non-IDE trial in Europe to compare staged hybrid ablation treatment (minimally invasive surgical ablation procedure is first performed and the patient undergoes the intracardiac catheter procedure approximately 91-180 days later) versus catheter ablation alone. We expect the study to have an enrollment of approximately 210 patients at twelve sites. Enrollment began in November 2015 and remains ongoing.

**ICE-AFIB.** The ICE-AFIB clinical trial is designed to study the safety and efficacy of the cryoICE<sup>®</sup> system for persistent and long-standing persistent Afib treatment during concomitant on-pump cardiac surgery. The trial provides for enrollment of up to 150 patients at up to 20 sites in the United States. We received IDE approval from FDA to proceed with the ICE-AFIB trial in November 2018. Enrollment is projected to start in the first quarter of 2019.

## **Sales, Marketing and Medical Education**

Our global sales and marketing efforts focus on educating physicians about our unique technologies and their technical benefits. We only promote our products for uses described in their labeling as cleared or approved by the relevant regulatory agencies. We train our sales force on the use of our products to the extent the products are cleared or approved.

Our sales team in the United States has approximately 140 employees supporting approximately 52 sales territories. We select our sales personnel based on their expertise, sales experience and reputation in the medical device industry, and their knowledge of cardiac surgery procedures and technologies.

We market and sell our products in selected markets outside of the United States through a combination of independent distributors and direct sales personnel. Our international sales team includes sales representatives focused on our direct markets, such as Germany, France, the United Kingdom and the Benelux region. We also maintain a network of distributors in Asia, South America and Canada, as well as certain countries in Europe, who market and sell our products. We continue to evaluate opportunities for further expansion into markets outside of the United States.

## **Competition**

Our industry is competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Most of our competitors have greater financial and human resources than we do and have established reputations with our target customers, as well as worldwide distribution channels that are more established and developed than ours. Our primary competitor is Medtronic, plc, who provides similar products to ours that have been adopted by physicians for the treatment of Afib and related conditions. Several other companies offer intracardiac catheter devices that are commonly used by electrophysiologists to treat Afib. These catheter devices are FDA-approved to treat the paroxysmal form of Afib, but they are not FDA indicated to treat persistent or long-standing persistent Afib. AtriCure's Isolator Synergy System is the only medical device that is FDA approved to treat Afib in a surgical setting, and the only medical device approved to treat persistent or long-standing persistent Afib in a concomitant setting. AtriCure is monitoring other companies who are conducting clinical trials that may support FDA approval of their devices to treat persistent and long-standing persistent Afib. We believe that our products compare favorably against competing products during both open-heart and minimally invasive procedures, and that our products compare favorably to intracardiac catheter devices when used to treat non-paroxysmal forms of Afib. Further, we believe our AtriClip system is an ideal medical device indicated for occlusion of the LAA.

To compete effectively, we strive to demonstrate that our products are an attractive alternative to other treatments by differentiating our products on the basis of safety, efficacy, performance, ease of use, reputation, service and price. In addition, we invest heavily in training and education to ensure that our customers understand available devices, techniques, and approaches for

optimal treatment. We have encountered and expect to continue to encounter potential customers who prefer products offered by our competitors.

### **Third-Party Reimbursement**

Payment for patient care in the United States is generally made by third-party payors. These payors include private insurers and government insurance programs, such as Medicare and Medicaid. The Medicare program, the largest single payor in the United States, is a federal health benefit program administered by the Centers for Medicare and Medicaid Services (CMS) and covers certain medical care items and services for eligible beneficiaries, such as individuals over 65 years old, as well as chronically disabled individuals. Because Medicare beneficiaries comprise a large percentage of the populations for which our products are used, and private insurers may follow the coverage and payment policies for Medicare, Medicare's coding, coverage and payment policies for cardiothoracic surgical procedures are significant to our business.

Medicare's Part A program pays hospitals for inpatient services, such as cardiothoracic surgery, under the Inpatient Prospective Payment System, which provides a predetermined payment based on the patient's discharge diagnoses and surgical procedure(s). Discharge diagnoses are grouped into Medicare Severity Diagnosis Related Groupings (MS-DRG). There are several cardiac surgery MS-DRGs associated with the surgical treatment of Afib, with and without a concomitant open-heart procedure. When an ablation device and/or LAA exclusion device (LAAM) is used during a concomitant open-heart procedure, Medicare's hospital reimbursement is based upon the patient's primary structural heart surgical procedure. Therefore, any additional procedure concomitant to the primary procedure would not receive incremental hospital payment. In contrast, sole therapy minimally invasive ablation or surgical LAAM procedures typically are reimbursed under a general cardiac surgery MS-DRG. We believe hospital reimbursement rates for sole therapy and concomitant therapy cardiac surgical ablation or LAAM are adequate to cover the cost of our products even when multiple procedures are performed.

Physicians are reimbursed for their services separately under the Medicare Part B physician fee schedule. When performing a surgical cardiac ablation with and without a concomitant open-heart procedure, surgeons report Current Procedural Terminology (CPT) codes to receive a professional fee payment. Multiple CPT codes may be reported by a physician during a procedure if multiple procedures are performed. There are category one CPT codes for both concomitant and standalone surgical Afib treatment. At this time, there are no category one CPT codes for the physician to report surgical LAAM. However, some providers utilize unlisted CPT codes to obtain reimbursement in these situations.

In addition to the Medicare program, many private payors look to CMS policies as a guideline in setting their coverage policies and payment amounts. The current coverage policies of these private payors may differ from the Medicare program, and payment rates may be higher, lower, or the same as the Medicare program. In some cases, certain private payors adopt negative coverage policies with respect to therapies involving our products. We engage a third-party reimbursement consultant that provides support to our customers in the event of a coverage denial.

Outside of the United States, third-party reimbursement varies widely by geography and by the type of therapy in which our devices are used. For example, even though a new medical device may have been approved for commercial distribution, we may find limited demand for the device until coverage and sufficient reimbursement levels have been obtained from governmental and private third-party payors. In addition, some private third-party payors require that certain procedures or the use of certain products be authorized in advance as a condition of reimbursement. In some countries, cost containment initiatives and health care reforms include initiatives like governmental reviews of reimbursement rate benchmarks, which may significantly reduce reimbursement for procedures using our medical devices or deny coverage for those procedures altogether. We are actively working to pursue market access initiatives in certain geographies, which includes applying for new reimbursement for therapies in which our devices are being used, or pursuing specific reimbursement for utilization of our devices.

### **Government Regulation**

Our products are medical devices and are subject to regulation in the United States by FDA and other federal agencies, and by comparable authorities in other countries. All of our products marketed in the United States have been cleared by FDA pursuant to section 510(k) of the Food, Drug & Cosmetic Act (FDCA). In addition, our Isolator Synergy System has received premarket approval from FDA for the treatment of patients with persistent and long-standing persistent Afib concomitant to another open-heart surgical procedure such as coronary artery bypass grafting or cardiac valve replacement or repair.

FDA regulations govern nearly all of the activities that we perform, or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses. The activities that FDA regulates include the following:

- product design, development and manufacture;
- product safety, testing, labeling and storage;
- pre-clinical testing in animals and in the laboratory;
- clinical investigations in humans;
- premarket clearance or approval;
- record keeping and document retention procedures;
- advertising and promotion;
- the import and export of products;
- product marketing, sales and distribution;
- post-marketing surveillance and medical device reporting, including reporting of deaths, serious injuries, device malfunctions or other adverse events; and
- corrective actions, removals and recalls.

Unless an exemption applies, most medical devices distributed commercially in the United States require either 510(k) clearance or PMA from FDA.

**510(k) Clearance Pathway.** To obtain 510(k) clearance, we must submit a notification to FDA demonstrating that our proposed device is substantially equivalent to a predicate device, i.e., a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976 for which FDA has not yet called for the submission of a PMA. Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, or a change in its design or manufacture that could significantly affect the safety or effectiveness of the device, requires a new 510(k) clearance or approval of a PMA. FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but FDA may review any manufacturer's decision.

**Premarket Approval Pathway.** A PMA must be submitted to FDA if the device cannot be cleared through the 510(k) process and is not otherwise exempt. A PMA must be supported by extensive data, including but not limited to technical, preclinical, clinical, manufacturing and labeling, to demonstrate the safety and effectiveness of the device for its intended use.

After a PMA is submitted and FDA has determined that the application is sufficiently complete to permit a substantive review, FDA will accept the application for filing. During the review period, FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside FDA may be convened to review and evaluate the application and provide recommendations to FDA as to the approvability of the device. In addition, FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. Any approvals we receive may be limited in scope or may be contingent upon further post-approval study commitments or other conditions. A new PMA or PMA supplement is required for significant modification to a PMA-approved device, including indicated use, manufacturing process, labeling and design of a device that is approved through the premarket approval process. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel.

**Clinical Trials.** Clinical trials are required to support a PMA and are sometimes required for 510(k) clearance. Clinical trials are subject to extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an Institutional Review Board (IRB) for the relevant clinical trial sites and must comply with FDA regulations, including, but not limited to, those relating to current good clinical practices. We are also required to obtain the written informed consent of patients in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. Similarly, in Europe, the clinical study must be approved by a local ethics committee and, in some cases including studies with high-risk devices, by the ministry of health in the applicable country.

**Educational Grants.** FDA regulates manufacturers of medical devices and, in particular, the promotion of medical devices by manufacturers. FDA does not regulate the practice of medicine or the conduct or content of medical education conducted by third parties. Manufacturers may provide financial support for such third-party medical education programs in the form of educational grants intended to offset the cost of such programs. If the manufacturer controls or unduly influences the content of such programs, FDA considers those programs to be promotional activities by the manufacturer and thus subject to FDA regulation including promotional restrictions. We seek to ensure that the activities we support pursuant to our educational grants program are in accordance with FDA criteria for independent educational activities. However, we cannot provide an assurance that FDA or other government authorities would view the programs we have supported as being independent.

***Pervasive and Continuing Regulation.*** There are numerous regulatory requirements that apply after a product is cleared or approved. These include:

- FDA's Quality System Regulation (QSR) which requires manufacturers, including third-party manufacturers, 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 false or misleading promotion or the promotion of products for uncleared, unapproved or off-label use or indication;
- requirements to obtain clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use;
- medical device reporting regulations which require that manufacturers comply with reporting requirements of FDA and report 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;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and
- requirements to issue notices of correction or removal, or conduct market withdrawals or recalls where quality or other issues arise.

Under FDA's Medical Device Reporting regulation, we must submit a Medical Device Report (MDR) to FDA within 30 days whenever we receive information that reasonably suggests that one of our products may have caused or contributed to a death or serious injury, or that one of our products malfunctioned in a manner which, if the malfunction were to recur, could cause or contribute to a death or serious injury. Our products are often used to treat very ill patients in highly complex surgeries of which only a small portion of the surgery may involve our products, and it is frequently difficult to determine whether our products caused or contributed to a patient injury or death that occurred during or after the procedure. If we are able to determine that our product caused or potentially contributed to a death or serious injury in the particular case, or that a malfunction of the type reported could cause death or serious injury, we submit an MDR on the case. Other incidents, including serious injuries or deaths, which occurred during procedures utilizing our products and that are not the subject of MDRs, may occur either because we are not aware of those incidents or because our investigation determined that the incident did not involve a malfunction of an AtriCure device and/or that an AtriCure device did not cause or contribute to a serious injury or death.

In addition to FDA regulation, the advertising and promotion of medical devices are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, some promotional activities for FDA-regulated products have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the Federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

We have registered with FDA as a medical device manufacturer and listed our devices. FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by FDA and our Notified Body and other Regulatory Authorities to determine our compliance with the QSR, the European Union's Medical Device Directive and other regulations. Such inspections may include the manufacturing facilities of our suppliers.

***Fraud, Abuse and False Claims.*** We are directly and indirectly subject to various federal and state laws governing our relationship with healthcare providers. In particular, the Anti-Kickback Statute is a criminal law that applies broadly and prohibits the knowing and willful payment of remuneration to induce or reward patient referrals or the generation of business involving any item or service payable by a Federal health care program.

The Federal False Claims Act (FCA) imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the United States government. Damages under the FCA consist of the imposition of fines and penalties, and can be significant. The FCA also allows a private individual or entity with knowledge of past or present fraud against the federal government to sue on behalf of the government to recover the civil penalties and treble damages. The U.S. Department of Justice (DOJ), on behalf of the government, has previously alleged that the marketing and promotional practices of pharmaceutical and medical device manufacturers that included the off-label promotion of products or the payment of prohibited kickbacks to doctors violated the FCA by causing or contributing to the submission of improper claims to federal and state healthcare programs such as Medicare and Medicaid. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

The Advanced Medical Technology Association (AdvaMed) is one of the primary voluntary United States trade associations for medical device manufacturers. This association has established guidelines and protocols for medical device manufacturers in their relationships with healthcare professionals on matters including research and development, product training and education, grants and

charitable contributions, support of third-party educational conferences and consulting arrangements. Adoption of the AdvaMed Code of Ethics for Interactions with Healthcare Professionals (the “AdvaMed Code”) by a medical device manufacturer is voluntary, and while the Office of the Inspector General and other federal and state healthcare regulatory agencies encourage its adoption and may look to the AdvaMed Code, they do not view adoption of the AdvaMed Code as proof of compliance with applicable laws. We have adopted the AdvaMed Code and incorporated its principles in our standard operating procedures, sales force training programs, and relationships with medical professionals. In addition, we have conducted training sessions for employees on these principles.

**Regulation Outside of the United States.** Sales of medical devices outside of the United States are subject to foreign governmental regulations which vary substantially from country to country. The time required to obtain certification or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval and the requirements may be different.

In the European Union, various directives and voluntary standards regulate the design, manufacture and labeling of medical devices. Devices may only be placed on the market in the European Union if they comply with the essential requirements of a relevant directive and bear the CE mark. Manufacturers must demonstrate that their devices comply with the relevant essential requirements through a conformity assessment procedure. The method for assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a notified body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment will include a review of documentation relating to the device and may consist of an audit of the manufacturer’s quality system and specific testing of the manufacturer’s device. Successful completion of a conformity assessment procedure allows a manufacturer to issue a declaration of conformity with the requirements of the relevant directive and affix the CE mark to the device. Devices that bear the CE mark may be commercially distributed throughout the member states of the European Union and other countries that comply with or mirror the medical device directives. A notified body has granted us a certificate of compliance with the International Organization for Standardization, (ISO) 13485:2016 Quality Management System. Compliance with this standard establishes the presumption that our quality system conforms with the essential requirements or the relevant directive. We have successfully completed the conformity assessment procedure and affixed the CE mark to our Isolator Synergy clamps, Isolator Synergy pens, Coolrail® linear pen, cryosurgery devices, certain products of the AtriClip LAA Exclusion System, COBRA® Fusion Ablation System, Numeris System and the EPI-Sense® Guided Coagulation System with VisiTrax® technology.

## **Intellectual Property**

Protection of our intellectual property is a priority for our business, and we rely on a combination of patent, copyright, trademark and trade secret laws to protect our interests. Our ability to protect and use our intellectual property rights in the continued development and commercialization of our technologies and products, operate without infringing the proprietary rights of others, and prevent others from infringing our proprietary rights is important to our continued success. We will be able to protect our products and technologies from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents, trademarks or copyrights, or are effectively maintained as trade secrets, know-how or other proprietary information.

We hold numerous issued United States and international patents. We also have multiple pending United States and international patent applications. We seek patent protection relating to technologies and products we develop in both the United States and in selected foreign countries. While we own much of our intellectual property, including patents, patent applications, trademarks, trade secrets, know-how and proprietary information, we also license patents and related technology of importance to the commercialization of our products. To continue developing and commercializing our current and future products, we may license intellectual property from commercial or academic entities to obtain the rights to technology that is required for our research, development and commercialization activities.

All of our employees and technical consultants are required to execute confidentiality agreements in connection with their employment and consulting relationships with us. We also generally require them to agree to disclose and assign to us all inventions conceived in connection with their relationship with us. We devote significant resources to obtaining patents and other intellectual property and protecting our other proprietary information. If valid and enforceable, these patents may give us a means of blocking competitors from using infringing technology to compete directly with our products. We also have proprietary information that may not be patentable. With respect to proprietary information that is not patentable, we have chosen to rely on trade secret protection and confidentiality agreements to protect our interests.

## **Manufacturing**

We assemble, inspect, test and package the majority of our products at our facility in Ohio, and our products are sterilized by third parties. Purchased components are generally sourced from a single supplier but alternatives to these suppliers are available. However, some products which are critical components of our RF ablation lines, such as our RF generators, Fusion and EPI-Sense products, have relatively few alternative sources of supply available.



Order quantities and lead times for components purchased from outside suppliers are based on our forecasts derived from historical demand and anticipated future demand. Lead times may vary significantly depending on the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the components and subassemblies. To date, we have not experienced significant delays in obtaining any of our components.

We regularly audit our suppliers for compliance with our quality system requirements, the QSR and/or applicable ISO standards. We are an FDA-registered medical device manufacturer and certified to ISO 13485:2016. In addition, we have successfully participated in the Medical Device Single Audit Program (MDSAP) and have been certified accordingly. The MDSAP program is recognized in Australia, Brazil, Canada, Europe, Japan and the United States.

We are subject to numerous federal, state and local laws relating to such matters as laboratory practices, the experimental use of animals, the use and disposal of hazardous or potentially hazardous substances, safe working conditions, manufacturing practices, environmental protection and fire hazard control.

### **Consulting Relationships**

We have developed consulting relationships with scientists and physicians throughout the world to support our research and development, clinical and training and education programs. We work closely with these thought leaders to understand unmet needs and emerging applications for the treatment of Afib.

Our physician consulting agreements are intended to satisfy the requirements of the personal services “Safe Harbor” regulation as well as the AdvaMed and MedTech Europe Codes. As such, they provide for payment of a fair market value fee only for legitimate services rendered to us. We do not expect or require the consultant to utilize or promote our products, and consultants are required to disclose their relationship with us as appropriate, such as when publishing an article in which one of our products is discussed. Amounts paid to physicians in the United States are disclosed by us in annual reports submitted to CMS under the federal “Open Payments” law. Amounts paid to physicians in certain other countries are also disclosed by us in reports submitted to various governmental agencies in those countries, in accordance with the laws of the jurisdictions where those physicians reside or practice, or where the payments are made.

### **Employees**

We had approximately 620 full-time employees as of January 31, 2019. None of the employees were represented by a labor union or covered by a collective bargaining agreement. We have never experienced any employment-related work stoppages and consider our employee relations to be in good standing.

### **Available Information**

Our principal executive offices are located at 7555 Innovation Way, Mason, Ohio and our telephone number is 513-755-4100. We are subject to the reporting requirements under the Securities Exchange Act of 1934. Consequently, we are required to file reports and information with the Securities and Exchange Commission (SEC) including reports on the following forms: Form 10-K, Form 10-Q, Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. These reports and other information concerning us may be accessed through the SEC’s website at <http://www.sec.gov>. You may also find, free of charge, on our website at <http://www.atricure.com>, electronic copies of our Form 10-Ks, Form 10-Qs, Form 8-Ks, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. Such filings are placed on our website as soon as reasonably practicable after they are filed or furnished, as the case may be, with the SEC. Our charters for our Audit, Compensation, Nominating and Corporate Governance, Strategy and Compliance, Quality and Risk Committees and our Code of Conduct are available on our website. In the event that we grant a waiver under our Code of Conduct to any of our officers or directors or make any material amendments to the Code of Conduct, we will publish it on our website within four business days. Information on our website is not deemed to be a part of this Form 10-K.

## **ITEM 1A. RISK FACTORS**

### **Risks Relating To Our Business and Industry**

**We rely on our ablation, ablation-related and left atrial appendage management products as our primary sources of revenue. If we are not successful in selling these products our operating results will be harmed.**

Our ablation and ablation-related products, along with our left atrial appendage management products, generate a large majority of our revenue. We expect that sales of these products will continue to account for a majority of our revenue for the foreseeable future and that our future revenue will depend on the increasing acceptance by the medical community of our products as a standard surgical treatment of Afib. We may not be able to maintain or increase market acceptance of our products for a number of additional reasons, including those set forth elsewhere in this “Risk Factors” section. Since we believe that physicians are using our ablation and ablation-related products largely for the surgical treatment of Afib, if physicians do not use our products to treat Afib, we would lose substantially all of our revenue.

**If our products do not achieve widespread market acceptance in the United States, our operating results will be harmed, and we may not achieve or sustain profitability.**

Our success will depend, in large part, on the medical community's acceptance of our principal products in the United States, which is the largest revenue market in the world for medical devices. The U.S. medical community's acceptance of our products will depend upon our ability to demonstrate the safety and efficacy, advantages, long-term clinical performance and cost-effectiveness of our products. In addition, acceptance of products for the treatment of Afib is dependent upon, among other factors, the level of screening for Afib general awareness and education of the medical community about the surgical treatment of Afib and the existence, effectiveness and safety of our products. Market acceptance and adoption of our products for the treatment of Afib also depends on the level of health insurer (including Medicare) reimbursement to physicians and hospitals for the use of our products.

We cannot predict whether the U.S. medical community will accept our products or, if accepted, the extent of their use. Negative publicity resulting from incidents involving our products, other products related to those we sell or products or procedures subject to our clinical trials could have a significant adverse effect on the overall acceptance of our products. If we encounter difficulties growing the market for our products in the U.S., we may not be able to increase our revenue enough to achieve or sustain profitability, and our business and operating results will be seriously harmed.

**Competition from existing and new products and procedures may decrease our market share and may cause our revenue to decline, and could adversely affect our operating results**

The medical device industry, including the market for the treatment of Afib, is highly competitive, subject to rapid technological change and significantly affected by new product introductions and promotional activities of its participants. There is no assurance that our products will compete effectively against drugs, catheter-based ablation, implantable devices, other ablation systems, other products or techniques to occlude the left atrial appendage, or other surgical Afib treatments, which may be more well-established among physicians and hospitals. Our products may become obsolete prior to the end of their anticipated useful lives or we may introduce new products or next-generation products prior to the end of the useful life of a prior generation, either of which may require us to dispose of existing inventory and related capital equipment and/or write off their value or accelerate their depreciation. In addition, such other products or techniques may be sold or implemented at lower prices. Due to the size of the Afib and LAA exclusion markets, and the unmet need for an Afib cure, we anticipate that new or existing competitors may develop competing products, procedures and/or clinical solutions. There are few barriers to prevent new entrants or existing competitors from developing products to compete directly with ours. Companies also compete with us to attract qualified scientific and technical personnel as well as funding. Most of our competitors and potential competitors have greater financial, manufacturing, marketing and research and development capabilities than we have and may obtain FDA approval or clearance for their products before we do. The introduction of new products, procedures or clinical solutions, or of our competitors obtaining FDA approvals or clearances, may result in price reductions, reduced margins, loss of market share, or may render our products obsolete, which could adversely affect our revenue and future profitability.

**Worldwide economic conditions may reduce demand for procedures using our products or otherwise result in adverse implications on our business, operating results and financial condition.**

General worldwide economic conditions may deteriorate due to the effects of, among other developments, general credit market crises, collateral effects on the finance and banking industries, concerns about inflation, slower economic activity which may be caused by many factors, including natural disasters or other catastrophes, decreased consumer confidence, reduced corporate profits and capital spending, adverse business conditions and liquidity concerns. We are unable to predict the extent to which current or future worldwide economic conditions may impact our business. Specifically, because many procedures using our products are elective, they can be deferred by patients. In addition, patients may not be as willing under current or future economic conditions to take time off from work or spend their money on deductibles and co-payments often required in connection with the procedures that use our products.

Beyond patient demand, any current or future deterioration in worldwide economic conditions, including in particular their effects on the credit and capital markets, may have other adverse implications for our business. For example, our customers' ability to borrow money from their existing lenders or to obtain credit from other sources to purchase our products may be impaired, resulting in a decrease in sales. Although we maintain allowances for estimated losses resulting from the inability of our customers to make required payments, we cannot guarantee that we will accurately predict the loss rates we will experience, especially given any continuing turmoil in the worldwide economy. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in our receivable collections and additional allowances may be required, which could adversely affect our operating results. Further, given the economic and political challenges facing Eurozone countries, concerns have been raised regarding the stability and suitability of the Euro as a single currency. The failure of the Euro as a single currency could adversely affect our operating results.

**Healthcare costs have risen significantly over the past decade. There have been and may continue to be proposals by legislators, regulators and third-party payors to keep, contain or reduce healthcare costs.**

The continuing efforts of governments, insurance companies and other payors of healthcare costs to contain or reduce these costs, combined with closer scrutiny of such costs, could lead to patients being unable to obtain approval for payment from these

third-party payors. The cost containment measures that healthcare providers are instituting both in the U.S. and internationally could harm our business. Some healthcare providers in the U.S. have adopted or are considering a managed care system in which the providers contract to provide comprehensive healthcare for a fixed cost per person. Healthcare providers may attempt to control costs by authorizing fewer elective surgical procedures or by requiring the use of the least expensive devices possible, which could adversely affect the demand for our products or the price at which we can sell our products. Some healthcare providers have sought to consolidate and create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide products and services has become and will continue to become more intense. This has resulted and likely will continue to result in greater pricing pressures and the exclusion of certain suppliers from important marketing segments.

**We face significant uncertainty in the industry due to government healthcare reform.**

The U.S. Patient Protection and Affordable Care Act (PPACA), as amended, and other healthcare reform have a significant impact on our business. The impact of the PPACA on the healthcare industry is extensive and includes, among other things, the federal government assuming a larger role in the healthcare system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits. The PPACA impacted our business by requiring an excise tax on all U.S. medical device sales beginning in January 2013. In December 2015, the U.S. government approved the suspension of the excise tax on medical device sales beginning January 1, 2016 through December 31, 2017. Then, in January 2018, the U.S. government approved an additional suspension of the excise tax on medical device sales from January 1, 2018 to December 31, 2019. In July 2018, the House of Representatives voted to repeal the excise tax, and the bill to repeal the excise tax is awaiting a Senate vote. When in effect, the increased tax burden from the PPACA impacts our results of operations and cash flows.

It is possible that legislation will be introduced and passed by Congress repealing the PPACA in whole or in part and signed into law. Because of the continued uncertainty about the implementation or continued effectiveness of the PPACA, including the potential for further legal challenges or repeal of that legislation, we cannot quantify or predict with any certainty the likely impact of the PPACA or its repeal on our business model, prospects, financial condition or results of operations.

Any healthcare reforms enacted in the future may, like the PPACA, be phased in over a number of years but, if enacted, could reduce our revenue, increase our costs or require us to revise the ways in which we conduct business or put us at risk for loss of business. In addition, our results of operations, financial position and cash flows could be materially adversely affected by changes under the PPACA and changes under any federal or state legislation adopted in the future.

**We sell our products outside of the United States, and we are subject to various regulatory and other risks relating to international operations, which could harm our revenue and profitability.**

Doing business outside of the United States exposes us to risks distinct from those we face in our domestic operations. For example, our operations outside of the United States are subject to different regulatory requirements in each jurisdiction where we operate or have sales. Our failure, or the failure of our distributors, to comply with current or future foreign regulatory requirements, or the assertion by foreign authorities that we or our distributors have failed to comply, could result in adverse consequences, including enforcement actions, fines and penalties, recalls, cessation of sales, civil and criminal prosecution, and the consequences could be disproportionate to the relative contribution of our international operations to our results of operations. Moreover, if political or economic conditions deteriorate in these countries, or if any of these countries are affected by a natural disaster or other catastrophe, our ability to conduct our international operations or collect on international accounts receivable could be limited and our costs could be increased, which could negatively affect our operating results. Engaging in business outside of the United States inherently involves a number of other difficulties and risks, including, but not limited to:

- export restrictions and controls relating to technology;
- pricing pressure that we may experience internationally;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- consequences arising from natural disasters and other similar catastrophes, such as hurricanes, tornados, earthquakes, floods and tsunamis;
- potentially adverse tax consequences, tariffs and other trade barriers;
- the need to hire additional personnel to promote our products outside of the United States;
- international terrorism and anti-American sentiment;
- fluctuations in exchange rates for future sales denominated in foreign currency, which represent a majority of our sales outside of the United States; and
- difficulty in obtaining and enforcing intellectual property rights.

In addition, our business practices in foreign countries must comply with U.S. laws, including the Foreign Corrupt Practices Act (FCPA). We have a compliance program in place designed to reduce the likelihood of potential violations of the FCPA and other U.S.

and foreign anti-bribery and anti-corruption laws. If violations were to occur, they could subject us to fines and other penalties as well as increased compliance costs.

Our exposure to each of these risks may increase our costs and require significant management attention. We cannot assure you that one or more of these factors will not harm our business.

**Compliance with developing European Union medical device regulation may limit our ability to maintain sales of our products in European markets or introduce new products into European markets.**

Many foreign countries which we market or may market our products have regulatory bodies and restrictions similar to those of FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance and the requirements may differ. In particular, marketing of medical devices in the European Union (EU) is subject to compliance with the Medical Device Directive 93/92/EEC (MDD). A medical device may be placed on the market within the EU only if it conforms to certain “essential requirements” and bears the CE Mark. The most fundamental and essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the essential performance intended by the manufacturer and be designed, manufactured and packaged in a suitable manner.

Manufacturers must demonstrate that their devices conform to the relevant essential requirements through a conformity assessment procedure. The nature of the assessment depends upon the classification of the device. The classification rules are mainly based on three criteria: the length of time the device is in contact with the body, the degree of invasiveness and the extent to which the device affects the anatomy. Conformity assessment procedures for all but the lowest risk classification of device involve a notified body. Notified bodies are often private entities and are authorized or licensed to perform such assessments by government authorities. Manufacturers usually have some flexibility to select a notified body for conformity assessment procedures for a particular class of device and to reflect their circumstances, e.g., the likelihood that the manufacturer will make frequent modifications to its products. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Notified bodies also may review the manufacturer’s quality systems. If satisfied that the product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which allows the general commercializing of a product in the EU. The product can also be subjected to local registration requirements depending on the country. We maintain CE Marking on all of our products that require such markings as well as local registrations as required.

In May 2017, the EU adopted a new Medical Device Regulation (EU) 2017/745 (MDR), which will repeal and replace the MDD with effect from May 26, 2020. The MDR clearly envisages, among other things, stricter controls of medical devices, including strengthening of the conformity assessment procedures, increased expectations with respect to clinical data for devices and pre-market regulatory review of high-risk devices. The MDR also envisages greater control over notified bodies and their standards, increased transparency, more robust device vigilance requirements and clarification of the rules for clinical investigations. Under transitional provisions, medical devices with notified body certificates issued under the MDD prior to May 26, 2020 may continue to be placed on the market for the remaining validity of the certificate, until May 27, 2024 at the latest. After the expiry of any applicable transitional period, only devices that have been CE marked under the MDR may be placed on the market in the EU. If we fail to comply with the new MDR, we may not be able to continue to sell existing products in the EU or develop new products for sale in the EU, either of which could materially harm our results of operations and financial condition.

**Our quarterly financial results are likely to fluctuate significantly because our sales prospects are uncertain.**

Due to current worldwide economic conditions, natural disasters and other factors discussed in this “Risk Factors” section which may impact our sales results, our quarterly operating results are difficult to predict and may fluctuate significantly from quarter to quarter or from prior year to current year periods. These fluctuations may also affect our annual operating results and may cause those results to fluctuate unexpectedly from year to year.

**Surgeons may not commit enough time to sufficiently learn our products, and restrictions in our ability to train surgeons in the use of our products could reduce the market acceptance of our products and in turn could reduce our revenue or result in injuries to patients or other adverse events that could possibly lead to litigation that could harm us.**

It is critical to the success of our sales efforts to ensure that there are a sufficient number of surgeons familiar with, trained on and proficient in the use of our products. In order for surgeons to learn to use our products, they must attend structured training sessions in order to familiarize themselves with the products, and they must be committed to learning the technology. Further, surgeons must utilize the technology on a regular basis to ensure they maintain the skill set necessary to use the products. Continued market acceptance could be delayed by lack of surgeon willingness to attend training sessions, by the time required to complete this training or by state or institutional restrictions on our ability to provide training.

While we train providers in the safe and effective use of our products, we do not train them to use any of our products specifically to treat Afib unless the product is FDA-approved specifically for the treatment of Afib. Our Isolator Synergy System is approved for the treatment of persistent and long-standing persistent forms of Afib concomitant to open-heart bypass graft or valve



replacement surgery. The procedure using our Isolator Synergy System in this manner is known as the MAZE IV procedure. Following FDA approval, we instituted a program to train all new and existing users of the Isolator Synergy System in the MAZE IV procedure. We also make available training on the safe and effective use of our other products consistent with their FDA approved or cleared indications. We cannot assure that we will be able to maintain a consistent level of funding for these training programs or a sufficient number of surgeons will become aware of training programs. An inability to train a sufficient number of surgeons to generate adequate demand for our products could have a material adverse impact on our financial condition.

**Our marketing strategy is dependent on collaboration with physician “thought leaders”.**

Our research and development efforts and our marketing strategy depend heavily on obtaining support, physician training assistance and collaboration from highly-regarded physicians at leading commercial and research hospitals, particularly in the U.S. and Europe. If we are unable to gain and/or maintain such support, training services and collaboration, or if the reputation or standing of these physicians is impaired or otherwise adversely affected, our ability to market our products and, as a result, our financial condition, results of operations and cash flow, could be materially and adversely affected.

**Unless and until we obtain additional FDA approval for our products, we will not be able to promote most of them to treat Afib or to prevent stroke, and our ability to maintain and grow our business could be harmed.**

Although our Isolator Synergy System received FDA approval for the treatment of some forms of Afib in certain procedures, we have not received FDA clearance or approval to promote our other products for the treatment of Afib or the prevention of stroke. See “Business—Government Regulation”. Unless and until we obtain FDA clearance or approval for the use of our products to treat Afib or prevent stroke, we, and others acting on our behalf, may not claim in the U.S. that our products are safe and effective for such uses or otherwise promote them for such uses. Similar restrictions exist outside of the U.S. There is no assurance that future clearances or approvals of our products will be granted or that current or future clearances or approvals will not be withdrawn. Failure to obtain a clearance or approval or loss of an existing clearance or approval, could hurt our ability to maintain and grow our business.

In order to obtain additional FDA approvals to promote our products for the treatment of Afib or reduction in stroke risk, we will need to demonstrate in clinical trials that our products are safe and effective for such use. Development of sufficient and appropriate clinical protocols to demonstrate quality, safety and efficacy may be required and we may not adequately develop such protocols to support approval. We cannot assure you that any of our clinical trials will be completed in a timely manner or successfully or that the results obtained will be acceptable to FDA. We, FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. In addition, if the results obtained from our clinical trials, any other clinical studies, or clinical or commercial experience indicate that any of our products are not safe or effective, or not as safe or effective as other treatment options, FDA may not approve our products for the treatment of Afib or reduction in stroke risk, and the adoption of the use of our products may suffer and our business would be harmed.

Our clinical trials are typically time consuming, expensive and the outcome uncertain. Delays in patient enrollment or failure of patients to consent or continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. Conducting successful clinical studies may require the enrollment of large numbers of clinical sites and patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites; and the ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products or they can obtain the treatment without participating in our trial.

**We may experience unfavorable publicity relating to our business and our industry. This publicity could have a negative impact on our ability to attract and retain customers, our sales, clinical studies involving our products, our reputation and our stock price.**

We may experience a negative impact on our business from newspaper articles or other media reports relating to, among other things, our compliance with FDA regulations for medical device reporting, adverse patient and clinical outcomes and concerns over disclosure of financial relationships between us and certain of our consultants who are involved with clinical studies and the publication of articles concerning our products. We believe that such publicity would potentially have a negative impact on our clinical studies, business, results of operations and financial condition or cause other adverse effects, including a decline in the price of our stock.



**We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for unapproved, or off-label, uses.**

Our business and future growth depend on the continued use of our products for the treatment of Afib or prevention of stroke. Unless the products are approved or cleared by FDA specifically for the treatment of Afib or prevention of stroke, we may not make claims about the safety or effectiveness of our products for such uses.

These limitations present a material risk that FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales, marketing and/or support activities, though designed to comply with all FDA requirements, constitute the promotion of our products for an unapproved use in violation of the FDCA. We also face the risk that FDA or other governmental authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities. Investigations concerning the promotion of unapproved uses and related issues, are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law, we may face significant fines and penalties and may be required to substantially change our sales, promotion, grant and educational activities. There is also a possibility that we could be enjoined from selling some or all of our products for any unapproved use. In addition, as a result of an enforcement action against us or our executive officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid.

**We are currently under investigation by the United States Department of Justice, and any adverse finding, allegation, or exercise of enforcement or regulatory discretion by the DOJ could materially and adversely affect our business, financial condition, or results of operations.**

As previously disclosed, on December 11, 2017, the Company received a Civil Investigative Demand (CID) from the U.S. Department of Justice (DOJ) stating that it is investigating the Company to determine whether the Company has violated the False Claims Act, relating to the promotion of certain medical devices related to the treatment of atrial fibrillation for off-label use and submitted or caused to be submitted false claims to certain federal and state health care programs for medically unnecessary healthcare services related to the treatment of Afib. The CID covers the period from January 2010 to December 2017 and requires the production of documents and answers to written interrogatories. The Company had no knowledge of the investigation prior to receipt of the CID. The Company maintains rigorous policies and procedures to promote compliance with the False Claims Act and other applicable regulatory requirements. The Company provided the DOJ with documents and answers to the written interrogatories and is cooperating with the investigation. However, the Company cannot predict when the investigation will be resolved, the outcome of the investigation or its potential impact on the Company. While the Company believes its practices are lawful, there can be no assurance that the DOJ's ongoing investigation or future exercise of its enforcement, regulatory, discretionary or other powers will not result in findings or alleged violations of federal laws that could lead to enforcement actions, proceedings or litigation and the imposition of damages, fines, penalties, restitution, other monetary liabilities, sanctions, settlements or changes to the Company's business practices or operations that could have a material adverse effect on the Company's business, financial condition or results of operations or eliminate altogether the Company's ability to operate its business or on terms substantially similar to those on which it currently operates.

**The use of products we sell may result in injuries or other adverse events that lead to product liability suits, which could be costly to our business or our customers' businesses.**

The use of products we sell may result in a variety of serious complications, including damage to the heart, internal bleeding, death or other adverse events, potentially leading to product liability claims. Serious complications are commonly encountered in connection with surgical procedures. If products we sell are defectively designed, manufactured or labeled, contain inadequate warnings, contain defective components, are misused or are associated with serious injuries or deaths, we may become subject to costly litigation by our customers or their patients. We carry product liability insurance that is limited in scope and amount and may not be adequate to fully protect us against product liability claims. We could be required to pay damages that exceed our insurance coverage. Any product liability claim, with or without merit, could result in an increase in our product insurance rates or our inability to secure coverage on reasonable terms, if at all. Even in the absence of a claim, our insurance rates may rise in the future. Any product liability claim, even a meritless or unsuccessful one, would be time-consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, withdrawal of clinical trial participants, injury to our reputation and loss of revenue. Any of these events could negatively affect our financial condition.

**Our intellectual property rights may not provide meaningful commercial protection for our products, which could enable third parties to use our technology or methods, or very similar technology or methods, and could reduce our ability to compete.**

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our patent applications may not issue as patents at all or in a form that will be advantageous to us. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. Although

we have taken steps to protect our intellectual property and proprietary technology, we cannot assure you that third parties will not be able to design around our patents or, if they do infringe upon our technology, that we will be successful in or will have sufficient resources to pursue a claim of infringement against those third parties. We believe that third parties may have developed or are developing products that could infringe upon our patent rights. Any pursuit of an infringement claim by us may involve substantial expense or diversion of management attention. In addition, although we have generally entered into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, investigators and advisors, such agreements may be breached, may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. Additionally, as is common in the medical device industry, some of these individuals were previously employed at other medical equipment or biotechnology companies, including our competitors. Although no claims are currently pending against us, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers.

The laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Foreign countries generally do not allow patents to cover methods for performing surgical procedures. If our intellectual property does not provide significant protection against foreign or domestic competition, our competitors could compete more directly with us, which could result in a decrease in our market share. All of these factors may harm our competitive position.

**The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights and any litigation or claim against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation.**

Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our products or obtain and use information that we regard as proprietary. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Any patent dispute, even one without merit or an unsuccessful one, would be time-consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, the disruption of development and marketing efforts, injury to our reputation and loss of revenue. Litigation also puts our patent applications at risk of being rejected and our patents at risk of being invalidated or interpreted narrowly and may provoke third parties to assert claims against us. Any of these events could negatively affect our financial condition.

In the event of a patent dispute, if a third party's patents were upheld as valid and enforceable and we were found to be infringing, or found to be inducing infringement by others, we could be prevented from selling our products unless we were able to obtain a license to use technology or ideas covered by such patent or are able to redesign our system to avoid infringement, or we may be ordered to pay substantial damages to the patent holders. A license may not be available at all or on terms acceptable to us, and we may not be able to redesign our products to avoid any infringement. Modification of our products or development of new products could require us to conduct additional clinical trials and to revise our filings with FDA and other regulatory bodies, which would be time-consuming and expensive. If we are not successful in obtaining a license or redesigning our products, we may be unable to sell our products and our business could suffer.

**The increase in cost of medical malpractice premiums to physicians and hospitals or the lack of malpractice insurance coverage due to the use of our products by physicians for an off-label indication may cause certain physicians or hospitals to decide not to use our products and may damage our ability to maintain or grow the market for our products.**

Insurance carriers have been raising premiums charged for medical malpractice insurance due, at least in part, to increased risks associated with off-label procedures, including higher damage awards for successful plaintiffs. Insurance carriers may continue to raise premiums or they may deny malpractice coverage for procedures performed using products such as ours on an off-label basis. If this trend continues or worsens, our revenue may fall as physicians or hospitals decide against purchasing our products due to the cost or unavailability of insurance coverage.

**We have a history of net losses, and we may never become profitable.**

We have incurred net losses each year since our inception, including, most recently, net losses of \$21,137 in 2018, \$26,892 in 2017 and \$33,338 in 2016. As of December 31, 2018, we had an accumulated deficit of \$247,003.

Our net losses have resulted principally from costs and expenses relating to sales, training and promotional efforts, research and development, clinical trials, seeking regulatory clearances and approvals and general operating expenses. We expect to continue to incur substantial expenditures and to potentially incur additional operating losses in the future as we further develop and commercialize our products. If sales of our products do not continue to grow as we anticipate, we will not be able to achieve profitability. Our expansion efforts may prove to be more expensive than we currently anticipate, and we may not succeed in increasing our revenue sufficiently to offset these higher expenses. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and accumulated deficit.

**Our capital needs after the next twelve months are uncertain, and we may need to raise additional funds in the future and such funds may not be available on acceptable terms, if at all.**

We believe that our current cash, cash equivalents and investments, including additional cash generated from our public offering of common stock in October 2018 along with the cash we expect to generate or use for operations or access via our term loan and revolving line of credit will be sufficient to meet our projected capital requirements for at least the next 12 months. The October 2018 common stock offering generated \$82,873 in net proceeds through the issuance of 2,875 shares. Our Loan and Security Agreement with Silicon Valley Bank (SVB), as amended and restated effective February 23, 2018 and as further amended December 28, 2018 (the “Loan Agreement”), provides for a \$40,000 term loan and \$20,000 revolving line of credit, with an option to increase the revolving line of credit by an additional \$20,000. The term loan and revolving credit facility both mature in February 2023. According to the Loan Agreement, principal payments on the term loan are to be made ratably commencing eighteen months after the inception of the loan through the loan’s maturity date. If we meet certain conditions, as specified by the agreement, the commencement of term loan principal payments may be deferred by an additional six months. The term loan accrues interest at the greater of the Prime Rate plus 0.50% or 5.00 %. As of December 31, 2018, we had outstanding borrowings under the term loan of \$40,000. Borrowing availability under the revolving credit facility is based on the lesser of \$20,000 or a borrowing base calculation as defined by the Loan Agreement. The applicable borrowing rate on advances outstanding under the revolving credit facility is the greater of the Prime Rate and 4.50%. The Loan Agreement also provides for certain prepayment and early termination fees, as well as establishes a minimum liquidity covenant and includes other customary terms and conditions. As of December 31, 2018, we had no borrowings under the revolving credit facility, and we had borrowing availability of \$20,000.

The nContact acquisition provided for contingent consideration to be paid upon attaining specified regulatory approvals and revenue milestones over the next two years. Subject to the terms and conditions of the nContact merger agreement, such contingent consideration is paid in AtriCure common stock and cash, with a requirement to make payments in AtriCure common stock first, up to a specified maximum number of shares. Over the next twelve months, we do not expect our cash requirements to include significant payments of contingent consideration based on terms of the acquisition agreement and related milestones. Significant changes to the estimated consideration to be paid could result in a substantial increase in liabilities for contingent consideration and our accumulated deficit and reduce our net income or increase our net loss for the year in which the changes occur, which could contribute to difficulty in raising additional funds. The issuance of our stock to nContact shareholders to settle contingent consideration obligations would dilute the holdings of our existing stockholders.

We believe we have adhered to the nContact contract provisions that provide for contingent consideration if the conditions described above are met. nContact representatives have disputed, and in the future may dispute our adherence to the contract and pursue a claim for non-adherence which could involve complex legal and factual issues, the determination of which is often uncertain. Any such claim, even one without merit or an unsuccessful one, would be time-consuming and expensive to defend and could result in the diversion of our management’s attention from our business, adverse publicity, the disruption of development and marketing efforts, injury to our reputation and adversely impact our financial condition.

If we need to raise additional funds for any reason, we cannot be certain that such funds will be available to us on acceptable terms, if at all. Furthermore, if we issue equity securities to raise additional funds, our existing stockholders will experience dilution, and if we issue equity or debt securities, such securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our future products or proprietary technologies or grant licenses on terms that are not favorable to us. If we cannot raise funds on acceptable terms, we may not be able to expand our operations, develop new products, take advantage of future opportunities or respond to competitive pressures or unanticipated customer requirements.

**We may be unable to comply with the covenants of our Loan Agreement.**

Our Loan Agreement with SVB contains a minimum liquidity covenant and other customary terms and conditions. The occurrence of an event of default could result in an increase to the applicable interest rate by 3.0%, an acceleration of all obligations, an obligation to repay all obligations in full and a right by SVB to exercise all remedies available to them. If we are unable to pay those amounts, SVB could proceed against the collateral granted to it pursuant to the Loan Agreement, and we may in turn lose access to our current source of borrowing availability.

**Our federal tax net operating loss (NOL) and general business credit carryforwards generated or acquired may expire or will be limited because we experienced an ownership change of more than 50 percent, which could result in greater future income tax expense and adversely impact future cash flows.**

On June 30, 2001, we experienced an ownership change as defined by Section 382 of the Internal Revenue Code of 1986. Section 382 imposes limitations (Section 382 limitation) on a company’s ability to use net operating loss and general business credit carryforwards if a company experiences a more-than-50-percent ownership change over a three-year testing period. Additionally, in connection with acquisitions, additional acquired NOLs are also subject to Section 382 limitation. The Section 382 limitations could limit the availability of our net operating loss and general business credit carryforwards to offset any future taxable income, which may increase our future income tax expense and adversely impact future cash flows. Net operating losses generated prior to 2018 are also subject to expiration under current IRS regulations. We have total federal income tax net operating loss and research and

development credit carryforwards that, if not used to reduce our taxable income, will begin to expire in 2021. We have generated or acquired available net operating loss and research and development credit carryforwards of \$239,162 and \$6,154.

**If our goodwill or other intangible assets become impaired, it could materially reduce the value of our assets and reduce our net income or increase our net loss for the year in which the impairment occurs.**

As of December 31, 2018, we had \$105,257 in goodwill related to acquisitions, which represents the purchase price we paid in excess of the fair value of the net assets we acquired. The Financial Accounting Standards Board's (FASB) Accounting Standards Codification (ASC) 350, "Goodwill and Other Intangible Assets" requires that goodwill be tested for impairment at least annually (absent any impairment indicators). The testing includes comparing the fair value of each reporting unit with its carrying value. We estimate fair value using several valuation methods, including discounted cash flows, market multiples and market capitalization. Impairment adjustments, if any, are required to be recognized as operating expenses. We may have future impairment adjustments to our recorded goodwill. Any finding that the value of our goodwill has been impaired would require us to record an impairment charge which could materially reduce the value of our assets and reduce our net income or increase our net loss for the year in which the impairment charge occurs and increase our accumulated deficit.

In Process Research and Development (IPR&D) valued at \$44,021 was recorded as an intangible asset in connection with the nContact acquisition. If we do not obtain the regulatory approvals that would confirm the technological feasibility of the IPR&D project, or if the IPR&D project is abandoned for any other reason, we would have an impairment adjustment of this asset that would require us to write it off. Additionally, and similar to goodwill, if the IPR&D asset is deemed to be impaired (as a result of the estimated fair value being less than carrying value), we would be required to write off the impaired portion of the IPR&D asset. This would materially reduce the value of our assets and reduce our net income or increase our net loss for the year in which the write off occurs and increase our accumulated deficit.

**An inability to forecast future revenue or estimate life cycles of products may result in inventory-related charges that would negatively affect our gross margins and results of operations.**

To mitigate the risk of supply interruptions, we may choose to maintain additional inventory of our products or component parts. Managing our inventory levels is important to our cash position and results of operations and is challenging in the current economic environment. As we grow and expand our product offerings, managing our inventory levels becomes more difficult, particularly as we expand into new product areas and bring product enhancements to market. While we rely on our personnel and information technology systems for inventory management to effectively manage accounting and financial functions, our personnel and information technology systems may fail to adequately perform these functions or may experience an interruption. An excessive amount of inventory reduces our cash available for operations and may result in excess or obsolete materials. Conversely, inadequate inventory levels may make it difficult for us to meet customer product demand, resulting in decreased revenue. An inability to forecast future revenue or estimated life cycles of products may result in inventory-related charges that would negatively affect our gross margins and results of operations and increase our accumulated deficit, any of which could contribute to difficulty in raising additional funds.

**We rely upon single and limited source third-party suppliers and third-party logistics providers, making us vulnerable to supply problems and price fluctuations which could harm our business.**

We rely on single and limited source third-party vendors for the manufacture and sterilization of components used in our products. For example, we rely on one vendor to manufacture several of our RF generators, as well as separate vendors to manufacture our COBRA Fusion Surgical Ablation Systems, EPi-Sense Guided Coagulation System with VisiTrax technology, and nContact RF generator. It would be a time consuming and lengthy process to secure these products from an alternative supplier. In addition, in some cases there are relatively few alternative sources of supply for certain other components that are critical to our products. We also rely on a third party to handle our warehousing and logistics functions for European and Middle Eastern markets on our behalf.

Our reliance on outside manufacturers, sterilizers and suppliers also subjects us to risks that could harm our business, including:

- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- we may have difficulty timely locating and qualifying alternative suppliers;
- switching components may require product redesign and new submissions to FDA which could significantly delay production or, if FDA refuses to approve the changes, completely eliminate our ability to manufacture or sell our products;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products those suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

Identifying and qualifying additional or replacement suppliers for any of the components used in our products or a replacement warehousing and logistics provider, if required, may not be accomplished quickly and could involve significant additional costs. Any



interruption or delay in the supply of components, materials or warehousing and logistics, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products and could therefore have a material adverse effect on our business, financial condition and results of operations.

**If we or our third-party vendors fail to comply with extensive FDA regulations relating to the manufacturing of our products or any component part, we may be subject to fines, injunctions and penalties, and our ability to commercially distribute and sell our products may be hurt.**

Our manufacturing facility and the manufacturing facility of any of our third-party component manufacturers, critical suppliers or third-party sterilization facility are required to comply with FDA's Quality System Regulation (QSR) which sets forth minimum standards for the procedures, execution and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of the products we sell. FDA may evaluate our compliance with the QSR, among other ways, through periodic announced or unannounced inspections which could disrupt our operations and interrupt our manufacturing. If in conducting an inspection of our manufacturing facility or the manufacturing facility of any of our third-party component manufacturers, critical suppliers or third-party sterilization facility, an FDA investigator observes conditions or practices believed to violate the QSR, the investigator may document their observations on a Form FDA-483 that is issued at the conclusion of the inspection. A manufacturer that receives an FDA-483 may respond in writing and explain any corrective actions taken in response to the inspectional observations. FDA will typically review the facility's written response and may re-inspect to determine the facility's compliance with the QSR and other applicable regulatory requirements. Failure to take adequate and timely corrective actions to remedy objectionable conditions listed on an FDA-483 could result in FDA taking administrative or enforcement actions. Among these may be FDA's issuance of a Warning Letter to a manufacturer, which informs the manufacturer that FDA considers the observed violations to be of "regulatory significance" that, if not corrected, could result in further enforcement action. FDA enforcement actions, which include seizure, injunction and criminal prosecution, could result in total or partial suspension of a facility's production and/or distribution, product recalls, fines, suspension of FDA's review of product applications and FDA's issuance of adverse publicity. Thus, an adverse inspection could force a shutdown of our manufacturing operations or a recall of our products. Adverse inspections could also delay FDA approval of our products and could have an adverse effect on our production, sales and financial condition.

We and any of our third-party vendors may also encounter other problems during manufacturing including failure to follow specific protocols and procedures, equipment malfunction and environmental factors, any of which could delay or impede our ability to meet demand. The manufacture of our product also subjects us to risks that could harm our business, including problems relating to the sterilization of our products or facilities and errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products. Any interruption or delay in the manufacture of the product or any of its components could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products and could, therefore, have a material adverse effect on our business, financial condition and results of operations.

**If we fail to comply with the extensive FDA regulations relating to our business, we may be subject to fines, injunctions and penalties, and our ability to commercially distribute and promote our products may be hurt.**

Our products are classified by FDA as medical devices and, as such, are subject to extensive regulation in the United States by FDA and numerous other federal, state and foreign governmental authorities. FDA regulations, guidance, notices and other issuances specific to medical devices are broad and regulate numerous aspects of our business.

Compliance with FDA, state and other regulations can be complex, expensive and time-consuming. FDA and other authorities have broad enforcement powers. Furthermore, changes in the applicable governmental regulations could prevent further commercialization of our products and technologies and could materially harm our business.

If a serious failure to comply with applicable regulatory requirements was determined, it could result in enforcement action by FDA or other state or federal agencies, including the DOJ, which may include any of the following sanctions, among others:

- 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;
- suspension or termination of our clinical trials;
- refusing or delaying our pending requests for 510(k) clearance or PMAs, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or PMAs that have already been granted; and
- criminal prosecution.

If any of these events were to occur, we could lose customers and our production, product sales, business, results of operations and financial condition would be harmed.



We are also subject to medical device reporting regulations that require us to file reports with FDA if our products may have caused or contributed to a death or serious injury or, in the event of product malfunction, that if such malfunction were to recur, would likely cause or contribute to a death or serious injury. There have been incidents, including patient deaths, which have occurred during or following procedures using our products that we have not, and believe were not required to be, reported to FDA because we determined that our products did not cause or contribute to the outcomes in these incidents. If FDA disagrees with us, however, and determines that we should have submitted reports for these adverse events, we could be subject to significant regulatory fines or other penalties. In addition, the number of medical device reports we make, or the magnitude of the problems reported, could cause us or FDA to terminate or modify our clinical trials or recall or cease the sale of our products, and could hurt commercial acceptance of our products and harm our reputation with customers.

**Modifications to our products may require new clearances or approvals or may require us to cease promoting or to recall the modified products until such clearances or approvals are obtained and FDA may not agree with our conclusions regarding whether new clearances or approvals were required.**

Any modification to a 510(k)-cleared device that would constitute a change in its intended use, design or manufacture could require a new or supplemental 510(k) clearance or, possibly, submission and FDA approval of a PMA. FDA requires every medical device company to make the determination as to whether a 510(k) must be filed, but FDA may review any medical device company's decision. We have made modifications to our products and concluded that such modifications did not require us to submit a 510(k). FDA may not agree with our decisions regarding whether submissions were required.

If FDA were to disagree with us and require us to submit a 510(k), PMA or a PMA supplement for then-existing modifications, we could be required to cease promoting or to recall the modified product until we obtain clearance or approval. In addition, we could be subject to significant regulatory fines or other penalties. Furthermore, our products could be subject to recall if FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Delays in receipt or failure to receive clearances or approvals, the loss of previously received clearances or approvals or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects.

**We spend considerable time and money complying with federal, state and foreign regulations in addition to FDA regulations, and, if we are unable to fully comply with such regulations, we could face substantial penalties.**

We are subject to extensive regulation by the federal government and foreign countries in which we conduct business. The laws that affect our ability to operate our business in addition to the FDCA and FDA regulations include, but are not limited to, the following:

- state consumer protection, fraud and business practice laws;
- the Federal Anti-Kickback Statute, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid Programs;
- the Federal False Claims Act, which prohibits submitting a false claim or causing of the submission of a false claim to the government;
- Medicare laws and regulations that prescribe the requirements for coverage and payment, including the amount of such payment, and laws prohibiting false claims for reimbursement under Medicare and Medicaid;
- state laws that prohibit the practice of medicine by non-doctors and by doctors not licensed in a particular state, and fee-splitting arrangements between doctors and non-doctors, as well as state law equivalents to the Anti-Kickback Statute and the Stark Law, which may not be limited to government-reimbursed items;
- federal and state healthcare fraud and abuse laws or laws protecting the privacy of patient medical information, including the Health Insurance Portability and Accountability Act (HIPAA) which protects medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting reasonably necessary to accomplish the intended purpose;
- laws and regulations with respect to the collection, use, disclosure, transfer, and storage of personal data that we may collect from our employees, consultants or in conjunction with clinical trials such as the General Data Protection Regulation in the European Union;
- the Federal Trade Commission Act and similar laws regulating advertising and consumer protection; and
- similar and other regulations outside the United States.

Healthcare fraud and abuse regulations are complex, and even minor, inadvertent irregularities can potentially give rise to claims that a law has been violated. Any violations of these laws could result in a material adverse effect on our business, financial condition and results of operations. For example, if we were found to be in violation of the Federal False Claims Act, we would likely face significant fines and penalties and would likely be required to change substantially our sales, promotion, grant and educational activities. There is also a possibility that we could face an injunction that would prohibit in whole or in part our current business

activities, and, as a result of enforcement actions against us or our senior officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations.

Our manufacturing operations and research and development activities involve the use of biological materials and hazardous substances and are subject to a variety of federal, state and local environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of and human exposure to hazardous substances. Our research and development and manufacturing operations may produce biological waste materials, such as animal tissues and certain chemical waste. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in compliance with environmental laws and regulations. Compliance with these laws and regulations may be expensive, and non-compliance could result in substantial liabilities. In addition, we cannot completely eliminate the risk of accidental contamination or injury to third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed any applicable insurance coverage we may have. Our manufacturing operations may result in the release, discharge, emission or disposal of hazardous substances that could cause us to incur substantial liabilities, including costs for investigation and remediation.

If our past or present operations are found to be in violation of any of the laws described above or the other governmental regulations to which we, our distributors or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from Medicare, Medicaid and other government programs and the curtailment or restructuring of our operations. If we are required to obtain permits or licensure under these laws that we do not already possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully or clearly interpreted by the regulatory authorities or the courts, and their provisions are subject to a variety of interpretations and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

**We have traditionally had limited clinical data regarding the safety and efficacy of our products. Any data that is generated may not be positive or consistent, which would affect the rate at which our products are adopted by the medical community.**

Important factors upon which the efficacy of our products will be measured include data on the number of patients that experience Afib or stroke following treatment with our products and the number of patients that have serious complications resulting from ablations or LAA occlusion using our products. While we believe we are now well-positioned to provide sufficient data regarding the safety and efficacy of our products, such data could identify unexpected safety issues. We cannot provide any assurance that the data collected during our clinical trials will be compelling to the medical community because it may not be scientifically meaningful and may not demonstrate that procedures utilizing our products are an attractive option when compared against data from alternative procedures and products. Negative data would affect the use of our products and harm our business and prospects.

**Adverse changes in payors' policies toward coverage and reimbursement for surgical procedures would harm our ability to promote and sell our products.**

Third-party payors are increasingly exerting pressure on medical device companies to reduce their prices. Even to the extent that the use of our products is reimbursed by private payors and governmental payors, adverse changes in payors' policies toward coverage and reimbursement for surgical procedures would also harm our ability to promote and sell our products. Payors continue to review their policies and can, without notice, deny coverage for treatments that include the use of our products. Because each third-party payor individually approves coverage and reimbursement, obtaining these approvals may be time-consuming and costly. In addition, third-party payors may require us to provide scientific and clinical support for the use of our products. Adverse changes in coverage and reimbursement for surgical procedures could harm our business and reduce our revenue.

FDA does not regulate the practice of medicine. Physicians may use our products in circumstances where they deem it medically appropriate, such as for the treatment of Afib or the reduction in stroke risk, even though FDA may not have approved or cleared our products to be marketed specifically for those indications. Some payors may deem the use of our products for indications not specifically approved or cleared by FDA to be experimental and, as such, may deny coverage or payment. Often, these denials can be overcome through an appeals process, but there is no guarantee of success in these cases.

**If coverage and adequate levels of reimbursement from governmental and third-party payors outside of the United States are not obtained and maintained, sales of our products outside of the United States may decrease, and we may fail to achieve or maintain significant sales outside of the United States.**

Our revenue generated from sales outside of the United States is also dependent upon the availability of coverage and reimbursement within prevailing foreign healthcare payment systems. Foreign healthcare payors generally do not provide the same level of reimbursement for sole-therapy minimally invasive procedures utilizing ablation devices and related products as payors in the United States. In addition, healthcare cost containment efforts similar to those we face in the United States are prevalent in many of the other countries in which we sell our products, and these efforts are expected to continue. To the extent that the use of ablation

devices such as our Isolator Synergy System has historically received reimbursement under a foreign healthcare payment system, such reimbursement, if any, has typically been significantly less than the reimbursement provided in the United States. If coverage and adequate levels of reimbursement from governmental and third-party payors outside of the United States are not obtained and maintained, sales of our products outside of the United States may decrease, and we may fail to achieve or maintain significant sales outside of the United States.

**Fluctuations in foreign currency exchange rates could result in declines in our reported sales and results of operations.**

Because some of our international sales are denominated in local currencies and not in U.S. Dollars, our reported sales and earnings are subject to fluctuations in foreign currency exchange rates, primarily the Euro and British Pound. We translate results of transactions denominated in local currencies into U.S. Dollars using market conversion rates applicable to the period in which the transaction is reported. As a result, changes in exchange rates during a period can unpredictably and adversely affect our consolidated operating results and our asset and liability balances, even if the underlying value of the item in its original currency has not changed. At present, we do not hedge our exposure to foreign currency fluctuations. As a result, sales and expenses occurring in the future that are denominated in foreign currencies may be translated into U.S. Dollars at less favorable rates, resulting in reduced revenues and earnings.

**Our manufacturing operations are primarily conducted at a single location, and any disruption at our manufacturing facility could increase our expenses and decrease our revenue.**

Our manufacturing operations are conducted at a single location in Ohio. While we take precautions at this location, we do not maintain a backup manufacturing facility, making us dependent on our current facility for the continued operation of our business. A natural or other disaster could damage or destroy our manufacturing equipment and cause substantial delays in our manufacturing operations, which could lead to additional expense and decreased revenue due to lack of supply. The insurance we maintain may not be adequate to cover our losses in any particular case. With or without insurance, damage to our facility or our other property due to a natural disaster or casualty event could have a material adverse effect on our business, financial condition and results of operations.

**We rely on independent distributors to market and sell our products in certain markets outside of the United States, and a failure of our independent distributors to successfully market our products or any disruption in their ability to do so may adversely impact our sales.**

We depend on third-party distributors to sell our products in certain markets outside of the United States, and if these distributors do not perform, we may be unable to maintain or increase our level of international revenue. We intend to continue to grow our business outside of the United States, and to do so, we will need to attract additional distributors or hire direct sales personnel to expand the territories in which we sell our products. Independent distributors may terminate their relationship with us or devote insufficient sales efforts to our products. We are not able to control our independent distributors, and they may not be successful in implementing our marketing plans. In addition, many of our independent distributors outside of the United States initially obtain and maintain foreign regulatory approval for sale of our products in their respective countries. Our failure to maintain our relationships with our independent distributors outside of the United States, or our failure to recruit and retain additional skilled independent distributors in these locations, could have an adverse effect on our operations. Turnover among our independent distributors, even if replaced, may adversely affect our short-term financial results while we transition to new independent distributors or direct sales personnel. The ability of these third-party distributors to market and sell our products could also be adversely affected by unexpected events, including, but not limited to, power failures, nuclear events, natural or other disasters and war or terrorist activities. In addition, in light of the worldwide economic crisis, the ability of our distributors to borrow money from their existing lenders or to obtain credit from other sources to purchase our products may be impaired or our distributors could experience a significant change in their liquidity or financial condition, all of which could impair their ability to distribute our products and eventually lead to distributor turnover, and may adversely impact our sales.

**If we fail to properly manage our anticipated growth, our business could suffer.**

We may experience periods of rapid growth and expansion, which could place a significant strain on our personnel, information technology systems and other resources. In particular, the increase in our direct sales force requires significant management and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

To achieve our revenue goals, we must successfully increase production output as required by customer demand. In the future, we may experience difficulties in increasing production, including problems with production yields and quality control, component supply and shortages of qualified personnel. These problems could result in delays in product availability and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate revenues.

Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure. In order to manage our operations and growth, we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer.

**We depend on our officers and other skilled and experienced personnel to operate our business effectively. If we are not able to retain our current employees or recruit additional qualified personnel, our business will suffer and our future revenue and profitability will be impaired.**

We are highly dependent on the skills and experience of our President and Chief Executive Officer, Michael H. Carrel, and certain other officers and key employees. We do not have any insurance in the event of the death or disability of key personnel. Our officers and key employees, with the exception of our President and Chief Executive Officer, do not have employment agreements, and they may terminate their employment and work elsewhere without notice and without cause or good reason. Currently we have non-compete agreements with our officers and other employees. Due to the specialized knowledge of each of our officers with respect to our products and our operations and the limited pool of people with relevant experience in the medical device field, the loss of service of one or more of these individuals could significantly affect our ability to operate and manage our business. The announcement of the loss of one or more of our key personnel could negatively affect our stock price.

We depend on our scientific and technical personnel for successful product development and innovation, which are critical to the success of our business. In addition, to succeed in the implementation of our business strategy, our management team must rapidly execute our sales strategy, obtain expanded FDA clearances and approvals, achieve market acceptance for our products and further develop products, while managing anticipated growth by implementing effective planning, manufacturing and operating processes. Managing this growth will require us to attract and retain additional management and technical personnel. We rely primarily on direct sales employees to sell our products in the United States and failure to adequately train them in the use and benefits of our products will prevent us from achieving our market share and revenue growth goals. We have key relationships with physicians that involve procedure, product, market and clinical development. If any of these physicians end their relationship with us, our business could be negatively impacted. We cannot assure you that we will be able to attract and retain the personnel and physician relationships necessary to grow and expand our business and operations. If we fail to identify, attract, retain and motivate these highly skilled personnel and physicians, we may be unable to continue our development and sales activities.

**Our business growth strategy involves the potential for significant acquisitions, which involve risks and difficulties in integrating potential acquisitions and may adversely affect our business, results of operations and financial condition.**

All acquisitions involve inherent uncertainties, which may include, among other things, our ability to:

- successfully identify targets for acquisition;
- negotiate reasonable terms;
- properly perform due diligence and determine significant risks associated with a particular acquisition;
- properly evaluate target company management capabilities; and
- successfully transition and integrate the acquired company into our business and achieve the desired performance.

We may acquire businesses with unknown liabilities, contingent liabilities or internal control deficiencies. We have plans and procedures in place to conduct reviews of potential acquisition candidates for compliance with applicable regulations and laws prior to acquisition. Despite these efforts, realization of any of these liabilities or deficiencies may increase our expenses, adversely affect our financial position through the initiation, pendency or outcome of litigation or otherwise, or cause us to fail to meet our public financial reporting obligations.

We have consummated two significant acquisitions since 2013 and in the future may continue to invest a substantial amount of capital in acquisitions. We continue to evaluate potential acquisition opportunities to support, strengthen and grow our business. There can be no assurance that we will be able to locate suitable acquisition candidates, acquire possible acquisition candidates, acquire such candidates on commercially reasonable terms, or integrate acquired businesses successfully in the future. In addition, any governmental review or investigation of our proposed acquisitions, such as by the Federal Trade Commission, may impede, limit or prevent us from proceeding with an acquisition. Future acquisitions may require us to incur additional debt and contingent liabilities, which may adversely affect our business, results of operations and financial condition. The process of integrating acquired businesses into our existing operations may result in operating, contract and supply chain difficulties, such as the failure to retain customers or management personnel. Such difficulties may divert significant financial, operational and managerial resources from our existing operations and make it more difficult to achieve our operating and strategic objectives.

**Disruptions of critical information systems or material breaches in the security of our systems could harm our business, customer relations and financial condition.**

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers and employees in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the



privacy of personal information, regulatory penalties, disrupt our operations and the services we provide to customers, and damage our reputation and cause a loss of confidence in our products and services, which could adversely affect our business, operating margins, revenues and competitive position.

We also rely in part on information technology to store information, interface with customers, maintain financial accuracy, secure our data and accurately produce our financial statements. If our information technology systems do not effectively and securely collect, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, human error or cyber incident, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations would be materially impaired. Any such impairment could have a material adverse effect on our results of operations, financial condition and the timeliness with which we report our operating results.

**We are subject to credit risk from our accounts receivable related to our sales, which include sales to countries outside the United States that may experience economic turmoil.**

The majority of our accounts receivable arise from sales in the United States. However, we also have significant receivable balances from customers within the European Union and Asia. Our accounts receivable in the United States are primarily due from public and private hospitals. Our accounts receivable outside the United States are primarily due from public and private hospitals and from independent distributors. Our historical write-offs of accounts receivable have not been significant. We monitor the financial performance and credit worthiness of our customers so that we can properly assess and respond to changes in their credit profile. Our independent distributors operate in certain countries where economic conditions continue to present challenges to their businesses, and, thus, could place the amounts due to us at risk. These distributors are owed amounts from public hospitals that are funded by their governments. Adverse financial conditions in these countries may negatively affect the length of time that it will take us to collect associated accounts receivable or impact the likelihood of ultimate collection.

**The results of the United Kingdom's referendum on withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.**

In June 2016, a majority of voters in the United Kingdom elected to withdraw from the European Union, or the EU, in a national referendum, commonly referred to as Brexit. In March 2017, the United Kingdom formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the United Kingdom from the EU will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, on March 29, 2019. The referendum has created significant uncertainty about the future relationship between the United Kingdom and the EU, including with respect to the laws and regulations that will apply as the United Kingdom determines which EU laws to replace or replicate in the event of a withdrawal. From a regulatory perspective, the United Kingdom's withdrawal could give rise to significant complexity and risks. Since the medical device regulatory framework in the United Kingdom is derived from the EU Medical Devices Directive, the United Kingdom's withdrawal could materially impact the continued marketing of EU medical devices in the United Kingdom. Further, the withdrawal may also significantly delay the transport of our products into the United Kingdom, which could adversely impact our sales.

Because of the continued uncertainty about the effects, implementation, or potential repeal of Brexit, we cannot quantify or predict with any certainty the likely impact of Brexit or related legislation on our business model, prospects, financial condition or results of operations. In addition, these developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets.

**Our effective income tax rate may fluctuate, which may adversely affect our operations, earnings and earnings per share.**

Our effective income tax rate is influenced by our projected profitability in the various taxing jurisdictions in which we operate. The global nature of our business increases our tax risks. In addition, revenue authorities in many of the jurisdictions in which we operate are known to have become more active in their tax collection activities. Changes in the distribution of profits and losses among taxing jurisdictions may have a significant impact on our effective income tax rate, which in turn could have an adverse effect on our net income and earnings per share. The application of tax laws in various taxing jurisdictions, including the United States, is subject to interpretation, and tax authorities in various jurisdictions may have diverging and sometimes conflicting interpretations of the application of tax laws. Changes in tax laws or tax rulings, in the United States or other tax jurisdictions in which we operate, could materially impact our effective tax rate.

Factors that may affect our effective income tax rate include, but are not limited to:

- the requirement to exclude from our quarterly worldwide effective income tax calculations losses in jurisdictions where no income tax benefit can be recognized;
- actual and projected full year pre-tax income, including differences between actual and anticipated income before taxes in various jurisdictions;
- changes in tax laws, or in the interpretation or application of tax laws, in various taxing jurisdictions;
- changes in the relative mix and staffing levels in various tax jurisdictions;



- audits or other challenges by taxing authorities; and
- the establishment of valuation allowances against a portion or all of certain deferred income tax assets if we determined that it is more likely than not that future income tax benefits will not be realized.

These changes may cause fluctuations in our effective income tax rate that could adversely affect our results of operations and cause fluctuations in our earnings and earnings per share.

**Governmental authorities may question our intercompany transfer pricing policies or change their laws in a manner that could increase our effective tax rate or otherwise harm our business.**

As a U.S. company doing business in international markets through subsidiaries, we are subject to foreign tax and intercompany pricing laws, including those relating to the flow of funds between the parent and subsidiaries. Tax authorities in the United States and in foreign markets closely monitor our corporate structure and how we account for intercompany fund transfers. If tax authorities challenge our corporate structure, transfer pricing mechanisms or intercompany transfers, our operations may be negatively impacted and our effective tax rate may increase. Tax rates vary from country to country and if regulators determine that our profits in one jurisdiction should be increased, we might not be able to fully utilize all foreign tax credits that are generated, which would increase our effective tax rate. Additionally, the Organization for Economic Cooperation and Development, or OECD, has issued certain proposed guidelines regarding base erosion and profit sharing. Once these guidelines are formally adopted by the OECD, it is possible that separate taxing jurisdictions may also adopt some form of these guidelines. In such case, we may need to change our approach to intercompany transfer pricing in order to maintain compliance under the new rules. Our effective tax rate may increase or decrease depending on the current location of global operations at the time of the change. Finally, we might not always be in compliance with all applicable customs, exchange control, Value Added Tax and transfer pricing laws despite our efforts to be aware of and to comply with such laws. In such case, we may need to adjust our operating procedures and our business could be adversely affected.

**Due to the global nature of our business, we may be exposed to liabilities under the Foreign Corrupt Practices Act and various other anti-corruption laws, and any allegation or determination that we violated these laws could have a material adverse effect on our business.**

We are required to comply with the FCPA, UK Bribery Act of 2010 and other U.S. and foreign anti-corruption laws, which prohibit companies from engaging in bribery including corruptly or improperly offering, promising, or providing money or anything else of value to foreign officials and certain other recipients. In addition, the FCPA imposes certain books, records and accounting control obligations on public companies and other issuers. We operate in parts of the world in which corruption can be common and compliance with anti-bribery laws may conflict with local customs and practices. Our global operations face the risk of unauthorized payments or offers being made by employees, consultants, sales agents and other business partners outside of our control or without our authorization. It is our policy to implement safeguards (including mandatory training) to prohibit these practices by our employees and business partners with respect to our operations. However, irrespective of these safeguards, or as a result of monitoring compliance with such safeguards, it is possible that we or certain other parties may discover or receive information at some point that certain employees, consultants, sales agents, or other business partners may have engaged in corrupt conduct for which we might be held responsible. Violations of the FCPA or other foreign anti-corruption laws may result in restatements of, or irregularities in, our financial statements as well as severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition. In some cases, companies that violate the FCPA may be debarred by the U.S. government and/or lose their U.S. export privileges. Changes in anti-corruption laws or enforcement priorities could also result in increased compliance requirements and related costs which could adversely affect our business, financial condition and results of operations. In addition, the U.S. or other governments may seek to hold us liable for successor liability FCPA violations or violations of other anti-corruption laws committed by companies in which we invest or that we acquired or will acquire.

**The impact of restrictive trade policies in the United States and the potential corresponding actions by other countries could adversely affect our financial performance.**

The U.S. federal government has recently implemented tariffs on certain products imported into the United States from China, and the Chinese government has responded with retaliatory tariffs on certain products, including medical devices, exported from the United States to China. We cannot predict whether the United States will implement additional trade restrictions with respect to China or other countries and how such countries may respond to such trade restrictions. If these tariffs continue or are expanded, they may make it more difficult to sell our products in China or other markets outside of the United States. Restrictive trade policies may also harm the United States and global economies generally, which would adversely affect our business in a variety of ways, including reducing the market for our products, causing a downturn in the trading price of our common stock, and restricting access to credit if we seek it for future growth.

**Our insurance may not cover all of our indemnification obligations and other liabilities associated with our operations.**

We maintain insurance designed to provide coverage for ordinary risks associated with our operations and our ordinary indemnification obligations, which we believe to be customary for our industry. The coverage provided by such insurance may not be adequate for all claims we may make or may be contested by our insurance carriers. If our insurance is not adequate or available to pay liabilities associated with our operations, or if we are unable to purchase adequate insurance at reasonable rates in the future, our business, financial condition, results of operations or cash flows may be materially adversely impacted.

## Risks Relating To Our Common Stock

### **The price and trading volume of our common stock may experience extreme fluctuations and our stockholders could lose some or all of their investment.**

Because we operate within the medical device segment of the healthcare industry, our stock price is likely to be volatile. The market price of our common stock may have and has had a history of substantial fluctuation due to a variety of factors, including, but not limited to:

- variations in our quarterly financial and operating results;
- physician and patient acceptance of the surgical treatment of Afib or exclusion of the LAA using our products;
- adverse regulatory developments with respect to our products, such as recalls, new regulatory requirements, changes in regulatory requirements or guidance and timing of regulatory clearances and approvals for new products;
- coverage and reimbursement determinations for our products and the related procedures;
- the timing of orders received;
- delays or interruptions in manufacturing or shipping of our products;
- pricing of our products;
- clinical trial results;
- media reports, publications or announcements about products or new innovations that could compete with our products or about the medical device product segment in general;
- investigations, claims or allegations by regulatory agencies, such as the Department of Justice and Financial Industry Regulatory Authority;
- market conditions or trends related to the medical device and healthcare industries or the market in general;
- additions to or departures of our key personnel;
- disputes, litigation or other developments relating to proprietary rights, including patents, and our ability to obtain patent protection for our technologies;
- changes in financial estimates, investors' perceptions or recommendations by securities analysts;
- failure to achieve or maintain an effective healthcare compliance environment;
- changes in accounting principles; and
- failure to achieve and maintain an effective internal control environment.

These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. We believe the quarterly and annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The market prices of the securities of medical device companies, particularly companies like ours without consistent revenue and earnings, have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the operating performance of these particular companies. In the past, companies that experience volatility in the market price of their securities have often faced securities class action litigation. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management's attention and resources and harm our ability to grow our business.

### **We may be obligated to issue additional shares of our common stock to the former stockholders of nContact as a result of our satisfaction of certain milestones set forth in the merger agreement with nContact and the other parties thereto, resulting in stock ownership dilution.**

Under the terms of the merger agreement with nContact and the other parties thereto, we agreed to issue additional shares of our common stock, or make payments in cash, to the former stockholders of nContact as contingent consideration upon our satisfaction of milestones described in the merger agreement. The merger agreement limits the total number of shares of AtriCure common stock issued in connection with the acquisition to 5,660, of which 3,757 shares were issued at the closing of the nContact acquisition on October 13, 2015 and 232 shares were issued and delivered to the former shareholders of nContact on September 20, 2018 for satisfaction of the trial enrollment milestone. Issuing additional shares of our common stock to the former stockholders of nContact in satisfaction of contingent consideration dilutes the ownership interests of holders of our common stock on the dates of such issuances. If we are unable to realize the strategic, operational and financial benefits anticipated from our acquisition of nContact, our stockholders may experience dilution of their ownership interests in our company upon any such future issuances of shares of our common stock without receiving any commensurate benefit.

**The sale of material amounts of common stock could encourage short sales by third parties and depress the price of our common stock. As a result, our stockholders may lose all or part of their investment.**

The downward pressure on our stock price caused by the sale of a significant number of shares of our common stock or the perception that such sales could occur by any of our significant stockholders could cause our stock price to decline, thus allowing short sellers of our stock an opportunity to take advantage of any decrease in the value of our stock. The presence of short sellers in our common stock may further depress the price of our common stock. Some of our directors and executive officers have in the past and may in the future enter into Rule 10b5-1 trading plans pursuant to which they may sell shares of our stock from time to time in the future. Actual or potential sales by these insiders, including those under a pre-arranged Rule 10b5-1 trading plan, could be interpreted by the market as an indication that the insider has lost confidence in our stock and adversely impact the market price of our stock.

**Sales of common stock by us in a capital raising transaction may dilute stockholder ownership of common stock and cause a decline in the market price of our common stock.**

We may need to raise capital in the future to fund our operations or new initiatives or reduce or pay in full our indebtedness. If we raise funds by issuing equity securities, our stock price may decline and our existing stockholders may experience significant dilution. Furthermore, we may enter into capital raising transactions at prices that represent a substantial discount to market price. A negative reaction by investors and securities analysts to any sale of our equity securities could result in a decline in the trading price of our common stock.

**Anti-takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws and under Delaware law could inhibit a change in control or a change in management that stockholders consider favorable.**

Provisions in our certificate of incorporation and bylaws could delay or prevent a change of control or change in management that would provide a premium to the market price of common stock. These provisions include those:

- authorizing the issuance without further approval of “blank check” preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates;
- limiting the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law limits business combination transactions with 15% stockholders that have not been approved by our board of directors. These provisions and others could make it difficult for a third party to acquire us, or for members of our board of directors to be replaced, even if doing so would be beneficial to our stockholders. Because our board of directors is responsible for appointing the members of our management team, these provisions could, in turn, affect any attempt to replace the current management team. If a change of control or change in management is delayed or prevented, stockholders may lose an opportunity to realize a premium on shares of common stock or the market price of our common stock could decline.

**We do not expect to pay dividends in the foreseeable future. As a result, stockholders must rely on stock appreciation for any return on investment.**

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Accordingly, stockholders will have to rely on capital appreciation, if any, to earn a return on investment in our common stock. Furthermore, pursuant to our credit facility, we are currently subject to restrictions on our ability to pay dividends and we may in the future become subject to other contractual restrictions on, or prohibitions against, the payment of dividends.

**Securities analysts may not continue, or additional securities analysts may not initiate, coverage for our common stock or may issue negative reports. This may have a negative impact on the market price of our common stock.**

Several securities analysts provide research coverage of our common stock. Some analysts have already published statements that do not portray our technology, products or procedures using our products in a positive light and others may do so in the future. If we are unable to educate those who publicize such reports about the benefits we believe our business provides, or if one or more of the analysts who elects to cover us downgrades our stock, our stock price would likely decline rapidly. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline. The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about us or our business. If sufficient securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. It may be difficult for companies such as ours, with smaller market capitalizations, to

attract and maintain sufficient independent financial analysts that will cover our common stock. This could have a negative effect on the market price of our stock.

**We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could cause a decline in our stock price.**

We provide financial guidance about our business and future operating results. In developing this guidance, our management makes certain assumptions and judgments about our future operating performance, including projected hiring of sales professionals, continued increase of our market share, and continued stability of the macro-economic environment in our key markets. Furthermore, analysts and investors may develop and publish their own projections of our business, which may form a consensus about our future performance. Our business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of our control, and which could adversely affect our operations and operating results. Furthermore, if we make downward revisions of our previously announced guidance, or if our publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors, or other interested parties, the market price of our common stock could decline.

**The requirements of being a public company may strain our resources and distract management.**

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), and the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act). We are also subject to certain provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act). The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Dodd-Frank Act requires the SEC to adopt certain rules and regulations relating to our public disclosures, corporate governance and executive compensation, among other things, and such rules and regulations require significant attention from management. Compliance with all of these laws, rules and regulations may from time to time divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting and management is required to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year. In order to maintain the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight is required. If we are not successful in maintaining effective internal control over financial reporting, there could be inaccuracies or omissions in the consolidated financial information we are required to file with the Securities and Exchange Commission. Additionally, even if there are no inaccuracies or omissions, we will be required to publicly disclose the conclusion of our management that our internal control over financial reporting or disclosure controls and procedures are not effective. These events could cause investors to lose confidence in our reported financial information, adversely impact our stock price, result in increased costs to remediate any deficiencies, or attract regulatory scrutiny or lawsuits that could be costly to resolve and distract management's attention.

The SEC has adopted rules regarding the disclosure of the use of conflict minerals (commonly referred to as tantalum, tin, tungsten and gold) which are mined from the Democratic Republic of the Congo (DRC) and neighboring countries. Under the rules, we are required to disclose the procedures we employ to determine the sourcing of such minerals and metals produced from those minerals. The requirements require due diligence efforts and could affect the sourcing of components used in our products. If the conflict minerals included in our products are found to be sourced from the DRC or surrounding countries, we may take actions to change materials or product designs to reduce the possibility that our purchase of conflict minerals may fund armed groups in the region. These actions could add engineering and other costs to the manufacture of our products. We expect to continue to incur costs in the investigation of the origin of the conflict minerals used in our products and in the reporting of the findings of our investigation. Our reputation may suffer if we have included conflict minerals in our products that are found to have funded armed groups in the DRC region.

## **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

## **ITEM 2. PROPERTIES**

The Company maintains its headquarters in Mason, Ohio in a leased facility totaling approximately 92,000 square feet. The facility contains the Company's administrative, regulatory, engineering, product development, distribution and manufacturing functions. The monthly rent for this space is \$120. The initial lease term expires in September 2030. The Company also maintains the following locations:

- Mason, Ohio – This location is primarily used for distribution activities. The facility is approximately 37,500 square feet with monthly rent of \$18 for the first year of the lease term and \$20 thereafter. The lease will expire in May 2022.
- Minneapolis, Minnesota – This location includes both administrative and product development space. The office is approximately 27,500 square feet with monthly rent of \$31. The lease will expire in October 2022.
- San Ramon, California – This location is primarily used for product development and research and development activities and is approximately 3,800 square feet with monthly rent of \$8. The lease will expire in December 2019.
- Amsterdam, Netherlands – This location is primarily for the administration of our European subsidiaries and is approximately 9,000 square feet. The monthly rent for this space is \$21, and the lease will expire in January 2021.
- Hong Kong – This location is for the administration of business throughout Asia. Monthly rent under this lease, which expires in December 2019, is approximately \$6.
- Beijing, China – This location is for the administration of business in China. Monthly rent under this lease, which expires in July 2019, is approximately \$3.

The Company believes that its existing facilities are adequate to meet its immediate needs and that suitable additional space will be available in the future on commercially reasonable terms as needed.

## **ITEM 3. LEGAL PROCEEDINGS**

The Company is not party to any material pending or threatened litigation. We may from time to time become a party to additional legal proceedings that arise in the ordinary course of business. See Note 10 – Commitments and Contingencies to our Consolidated Financial Statements.

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.



## PART II

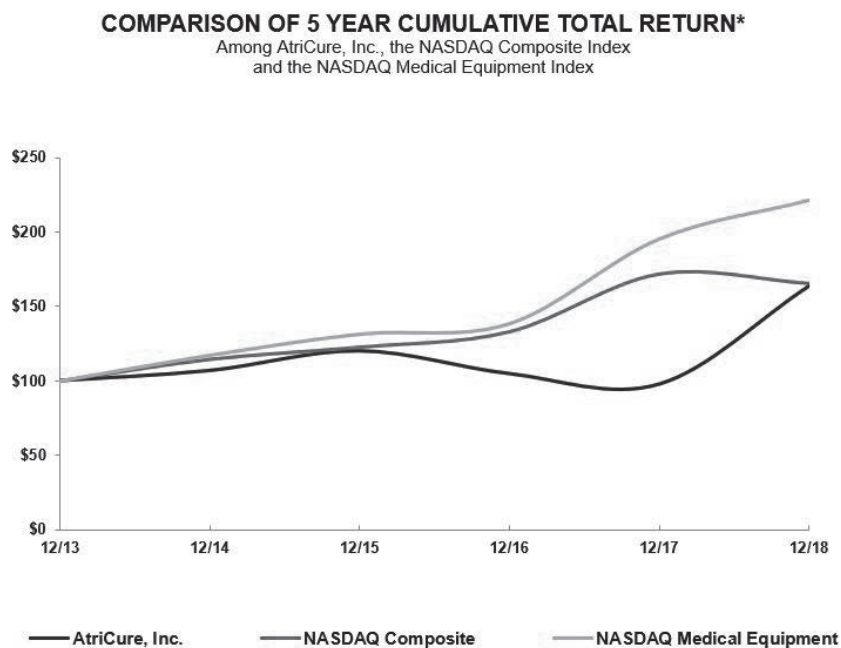
### ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### Common Stock Market Price

Our common stock is traded on the NASDAQ Global Market under the symbol “ATRC”. As of February 22, 2019, the closing price of our common stock on the NASDAQ Global Market was \$33.20 per share, and the number of stockholders of record was 81.

#### Performance Graph

The following graph compares the cumulative total stockholder return on our common stock with the cumulative total return of the NASDAQ Composite and the NASDAQ Medical Equipment Index for the period beginning on January 1, 2014 and ending on December 31, 2018.



\* \$100 invested on 12/31/13 in stock or index, including reinvestment of dividends.  
Fiscal year ending December 31.

\* This graph assumes that \$100.00 was invested on December 31, 2013 in our common stock, the NASDAQ Composite Index and the NASDAQ Medical Equipment Index, and that all dividends are reinvested. No dividends have been declared or paid on our common stock. Stock performance shown in the above chart for our common stock is historical and should not be considered indicative of future price performance.

	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
AtriCure, Inc.	\$ 100.00	\$ 106.85	\$ 120.13	\$ 97.64	\$ 163.81
NASDAQ Composite	\$ 100.00	\$ 114.62	\$ 122.81	\$ 172.11	\$ 165.84
NASDAQ Medical Equipment	\$ 100.00	\$ 117.22	\$ 131.48	\$ 195.37	\$ 221.45

## ITEM 6. SELECTED FINANCIAL DATA

The following table reflects selected financial data derived from our Consolidated Financial Statements for each of the last five years. The operating results data for the years ended December 31, 2018, 2017 and 2016 and the financial position data as of December 31, 2018 and 2017 are derived from our audited financial statements included in this Form 10-K. The operating results data for the years ended December 31, 2015 and 2014 and the financial position data as of December 31, 2016, 2015 and 2014 are derived from our audited financial statements not included in this Form 10-K. Historical results are not necessarily indicative of future results. The selected financial data set forth below should be read in conjunction with our financial statements, the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this Form 10-K.

	Year Ended December 31,				
	2018 (2)	2017	2016	2015 (1)	2014
(in thousands, except per share data)					
<b>Operating Results:</b>					
Revenue	\$ 201,630	\$ 174,716	\$ 155,109	\$ 129,755	\$ 107,454
Gross profit	147,120	126,163	111,101	92,875	75,750
Gross margin	73.0%	72.2%	71.6%	71.6%	70.5%
Net loss	(21,137)	(26,892)	(33,338)	(27,212)	(16,211)
Basic and diluted net loss per share	(0.62)	(0.83)	(1.05)	(0.97)	(0.61)
Weighted average shares outstanding	34,087	32,387	31,609	28,058	26,374
<b>Financial Position:</b>					
Cash, cash equivalents and investments	\$ 124,402	\$ 34,451	\$ 47,009	\$ 42,284	\$ 68,543
Working capital	134,457	50,355	56,889	43,164	67,865
Total assets	356,759	267,704	276,421	273,092	158,404
Long-term debt and capital leases	47,743	36,861	37,205	13,710	74
Stockholders’ equity	249,381	161,166	168,442	186,685	132,538

- (1) We acquired nContact for \$116.8 million on October 13, 2015. The acquisition is included in our Consolidated Balance Sheets beginning October 13, 2015, and the results of operations are included in our Consolidated Statements of Operations and Comprehensive Loss beginning with the period October 14, 2015 through December 31, 2015.
- (2) We adopted FASB ASC 606, “Revenue from Contracts with Customers” using the modified retrospective method effective January 1, 2018. The adoption of ASC 606 did not have a material impact on the amount and timing of revenue recognized in the Consolidated Financial Statements.

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

*(Dollar and share amounts referenced in this Item 7 are in thousands, except per share amounts.)*

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the accompanying consolidated financial statements and notes thereto contained in Item 8, “Financial Statements and Supplementary Data,” to provide an understanding of our results of operations, financial condition and cash flows. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those set forth under Item 1A “Risk Factors,” the cautionary statement regarding forward-looking statements at the beginning of Part I and elsewhere in this Form 10-K.

### Overview

We are a leading innovator in treatments for atrial fibrillation (Afib) and left atrial appendage (LAA) management. We have several product lines for the ablation of cardiac tissue, including our Isolator Synergy Ablation System, the first and only surgical device approved by the United States Food and Drug Administration (FDA) for the treatment of persistent and longstanding persistent forms of Afib in patients undergoing certain open concomitant procedures. We also offer a variety of minimally invasive ablation devices and access tools to facilitate the growing trend in less invasive cardiac and thoracic surgery. Our cryoICE cryosurgery product line offers a variety of cryoablation devices for use in various types of cardiothoracic surgery. Our AtriClip Left Atrial Appendage Exclusion System is a device specifically designed to occlude the heart’s left atrial appendage.

We believe that we are currently the market leader in the surgical treatment of Afib. Our products are used by physicians during both open-heart and minimally invasive surgical procedures, either in conjunction with heart surgery for other conditions (“concomitant” to such a procedure), or on a standalone basis. Our Isolator Synergy System is approved by FDA for the treatment of persistent and long-standing persistent Afib concomitant to other open-heart surgical procedures. All our other ablation devices are cleared for sale in the United States under FDA 510(k) clearances, including our other RF and cryoablation products, which are indicated for the ablation of cardiac tissue and/or the treatment of cardiac arrhythmias. In addition, our cryoICE probe is cleared for managing pain by temporarily ablating peripheral nerves. Our AtriClip products are 510(k)-cleared with an indication for the occlusion of the heart’s LAA, performed under direct visualization and in conjunction with other cardiac surgical procedures. Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope or other appropriate viewing technologies. We also sell reusable surgical instruments typically used in cardiac valve replacement or repair. Our Isolator Synergy clamps, Isolator Synergy pens, Coolrail® linear pen, cryosurgery devices, certain products of the AtriClip LAA Exclusion System, COBRA Fusion Ablation System, Numeris System and the EPi-Sense Guided Coagulation System with VisiTrax technology bear the CE mark and may be commercially distributed throughout the member states of the European Union and other countries that comply with or mirror the medical device directives. We anticipate that substantially all of our revenue for the foreseeable future will relate to products we currently sell, or are in the process of developing.

We sell our products to medical centers through our direct sales force in the United States and in certain international markets, such as Germany, France, the United Kingdom and the Benelux region. We also sell our products to distributors who in turn sell our products to medical centers in other international markets. Our business is primarily transacted in U.S. Dollars with the exception of transactions with our European customers, which are transacted in Euros or British Pounds.

## Results of Operations

### Year Ended December 31, 2018 compared to December 31, 2017

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts and as percentages of total revenue:

	Year Ended December 31,			
	2018		2017	
	Amount	% of Revenue	Amount	% of Revenue
	(dollars in thousands)			
Revenue	\$ 201,630	100.0 %	\$ 174,716	100.0 %
Cost of revenue	54,510	27.0	48,553	27.8
Gross profit	147,120	73.0	126,163	72.2
Operating expenses:				
Research and development expenses	34,723	17.2	34,144	19.5
Selling, general and administrative expenses	129,524	64.2	116,998	67.0
Total operating expenses	164,247	81.5	151,142	86.5
Loss from operations	(17,127)	(8.5)	(24,979)	(14.3)
Other income (expense):				
Interest expense	(4,607)	(2.3)	(2,264)	(1.3)
Interest income	1,006	0.5	227	0.1
Other	(183)	(0.1)	138	0.1
Other expense	(3,784)	(1.9)	(1,899)	(1.1)
Loss before income tax expense	(20,911)	(10.4)	26,878	(15.4)
Income tax expense	226	—	14	—
Net loss	\$ (21,137)	(10.5) %	\$ (26,892)	(15.4) %

**Revenue.** Total revenue increased 15.4% (14.9% on a constant currency basis). Revenue from customers in the United States increased \$23,759, or 17.2%, and revenue from international customers increased \$3,155, or 8.7% (6.1% on a constant currency basis). Sales in the United States grew across several key product categories. Ablation-related open-heart sales increased \$7,733, or 12.0% in primarily from increased volume in existing accounts, as well as the expansion of cryoablation into new accounts. Ablation-related minimally invasive (MIS) sales increased \$632, or 1.8%, reflecting growth in our EPi-Sense product line which was offset partially by a decline in legacy MIS and Fusion product sales. Growth in Epi-Sense products resulted from an increase in volume of procedures in existing accounts as well as the addition of new customer accounts. Appendage management sales increased \$15,610, or 41.9%, due to increased volume and pricing. Appendage management sales reflect the positive impact of the AtriClip PRO·V LAA Exclusion System and AtriClip ACH·V LAA Exclusion System, which launched in the third quarter of 2017 and first quarter of 2018. International revenue grew primarily in the United Kingdom, Germany, and Japan, partially offset by a decrease in sales in China. International growth results from increased volume in AtriClip, cryoablation and MIS product sales.

Revenue reported on a constant currency basis is a non-GAAP measure and is calculated by applying previous period foreign currency (Euro) exchange rates, which are determined by the average daily Euro to Dollar exchange rate, to each of the comparable periods. Revenue is analyzed on a constant currency basis to better measure the comparability of results between periods. Because changes in foreign currency exchange rates have a non-operating impact on revenue, we believe that evaluating growth in revenue on a constant currency basis provides an additional and meaningful assessment of revenue to both management and our investors.

**Cost of revenue and gross margin.** Cost of revenue increased \$5,957 and gross margin increased 0.8% from 72.2% in 2017 to 73.0% in 2018. Sales in 2018 reflect a higher concentration of higher-margin sales in the United States and direct markets in Europe, and a lower contribution to revenue from lower-margin sales in Asia and other distributor markets. Additionally, appendage management products launched in late 2017 and early 2018 are realizing a higher gross margin than legacy appendage management products. While overall product and geographic mix benefits margin in 2018, it is partially offset by a \$935 increase in share-based compensation expense in 2018.

**Research and development expenses.** Research and development expenses increased \$579, or 1.7%. The increases in expense reflects \$1,375 of product development, regulatory and clinical personnel costs resulting from increased headcount and \$531 of higher product development costs. These increases in expense were partially offset by \$973 of lower clinical trial and grant expenses, largely from a reduction in patient recruitment spending in 2018, and \$598 of compliance-related consulting expense.

**Selling, general and administrative expenses.** Selling, general and administrative expenses increased \$12,526, or 10.7%, primarily due to higher expense of \$16,539 related to personnel and related expenses resulting from increased headcount and variable compensation, \$1,336 of incremental legal expenses, \$1,100 related to bank fees, \$1,009 of share-based compensation, and \$1,356 related to various other operating expenses, including the provision for doubtful accounts and software maintenance and facilities

costs. These increases in expense were offset by a higher reduction in expense of \$6,747 related to the contingent consideration liability as compared to the prior period (see Note 3 – Fair Value in the Consolidated Financial Statements) and a \$1,652 decrease in marketing communication, tradeshow, and training expenses.

**Net interest expense.** Net interest expense was \$3,601 for 2018 and \$2,037 for 2017. Interest expense associated with outstanding amounts on our term loan and capital lease obligations, as well as the amortization of financing costs, are included in net interest expense. Also included in net interest expense is interest income from investments, including gains and losses on investments sold during the period. The increase in interest expense was driven by an increase in borrowings under the term loan starting in February 2018.

**Other income and expense.** Other income and expense consists primarily of foreign currency transaction gains and losses.

#### *Year Ended December 31, 2017 compared to December 31, 2016*

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts and as percentages of total revenue:

	Year Ended December 31,			
	2017		2016	
	Amount	% of Revenue (dollars in thousands)	Amount	% of Revenue
Revenue	\$ 174,716	100.0 %	\$ 155,109	100.0 %
Cost of revenue	48,553	27.8	44,008	28.4
Gross profit	126,163	72.2	111,101	71.6
Operating expenses:				
Research and development expenses	34,144	19.5	35,824	23.1
Selling, general and administrative expenses	116,998	67.0	106,415	68.6
Total operating expenses	151,142	86.5	142,239	91.7
Loss from operations	(24,979)	(14.3)	(31,138)	(20.1)
Other income (expense):				
Interest expense	(2,264)	(1.3)	(1,801)	(1.2)
Interest income	227	0.1	227	0.1
Other	138	0.1	(586)	(0.4)
Other income (expense)	(1,899)	(1.1)	(2,160)	(1.4)
Loss before income tax expense	(26,878)	(15.4)	(33,298)	(21.5)
Income tax expense	14	—	40	—
Net loss	\$ (26,892)	(15.4) %	\$ (33,338)	(21.5) %

**Revenue.** Total revenue increased 12.6% (12.4% on a constant currency basis). Revenue from sales to customers in the United States increased \$16,002, or 13.1%, and revenue from international customers increased \$3,605, or 11.0% (9.6% on a constant currency basis). Sales in the United States grew across several key product categories. Ablation-related open-heart sales increased \$6,467, or 11%, primarily due to growth in our cryo products line, including the impact of the cryoFORM® product which launched in the second quarter of 2016. Ablation-related minimally invasive (MIS) sales increased \$3,252, or 10%, reflecting strong growth in our EPi-Sense product line which was offset partially by a decline in legacy MIS product sales. Growth in EPi-Sense product resulted from both an increase in volume of procedures in existing accounts as well as the addition of new customer accounts. Legacy MIS product sales in the United States were impacted throughout 2017 by various disruptions to key accounts such as physician movement and wildfires in California. AtriClip sales increased \$6,960, or 23%, due to increased volume and pricing. AtriClip sales reflect the positive impact of the AtriClip PRO2® and AtriClip PRO·V LAA Exclusion System devices, which launched in the second quarter of 2016 and late third quarter of 2017, respectively. International revenue grew primarily in Asia, Germany, France, Turkey, Austria and the Benelux region as a result of increased volumes in AtriClip and cryo product sales.

**Cost of revenue and gross margin.** Cost of revenue increased \$4,545 and gross margin increased 0.6% from 71.6% in 2016 to 72.2% in 2017. While 2017 includes heavier capital equipment sales, this factor is offset by a slight increase in the percentage of total revenue from customers in the United States, favorable product mix and lower inventory obsolescence charges in 2017.

**Research and development expenses.** Research and development expenses decreased \$1,680, or 4.7%. The decrease in expense was primarily due to lower expense of \$1,887 related to product development projects resulting from the timing of project activities, \$474 related to regulatory filing fees, \$339 related to clinical trials and grants and \$276 related to amortization expense. These decreases in expense were partially offset by higher expense of \$1,115 related to product development, regulatory and clinical personnel costs resulting from increased headcount and \$227 related to share-based compensation expense.



**Selling, general and administrative expenses.** Selling, general and administrative expenses increased \$10,583, or 9.9%, primarily due to higher expense of \$9,136 related to personnel and related expenses, such as travel costs, resulting from increased headcount, \$2,563 related to professional education, marketing and tradeshow expenses, \$2,501 related to share-based compensation expense, \$1,405 related to legal expenses and \$530 related to product samples, largely related to the September 2017 launch of the AtriClip PRO·V LAA Exclusion System. These increases in expense were offset by a \$5,047 reduction in expense related to the contingent consideration adjustment and lower expenses related to consulting and professional services.

**Net interest expense.** Net interest expense was \$2,037 for 2017 and \$1,574 for 2016. Interest expense associated with outstanding amounts on our term loan and capital lease obligations, as well as the amortization of financing costs, are included in net interest expense. Also included in net interest expense is interest income from investments, including gains and losses on investments sold during the period. The increase in interest expense was driven by a full year of expense incurred on borrowings under the term loan in 2017, which was effective April 2016.

**Other income and expense.** Other income and expense consists primarily of foreign currency transaction gains and losses.

## Liquidity and Capital Resources

As of December 31, 2018, the Company had cash, cash equivalents and investments of \$124,402 and outstanding debt of \$40,000. We had unused borrowing capacity of \$20,000 under our revolving credit facility. Most of our operating cash and all cash equivalents and investments are held by United States financial institutions. We had net working capital of \$134,457 and an accumulated deficit of \$247,003 as of December 31, 2018.

**Cash flows used in operating activities.** Net cash used in operating activities was \$4,171 during 2018. The primary net uses of cash for operating activities were as follows:

- the net loss of \$21,137, which includes \$15,567 of non-cash expenses comprised of \$16,495 in share-based compensation, \$8,754 of depreciation and amortization and \$515 of debt fee amortization, offset by a decrease in fair value of contingent consideration of \$10,825; and
- a net increase in cash used related to changes in operating assets and liabilities of \$1,399, due primarily to the following:
  - an increase in accounts receivable of \$2,837, due primarily to increased sales and the timing of collections and
  - a \$4,618 increase in accounts payable and accrued liabilities reflecting increased accrued variable compensation payments.

**Cash flows used in investing activities.** Net cash used in investing activities was \$85,404 during 2018. The primary uses of cash were \$106,588 of purchases of available-for-sale securities and \$6,211 related to the purchase of property and equipment, which included the placement of generators with our customers. These uses of cash were offset by \$27,389 provided by sales and maturities of available-for-sale securities.

**Cash flows provided by financing activities.** Net cash provided by financing activities during 2018 was \$100,176, which was primarily due to net proceeds generated from a common stock offering of \$82,873, proceeds from debt borrowings of \$17,381, proceeds from stock option exercises of \$6,012 and proceeds from the issuance of common stock under our employee stock purchase plan of \$2,383. This was partially offset by shares repurchased for payment of taxes on stock awards of \$4,457, debt and capital lease payments of \$1,755, debt fee payments of \$1,136, and payment of contingent consideration to former nContact shareholders of \$1,125.

**Credit facility.** The Company's Loan and Security Agreement with Silicon Valley Bank (SVB), as amended, restated, and modified effective February 23, 2018 and as further amended on December 28, 2018 (Loan Agreement), provides for a \$40,000 term loan and a \$20,000 revolving line of credit with an option to increase the revolving line of credit by an additional \$20,000. The term loan and revolving credit facility both mature or expire, as applicable, in February 2023. According to the Loan Agreement, principal payments on the term loan are to be made ratably commencing eighteen months after the inception of the loan (September 2019) through the loan's maturity date. The term loan accrues interest at the greater of the Prime Rate plus 0.50% or 5.00%. Borrowing availability under the revolving credit facility is based on the lesser of \$20,000 or a borrowing base calculation as defined by the Loan Agreement. As of December 31, 2018, we had no borrowings under the revolving credit facility, and we had borrowing availability of \$20,000. The revolving line of credit is subject to an annual facility fee of 0.33% of the revolving line of credit, and any borrowings bear interest at the greater of the Prime Rate or 4.50%. The Loan Agreement also provides for certain prepayment and early termination fees only if the term loan is repaid before January 2020 and establishes a minimum liquidity ratio, along with other customary terms and conditions. Specified assets have been pledged as collateral. We are in compliance with the covenants of the Loan Agreement as of December 31, 2018.

In connection with the terms of our corporate headquarters lease agreement, a letter of credit in the amount of \$1,250 was issued to the landlord in October 2015. The letter of credit is renewed annually and remains outstanding as of December 31, 2018.

**Uses of liquidity and capital resources.** Our future capital requirements depend on a number of factors, including the rate of market acceptance of our current and future products, the resources we devote to developing and supporting our products, future expenses to expand and support our sales and marketing efforts, costs relating to changes in regulatory policies or laws that affect our operations and costs of filings, costs associated with clinical trials and securing regulatory approval for new products, costs associated with acquiring and integrating businesses, costs associated with prosecuting, defending and enforcing our intellectual property rights and possible acquisitions and joint ventures. Global economic turmoil may adversely impact our revenue, access to the capital markets or future demand for our products.

We have on file with the SEC a shelf registration statement which allows us to sell any combination of senior or subordinated debt securities, common stock, preferred stock, warrants, depositary shares and units in one or more offerings should we choose to do so in the future. We expect to maintain the effectiveness of this shelf registration statement for the foreseeable future.

We believe that our current cash, cash equivalents and investments, along with the cash we expect to generate or use for operations or access via our term loan and revolving line of credit, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next twelve months. The nContact transaction provides for contingent consideration to be paid upon attaining specified regulatory approvals and revenue milestones over the next two years. Subject to the terms and conditions of the nContact merger agreement, such contingent consideration will be paid in AtriCure common stock and cash, with a requirement to make payments in AtriCure common stock first, up to a specified maximum number of shares. Over the next twelve months, we do not expect our cash requirements to include significant payments of contingent consideration based on terms of the acquisition agreement and related milestones.

If our sources of cash are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a revised or additional credit facility. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. Finally, our term loan agreement and revolving line of credit require compliance with certain financial and other covenants. If we are unable to maintain these financing arrangements, we may be required to reduce the scope of our planned research and development, clinical activities and selling, training, education and marketing efforts.

## Contractual Obligations and Commitments

The following table sets forth our approximate aggregate obligations at December 31, 2018 for future payments under contracts and other contingent commitments:

Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-term debt <sup>(1)</sup>	\$ 40,000	\$ 3,810	\$ 22,857	\$ 13,333	\$ —
Capital leases <sup>(2)</sup>	19,020	1,493	3,032	3,102	11,393
Operating leases <sup>(3)</sup>	3,010	1,064	1,541	405	—
Royalty obligations <sup>(4)</sup>	2,715	2,715	—	—	—
Restricted grants	562	562	—	—	—
Total contractual obligations	<u>\$ 65,307</u>	<u>\$ 9,644</u>	<u>\$ 27,430</u>	<u>\$ 16,840</u>	<u>\$ 11,393</u>

- (1) Long-term debt represents principal repayments related to our term loan. Principal payments under the term loan commence in September 2019 and are made ratably until maturity in February 2023. Interest on the term loan accrues at the greater of the Prime Rate plus 0.50% or 5.00% and is payable monthly over the term of the loan. In addition, we have a contractual obligation to pay interest on amounts drawn on the revolving credit facility.
- (2) Capital leases consist of principal and interest payments related to our Mason, Ohio headquarters building and computer equipment. See Note 9 – Indebtedness to our Consolidated Financial Statements.
- (3) Represents lease commitments under various operating leases, primarily for office and warehouse space.
- (4) Represents obligations for royalty agreements ranging from 3% to 5% of specified product sales estimated using 2018 sales. See Note 10 – Commitments and Contingencies to our Consolidated Financial Statements.

We have contractual obligations for contingent consideration payments related to the nContact acquisition. Subject to the terms and conditions of the nContact merger agreement, such contingent consideration will be paid in AtriCure common stock and cash, with a requirement to make payments in AtriCure common stock first, up to a specified maximum number of shares.

## Off-Balance-Sheet Arrangements

As of December 31, 2018, we had operating lease agreements that were not recorded on the Consolidated Balance Sheets. Operating leases are used in the normal course of business.

## Inflation

Inflation has not had a significant impact on our historical operations, and we do not expect it to have a significant impact on our results of operations or financial condition in the foreseeable future.

## Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses, and disclosures of contingent assets and liabilities at the date of the financial statements. On a periodic basis, we evaluate our estimates, using authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates under different assumptions or conditions. We have described our significant accounting policies in Note 1 – Description of Business and Summary of Significant Accounting Policies to our consolidated financial statements included in this Form 10-K.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

**Revenue Recognition**— Revenue is generated primarily from the sale of medical devices. The Company recognizes revenue in an amount that reflects the consideration the Company expects to be entitled to in exchange for those devices when control of promised devices is transferred to customers. At contract inception, the Company assesses the products promised in its contracts with customers and identifies a performance obligation for each promise to transfer to the customer a product that is distinct. The Company's devices are distinct and represent performance obligations. These performance obligations are satisfied and revenue is recognized at a point in time upon shipment or delivery of products. Sales of devices are categorized as follows: open-heart ablation, minimally invasive ablation (MIS), appendage management and valve tools. Shipping and handling activities performed after control over products transfers to customers are considered activities to fulfill the promise to transfer the products rather than as separate promises to customers. Products are sold primarily through a direct sales force and through distributors in certain international

markets. Terms of sale are generally consistent for both end-users and distributors, except that payment terms are generally net 30 days for end-users and net 60 days for distributors, with limited exceptions. The Company does not maintain any post-shipping obligations to customers. No installation, calibration or testing of products is performed by the Company subsequent to shipment in order to render products operational.

We account for revenue in accordance with FASB ASC 606, “Revenue from Contracts with Customers”. Significant judgments and estimates involved in the Company’s recognition of revenue include the determination of the timing of transfer of control of products to customers and the estimation of a provision for returns. The Company considers the following indicators when determining when control of the product transfers to customers: (i) the Company has a right to payment in accordance with the shipping terms set forth in its contracts with customers; (ii) customers have legal title to products in accordance with shipping terms; (iii) the Company transfers physical possession of products either when the Company presents the products to a third party carrier for delivery to a customer (FOB shipping point) or when a customer receives the delivered goods (FOB destination); (iv) customers have the significant risks and rewards of ownership of products; and (v) customers have accepted products in connection with contractual shipping terms.

We maintain a provision for sales returns and allowances to account for potential returns of defective or damaged products, products shipped in error and invoice adjustments. We adjust the provision quarterly using a combination of specific identification and an estimated general reserve based on historical experience.

**Allowance for Doubtful Accounts Receivable**—We evaluate the collectability of accounts receivable to determine the appropriate reserve for doubtful accounts. In determining the amount of the reserve, we consider the aging of account balances, historical credit losses, customer-specific information and other relevant factors. We review accounts receivable and adjust the allowance based on current circumstances and charge off uncollectible receivables against the allowance when all attempts to collect the receivable have failed. Our history of write-offs against the allowance has not been significant.

**Inventories**—Our inventories are stated at the lower of cost or net realizable value based on the first-in, first-out cost method (FIFO) and consist of raw materials, work in process and finished goods. Our industry is characterized by rapid product development and frequent new product introductions. Uncertain timing of product approvals, variability in product launch strategies and variation in product use all impact excess and obsolete inventory. We estimate and record reserves for excess, expired and obsolete inventory on a quarterly basis.

**Property and Equipment**—We state property and equipment at cost less accumulated depreciation. Depreciation is computed using the straight-line method for financial reporting purposes and applied over the estimated useful lives of the assets. Included in property and equipment are generators and other capital equipment (such as our RF and cryo generators) that are placed with direct customers that use our disposable products. These generators and other capital equipment are depreciated over a period of one to three years, which approximates their useful lives, and such depreciation is included in cost of revenue. We estimate the useful lives of this equipment based on anticipated usage by our customers and the timing and impact of our expected new technology rollouts. To the extent we experience changes in the usage of this equipment or the introductions of new technologies, the estimated useful lives of this equipment may change in a future period.

**Intangible Assets**—Intangible assets with determinable useful lives are amortized on a straight-line basis over the estimated periods benefited. Included in intangible assets is In Process Research and Development (IPR&D), which represents the value of acquired technology which has not yet reached technological feasibility. The primary basis for determining the technological feasibility is obtaining specific regulatory approvals. IPR&D is accounted for as an indefinite-lived intangible asset until completion or abandonment of the IPR&D project. Upon completion of the development project, the IPR&D will be amortized over its estimated useful life. If the IPR&D project is abandoned or regulatory approvals are not obtained, the related IPR&D asset would be written off. We review intangible assets for impairment using our best estimates based on reasonable and supportable assumptions and projections.

**Goodwill**— Goodwill represents the excess of purchase price over the fair value of the net assets acquired in business combinations. We test goodwill for impairment annually on October 1, or more often if impairment indicators are present. Our goodwill is accounted for in a single reporting unit representing the Company as a whole.

**Share-Based Employee Compensation**—We account for share-based compensation for all share-based payment awards, including stock options, restricted stock awards, restricted stock units, performance share awards, and stock purchases related to an employee stock purchase plan, based on their estimated fair values. We estimate the fair value of time-based options on the date of grant using the Black-Scholes option pricing model (Black-Scholes model). Our determination of fair value of share-based payment awards is affected by our stock price, as well as assumptions regarding a number of subjective variables. These variables include but are not limited to our expected stock price volatility over the term of the awards and actual and projected employee stock option exercise behaviors. The fair value of our market-based performance option grants is estimated at the date of grant using a Monte-Carlo simulation. The value of the portion of the awards that is ultimately expected to vest is recognized as expense over the requisite service periods in our Consolidated Statements of Operations and Comprehensive Loss.

We estimate the fair value of restricted stock awards, restricted stock units and performance share awards based upon the grant date closing market price of our common stock.

We also have an employee stock purchase plan (ESPP) which is available to all eligible employees as defined by the plan document. Under the ESPP, shares of our common stock may be purchased at a discount. We estimate the number of shares to be purchased under the ESPP at the beginning of the purchase period and calculate estimated compensation expense using the Black-Scholes model based upon the fair value of the stock at the beginning of the purchase period. Compensation expense is recognized over each purchase period, and expense is adjusted at the time of stock purchase.

**Acquisition-Related Contingent Consideration**—Contingent consideration arrangements obligate the Company to pay former shareholders of an acquired entity certain amounts if specified future events occur or conditions are met, such as the achievement of certain technological milestones or the achievement of targeted revenue milestones. We measure such liabilities using unobservable inputs by applying an income approach, such as the discounted cash flow technique or the probability-weighted scenario method. Various key assumptions, such as the probability and timing of achievement of the agreed milestones, projected revenues from acquisitions and the discount rate, are used in the determination of fair value of contingent consideration arrangements and are not observable in the market. Subsequent revisions to key assumptions, which impact the estimated fair value of contingent consideration liabilities, are reflected in the Consolidated Statements of Operations and Comprehensive Loss.

**Income Taxes**—Deferred income tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred income tax assets and liabilities from a change in tax rates is recognized in the period that includes the enactment date.

Our estimate of the valuation allowance for deferred tax assets requires us to make significant estimates and judgments about our future operating results. Deferred income tax assets are reduced by valuation allowances if, based on the consideration of all available evidence, it is more-likely-than-not that some portion of the deferred tax asset will not be realized. Significant weight is given to evidence that can be objectively verified. We evaluate deferred income tax assets on an annual basis to determine if valuation allowances are required by considering all available evidence. Deferred income tax assets are realized by having sufficient future taxable income to allow the related tax benefits to reduce taxes otherwise payable. The sources of taxable income that may be available to realize the benefit of deferred tax assets are future reversals of existing taxable temporary differences, future taxable income, exclusive of reversing temporary differences and carryforwards, taxable income in carry-back years and tax planning strategies that are both prudent and feasible. In evaluating whether to record a valuation allowance, the applicable accounting standards deem that the existence of cumulative losses in recent years is a significant piece of objectively verifiable negative evidence that must be overcome by objectively verifiable positive evidence to avoid the need to record a valuation allowance.

We believe our critical accounting policies regarding revenue recognition, allowance for uncollectible accounts receivable, inventories, property and equipment, intangible assets, goodwill, share-based employee compensation, acquisition-related contingent consideration and income taxes affect our more significant judgments and estimates used in the preparation of our consolidated financial statements. We base our judgments and estimates on historical experience, current conditions and other reasonable factors.

## **Recent Accounting Pronouncements**

See Note 2 – Recent Accounting Pronouncements to our Consolidated Financial Statements for further information.



## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

*(Amounts referenced in this Item 7A are in thousands, except per share amounts.)*

The Company is exposed to various market risks, which include potential losses arising from adverse changes in market rates and prices, such as foreign exchange fluctuations and changes in interest rates. Interest on the term loan and revolving credit facility accrue at a variable rate based on the Prime Rate.

For the years ended December 31, 2018 and 2017, products sold by AtriCure Europe, B.V. accounted for 12.5% of the Company's total revenue. Since such revenue was primarily denominated in Euros or British Pounds, the Company is exposed to exchange rate fluctuations between the Euro and the U.S. Dollar and between the British Pound and the Euro. For the years ended December 31, 2018 and 2017, foreign currency transaction (losses) gains of \$(183) and \$138 were recorded primarily in connection with settlements of the intercompany receivable balance and invoices transacted in British Pounds. For revenue denominated in Euros, if there is an increase in the rate at which Euros are exchanged for U.S. Dollars, it will require more Euros to equal a specified amount of U.S. Dollars than before the rate increase. In such cases, and if products are priced in Euros, the Company will receive less in U.S. Dollars than was received before the rate increase went into effect. If products are priced in U.S. Dollars and competitors price their products in the local currency, an increase in the relative strength of the U.S. Dollar could result in the Company's price not being competitive in a market where business is not transacted in U.S. Dollars. The Euro to U.S. Dollar conversion rate fluctuations may impact our reported revenue and expenses.

The Company invests its cash primarily in money market accounts, U.S. government agencies and securities, corporate bonds, asset-backed securities and commercial paper. Although the Company believes its cash to be invested in a conservative manner, with cash preservation being the primary investment objective, the value of the securities held will fluctuate with changes in the financial markets including, among other things, changes in interest rates, credit quality and general volatility. This risk is managed by investing in high quality investment grade securities with short-term maturities.

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalent balances and investments in corporate bonds. Certain of AtriCure's cash and cash equivalents balances exceed FDIC insured limits or are invested in money market accounts with investment banks that are not FDIC-insured. The Company places its cash and cash equivalents in what it believes to be credit-worthy financial institutions. As of December 31, 2018, \$31,955 of the cash and cash equivalents balance was in excess of FDIC limits.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**ATRICURE, INC. AND SUBSIDIARIES  
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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of  
AtriCure, Inc.  
Mason, Ohio

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of AtriCure, Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and the schedule listed in the Index at Item 15 (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 1, 2019, expressed an unqualified opinion on the Company's internal control over financial reporting.

### Basis for Opinion

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

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

/s/ Deloitte & Touche LLP

Cincinnati, Ohio  
March 1, 2019

We have served as the Company's auditor since 2002.

**ATRICURE, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
**DECEMBER 31, 2018 and 2017**  
(In Thousands, Except Per Share Amounts)

	2018	2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 32,231	\$ 21,809
Short-term investments	92,171	12,642
Accounts receivable, less allowance for doubtful accounts of \$547 and \$32	25,195	23,083
Inventories	22,484	22,451
Prepaid and other current assets	2,592	2,273
Total current assets	174,673	82,258
Property and equipment, net	27,080	28,749
Intangible assets, net	49,254	50,764
Goodwill	105,257	105,257
Other noncurrent assets	495	676
Total Assets	<u>\$ 356,759</u>	<u>\$ 267,704</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 9,659	\$ 12,431
Accrued liabilities	25,840	18,911
Other current liabilities and current maturities of capital leases and long-term debt	4,717	561
Total current liabilities	40,216	31,903
Capital leases	12,172	12,761
Long-term debt	35,571	24,100
Other noncurrent liabilities	19,419	37,774
Total Liabilities	107,378	106,538
Commitments and contingencies (Note 10)		
Stockholders' Equity:		
Common stock, \$0.001 par value, 90,000 shares authorized and 38,604 and 34,586 issued and outstanding	39	35
Additional paid-in capital	496,544	386,963
Accumulated other comprehensive (loss) income	(199)	34
Accumulated deficit	(247,003)	(225,866)
Total Stockholders' Equity	249,381	161,166
Total Liabilities and Stockholders' Equity	<u>\$ 356,759</u>	<u>\$ 267,704</u>

See accompanying notes to consolidated financial statements.

**ATRICURE, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**YEARS ENDED DECEMBER 31, 2018, 2017 and 2016**  
(In Thousands, Except Per Share Amounts)

	2018	2017	2016
Revenue	\$ 201,630	\$ 174,716	\$ 155,109
Cost of revenue	54,510	48,553	44,008
Gross profit	147,120	126,163	111,101
Operating expenses:			
Research and development expenses	34,723	34,144	35,824
Selling, general and administrative expenses	129,524	116,998	106,415
Total operating expenses	164,247	151,142	142,239
Loss from operations	(17,127)	(24,979)	(31,138)
Other income (expense):			
Interest expense	(4,607)	(2,264)	(1,801)
Interest income	1,006	227	227
Other	(183)	138	(586)
Loss before income tax expense	(20,911)	(26,878)	(33,298)
Income tax expense	226	14	40
Net loss	<u>\$ (21,137)</u>	<u>\$ (26,892)</u>	<u>\$ (33,338)</u>
Basic and diluted net loss per share	\$ (0.62)	\$ (0.83)	\$ (1.05)
Weighted average shares outstanding – basic and diluted	34,087	32,387	31,609
Comprehensive loss:			
Unrealized (loss) gain on investments	\$ (31)	\$ 15	\$ 18
Foreign currency translation adjustment	(202)	487	125
Other comprehensive (loss) income	(233)	502	143
Net loss	(21,137)	(26,892)	(33,338)
Comprehensive loss, net of tax	<u>\$ (21,370)</u>	<u>\$ (26,390)</u>	<u>\$ (33,195)</u>

See accompanying notes to consolidated financial statements.



**ATRICURE, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**YEARS ENDED DECEMBER 31, 2018, 2017, and 2016**  
**(In Thousands)**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2015	32,274	\$ 32	\$ 352,900	\$ (165,636)	\$ (611)	\$ 186,685
Issuance of common stock under equity incentive plans	934	1	1,636	—	—	1,637
Issuance of common stock under employee stock purchase plan	134	—	1,618	—	—	1,618
Share-based employee compensation expense	—	—	11,697	—	—	11,697
Other comprehensive income	—	—	—	—	143	143
Net loss	—	—	—	(33,338)	—	(33,338)
Balance—December 31, 2016	33,342	\$ 33	\$ 367,851	\$ (198,974)	\$ (468)	\$ 168,442
Issuance of common stock under equity incentive plans	1,112	2	2,387	—	—	2,389
Issuance of common stock under employee stock purchase plan	132	—	2,110	—	—	2,110
Share-based employee compensation expense	—	—	14,615	—	—	14,615
Other comprehensive income	—	—	—	—	502	502
Net loss	—	—	—	(26,892)	—	(26,892)
Balance—December 31, 2017	34,586	\$ 35	\$ 386,963	\$ (225,866)	\$ 34	\$ 161,166
Issuance of common stock through public offering	2,875	3	82,870	—	—	82,873
Issuance of common stock for settlement of contingent consideration	232	—	6,279	—	—	6,279
Issuance of common stock under equity incentive plans	781	1	1,554	—	—	1,555
Issuance of common stock under employee stock purchase plan	130	—	2,383	—	—	2,383
Share-based employee compensation expense	—	—	16,495	—	—	16,495
Other comprehensive loss	—	—	—	—	(233)	(233)
Net loss	—	—	—	(21,137)	—	(21,137)
Balance—December 31, 2018	38,604	\$ 39	\$ 496,544	\$ (247,003)	\$ (199)	\$ 249,381

See accompanying notes to consolidated financial statements.

**ATRICURE, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2018, 2017 and 2016**  
**(In Thousands)**

	2018	2017	2016
Cash flows from operating activities:			
Net loss	\$ (21,137)	\$ (26,892)	\$ (33,338)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation expense	16,495	14,615	11,697
Depreciation	7,244	7,761	7,655
Amortization of intangible assets	1,510	1,367	1,644
Amortization of deferred financing costs	515	264	218
Loss on disposal of property and equipment and impairment of assets	323	336	433
Realized loss (gain) from foreign exchange on intercompany transactions	165	(173)	407
(Accretion) amortization of investments	(362)	30	126
Provision for doubtful accounts	598	(172)	149
Change in fair value of contingent consideration	(10,825)	(4,078)	969
Payment of contingent consideration in excess of purchase accounting amount	(96)	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(2,837)	(1,464)	(1,982)
Inventories	(146)	(4,477)	(79)
Other current assets	(367)	829	122
Accounts payable	(2,398)	1,290	(1,072)
Accrued liabilities	7,016	2,228	(1,915)
Other noncurrent assets and liabilities	131	(408)	(153)
Net cash used in operating activities	(4,171)	(8,944)	(15,119)
Cash flows from investing activities:			
Purchases of available-for-sale securities	(106,588)	(16,455)	(28,592)
Sales and maturities of available-for-sale securities	27,389	26,600	24,202
Purchases of property and equipment	(6,211)	(6,384)	(7,692)
Proceeds from sale of property and equipment	6	—	3
Net cash provided by (used in) investing activities	(85,404)	3,761	(12,079)
Cash flows from financing activities:			
Proceeds from sale of stock, net of offering costs of \$229	82,873	—	—
Proceeds from debt borrowings	17,381	—	25,000
Payments on debt and capital leases	(1,755)	(1,689)	(439)
Payment of debt fees	(1,136)	(50)	(120)
Proceeds from stock option exercises	6,012	4,402	3,337
Shares repurchased for payment of taxes on stock awards	(4,457)	(2,013)	(1,701)
Proceeds from issuance of common stock under employee stock purchase plan	2,383	2,110	1,618
Payment of contingent consideration liability previously established in purchase accounting	(1,125)	—	—
Net cash provided by financing activities	100,176	2,760	27,695
Effect of exchange rate changes on cash and cash equivalents	(179)	24	(53)
Net increase (decrease) in cash and cash equivalents	10,422	(2,399)	444
Cash and cash equivalents—beginning of period	21,809	24,208	23,764
Cash and cash equivalents—end of period	\$ 32,231	\$ 21,809	\$ 24,208
Supplemental cash flow information:			
Cash paid for interest	\$ 3,870	\$ 2,002	\$ 1,506
Cash paid for income taxes	65	37	30
Non-cash investing and financing activities:			
Accrued purchases of property and equipment	348	650	340
Assets acquired through capital lease	24	2	152
Share-settled portion of contingent consideration	6,279	—	—
Capital lease asset early termination	(6)	—	37

**ATRICURE, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(In Thousands, Except Per Share Amounts)**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Nature of the Business**—The “Company” or “AtriCure” consists of AtriCure, Inc. and its wholly-owned subsidiaries. The Company is a leading innovator in treatments for atrial fibrillation (Afib) and left atrial appendage (LAA) management and sells its products to medical centers globally through its direct sales force and distributors.

**Principles of Consolidation**—The Consolidated Financial Statements include the accounts of the Company, AtriCure, LLC, Endoscopic Technologies, LLC and nContact Surgical, LLC, the Company’s wholly-owned subsidiaries, all organized in the State of Delaware; AtriCure Europe B.V. (AtriCure Europe), the Company’s wholly-owned subsidiary incorporated in the Netherlands; AtriCure Spain, S.L., AtriCure Europe’s wholly-owned subsidiary incorporated in Spain; AtriCure Germany GmbH, AtriCure Europe’s wholly-owned subsidiary incorporated in Germany; AtriCure Hong Kong Limited, the Company’s wholly-owned subsidiary incorporated in Hong Kong; and AtriCure (Beijing) Medicine Information Consulting Services, Co., Ltd., AtriCure Hong Kong Limited’s wholly-owned subsidiary incorporated in Beijing. All intercompany accounts and transactions have been eliminated in consolidation.

**Cash and Cash Equivalents**—The Company considers highly liquid investments with maturities of three months or less at the date of acquisition as cash equivalents.

**Investments**—The Company places its investments primarily in U.S. Government agencies and securities, corporate bonds, commercial paper and asset-backed securities and classifies all investments as available-for-sale. Investments with maturities of less than one year are classified as short-term investments. Investments are recorded at fair value, with unrealized gains and losses recorded as accumulated other comprehensive income (loss). Gains and losses are recognized using the specific identification method when securities are sold and are included in interest income or expense.

**Revenue Recognition**—The Company recognizes revenue when control of promised goods is transferred to customers in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods. This generally occurs upon shipment of goods to customers. See Note 11 for further discussion on revenue.

**Sales Returns and Allowances**—The Company maintains a provision for potential returns of defective or damaged products, products shipped in error and invoice adjustments. The Company adjusts the provision quarterly using a combination of specific identification and an estimated general reserve based on historical experience. Increases to the provision result in a reduction of revenue and the provision is included in accrued liabilities.

**Allowance for Doubtful Accounts Receivable**—The Company evaluates the collectability of accounts receivable to determine the appropriate reserve for doubtful accounts. In determining the amount of the reserve, the Company considers aging of account balances, historical credit losses, customer-specific information and other relevant factors. An increase to the allowance for doubtful accounts results in a corresponding increase in selling, general and administrative expenses. The Company reviews accounts receivable and adjusts the allowance based on current circumstances and charges off uncollectible receivables against the allowance when all attempts to collect the receivable have failed. The Company’s history of write-offs has not been significant.

**Inventories**—Inventories are stated at the lower of cost or net realizable value based on the first-in, first-out cost method (FIFO) and consist of raw materials, work in process and finished goods. The Company’s industry is characterized by rapid product development and frequent new product introductions. Uncertain timing of regulatory approvals, variability in product launch strategies and variation in product use all impact inventory reserves for excess, obsolete and expired products. An inventory reserve for excess, slow moving and obsolete inventory is recorded quarterly. An increase to inventory reserves results in a corresponding increase in cost of revenue. Inventories are written off against the reserve when they are physically disposed.

**Property and Equipment**—Property and equipment is stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of assets (see Note 7). The Company reassesses the useful lives of property and equipment annually and retires assets if they are no longer in service. Maintenance and repair costs are expensed as incurred.

The Company’s RF and cryo generators are generally placed with customers served by our direct sales force. The estimated useful lives of this equipment are based on anticipated usage by customers and the timing and impact of expected new technology rollouts by the Company and may change in a future period if the Company experiences changes in the usage of the equipment or introduces new technologies. Depreciation related to generators and other capital equipment is recorded in cost of revenue.

**ATRICURE, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(In Thousands, Except Per Share Amounts)**

The Company reviews property and equipment for impairment using its best estimates based on reasonable and supportable assumptions and projections of expected future cash flows. Property and equipment impairments recorded by the Company have not been significant.

**Intangible Assets**—Intangible assets with determinable useful lives are amortized on a straight-line basis over the estimated periods benefited. The Company reassesses the useful lives of intangible assets annually.

Included in intangible assets is In Process Research and Development (IPR&D), representing the value of acquired technology which has not yet reached technological feasibility. The primary basis for determining the technological feasibility is obtaining specific regulatory approvals. IPR&D is accounted for as an indefinite-lived intangible asset until completion or abandonment of the IPR&D project. Upon completion of the development project, the IPR&D will be amortized over its estimated useful life. If the IPR&D project is abandoned, the related IPR&D asset would be written off. The IPR&D asset represents an estimate of the fair value of the pre-market approval (PMA) that may result from the CONVERGE IDE clinical trial.

The Company reviews intangible assets for impairment using its best estimates based on reasonable and supportable assumptions and projections at least annually. The Company has historically tested IPR&D for impairment annually on November 30. In 2018, the Company has changed its testing date from November 30 to October 1. This change in the method of applying an accounting principle is preferred as it better aligns with the Company's long-term planning process, which is a significant input to the testing, and it did not result in a material change to the Company's Consolidated Financial Statements.

**Goodwill**—Goodwill represents the excess of purchase price over the fair value of the net assets acquired in business combinations. The Company's goodwill is accounted for in a single reporting unit representing the Company as a whole. The Company has historically tested goodwill for impairment annually on November 30, or more often if impairment indicators are present. In 2018, the Company has changed its goodwill testing date from November 30 to October 1. This change in the method of applying an accounting principle is preferred by the Company as it better aligns with the Company's long-term planning process, which is a significant input to the testing, and it did not result in a material change to the Company's Consolidated Financial Statements.

**Other Noncurrent Liabilities**—Other noncurrent liabilities consist of contingent consideration recorded in business combinations, deferred revenues and other contractual obligations. The contingent consideration balance is included in noncurrent liabilities as such settlement is both required and expected to be made primarily in shares of the Company's common stock pursuant to the nContact merger agreement.

**Other Income (Expense)**—Other income (expense) consists of foreign currency transaction gains and losses generated by settlements of intercompany balances denominated in Euros and invoices denominated in British Pounds.

**Taxes**—Deferred income tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred income tax assets and liabilities from a change in tax rates is recognized in the period that includes the enactment date.

The Company's estimate of the valuation allowance for deferred income tax assets requires it to make significant estimates and judgments about its future operating results. Deferred income tax assets are reduced by valuation allowances if, based on the consideration of all available evidence, it is more-likely-than-not that some portion of the deferred income tax asset will not be realized. Significant weight is given to evidence that can be objectively verified. The Company evaluates deferred tax income assets on an annual basis to determine if valuation allowances are required by considering all available evidence. Deferred income tax assets are realized by having sufficient future taxable income to allow the related tax benefits to reduce taxes otherwise payable. The sources of taxable income that may be available to realize the benefit of deferred income tax assets are future reversals of existing taxable temporary differences, future taxable income, exclusive of reversing temporary differences and carryforwards, taxable income in carry-back years and tax planning strategies that are both prudent and feasible. In evaluating whether to record a valuation allowance, the applicable accounting standards deem that the existence of cumulative losses in recent years is significant objectively verifiable negative evidence that must be overcome by objectively verifiable positive evidence to avoid the need to record a valuation allowance. The Company has recorded a full valuation allowance against substantially all net deferred income tax assets as it is more-likely-than-not that the benefit of the deferred income tax assets will not be recognized in future periods.

**Net Loss Per Share**—Basic and diluted net loss per share is computed in accordance with FASB ASC 260 "Earnings Per Share" (ASC 260) by dividing the net loss by the weighted average number of common shares outstanding during the period. Since the Company has experienced net losses for all periods presented, net loss per share excludes the effect of 3,869, 4,321 and 4,320 stock options, restricted stock awards, restricted stock units and performance share awards as of December 31, 2018, 2017 and 2016 because

**ATRICURE, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(In Thousands, Except Per Share Amounts)

they are anti-dilutive. Therefore, the number of shares calculated for basic net loss per share is also used for the diluted net loss per share calculation.

**Comprehensive Income (Loss) and Accumulated Other Comprehensive Income (Loss)**—In addition to net losses, the comprehensive loss includes foreign currency translation adjustments and unrealized gains and losses on investments.

Accumulated other comprehensive (loss) income consisted of the following (net of tax):

	2018	2017	2016
Total accumulated other comprehensive income (loss) at beginning of period	\$ 34	\$ (468)	\$ (611)
<u>Unrealized losses on investments</u>			
Balance at beginning of period	\$ (6)	\$ (21)	\$ (39)
Other comprehensive (loss) income before reclassifications	(31)	15	18
Amounts reclassified from accumulated other comprehensive (loss) income to other income	—	—	—
Balance at end of period	\$ (37)	\$ (6)	\$ (21)
<u>Foreign currency translation adjustment</u>			
Balance at beginning of period	\$ 40	\$ (447)	\$ (572)
Other comprehensive (loss) income before reclassifications	(367)	660	532
Amounts reclassified from accumulated other comprehensive (loss) income to other income	165	(173)	(407)
Balance at end of period	\$ (162)	\$ 40	\$ (447)
Total accumulated other comprehensive (loss) income at end of period	<u>\$ (199)</u>	<u>\$ 34</u>	<u>\$ (468)</u>

**Research and Development Costs**— Research and development costs are expensed as incurred. These costs include compensation and other internal and external costs associated with the development of and research related to new and existing products or concepts, preclinical studies, clinical trials, healthcare compliance and regulatory affairs.

**Advertising Costs**— The Company expenses advertising costs as incurred. Advertising expense was \$785, \$900 and \$625 during the years ended December 31, 2018, 2017 and 2016.

**Share-Based Compensation**—The Company follows FASB ASC 718 “Compensation-Stock Compensation” (ASC 718) to record share-based compensation for all share-based payment awards, including stock options, restricted stock, performance shares and stock purchases related to an employee stock purchase plan, based on estimated fair values.

ASC 718 requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company’s Consolidated Statements of Operations and Comprehensive Loss. The expense has been reduced for estimated forfeitures. The Company estimates forfeitures at the time of grant and revises them, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company estimates the fair value of time-based options on the date of grant using the Black-Scholes option-pricing model (Black-Scholes model). The Company’s determination of fair value is affected by the Company’s stock price, as well as assumptions regarding several subjective variables. These variables include, but are not limited to, the Company’s expected stock price volatility over the term of the awards and actual and projected employee stock option exercise behaviors. The fair value of market-based performance option grants is estimated at the date of grant using a Monte-Carlo simulation. The value of the portion of the awards that is ultimately expected to vest is recognized as expense over the requisite service periods in the Consolidated Statements of Operations and Comprehensive Loss. The Company estimates the fair value of restricted stock awards, restricted stock units and performance share awards based upon the grant date closing market price of the Company’s common stock.

The Company also has an employee stock purchase plan (ESPP) which is available to all eligible employees as defined by the plan document. Under the ESPP, shares of the Company’s common stock may be purchased at a discount. The Company estimates the number of shares to be purchased under the ESPP at the beginning of each purchase period based upon the fair value of the stock at the beginning of the purchase period using the Black-Scholes model and records estimated compensation expense during the period. Expense is adjusted at the time of stock purchase.

**Use of Estimates**—The preparation of the financial statements in conformity with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expense during the reporting period. Actual results could differ from those estimates.



**ATRICURE, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(In Thousands, Except Per Share Amounts)**

**Fair Value Disclosures**— The Company classifies cash investments in U.S. government agencies and securities, accounts receivable, short-term other assets, accounts payable and accrued liabilities as Level 1. The carrying amounts of these assets and liabilities approximate their fair value due to their relatively short-term nature. Cash equivalents and investments in corporate bonds, commercial paper and asset-backed securities are classified as Level 2 within the fair value hierarchy. The fair value of fixed term debt is estimated by calculating the net present value of future debt payments at current market interest rates and is classified as Level 2. The book value of the Company’s fixed term debt approximates its fair value because the interest rate varies with market rates. Significant unobservable inputs with respect to the fair value measurement of the Level 3 contingent consideration liability are developed using Company data. See Note 3 – Fair Value for further information on fair value measurements.

## **2. RECENT ACCOUNTING PRONOUNCEMENTS**

In February 2016, the FASB issued ASU 2016-02, “Leases” (ASU 2016-02), codified as ASC 842, which requires lessees to record most leases onto their balance sheet but recognize expenses on their income statement in a manner similar to today’s accounting. The guidance is effective for interim and annual reporting periods beginning within 2019. We plan to adopt the standard using the transition method provided by ASU 2018-11, “Leases (Topic 842): Targeted Improvements”. Under this method, we will apply the new requirements to only those leases that exist as of January 1, 2019, rather than at the earliest comparative period presented in the financial statements. Prior periods will be presented under existing lease guidance. Upon transition, we plan to apply the package of practical expedients permitted under ASC 842 transition guidance. As a result, we are not required to reassess (1) whether expired or existing contracts contain leases under the new definition of a lease, including whether an existing or expired contract contains an embedded lease, (2) lease classification for expired or existing leases and (3) any initial direct costs of existing leases. The Company is finalizing procedures to validate the completeness of arrangements that meet the new definition of operating lease, in parallel with our assessment of policy elections, processes and internal controls. The Company currently estimates the adoption of this guidance will result in the recognition of right-of-use assets and lease liabilities for operating leases of approximately \$2,000 to \$4,000 as of January 1, 2019.

In January 2017, the FASB issued ASU 2017-04, “Intangibles - Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment” (ASU 2017-04). The guidance removes the requirement to perform a hypothetical purchase price allocation to measure goodwill impairment. Under ASU 2017-04, a goodwill impairment will be the amount by which a reporting unit’s carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. The guidance becomes effective for annual reporting periods beginning after December 15, 2019 and interim periods within those fiscal years, with early adoption permitted, and applied prospectively. The Company is evaluating the provisions of ASU 2017-04 to determine the impact on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820), Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement” (ASU 2018-13). The amendments modify the disclosure requirements for fair value measurements and are effective for all entities for interim and annual reporting periods beginning within 2020. Early adoption of either the entire standard or only the provisions that eliminate or modify the requirements is permitted. The Company is evaluating the provisions of ASU 2018-13 to determine the impact on its fair value measurement disclosures.

In August 2018, the FASB issued ASU 2018-15, “Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract” (ASU 2018-15). The amendments in this ASU align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). Entities should apply the guidance in ASC 350-40 on internal-use software when capitalizing implementation costs related to a hosting arrangement that is a service contract and expense the capitalized implementation costs related to a hosting arrangement that is a service contract over the hosting arrangement’s term, presenting the expense in the same line item in the statement of income as that in which the fee associated with the hosting arrangement is presented. The amendments are effective for all entities for interim and annual reporting periods beginning within 2020. Early adoption is permitted, and entities have the option of applying either a retrospective or prospective transition method. The Company is evaluating the provisions of ASU 2018-15 to determine the impact on its consolidated financial statements and related disclosures.

In August 2018, the SEC issued a final rule that amends certain of its disclosure requirements. The final rule was effective as of November 5, 2018. Among other amendments, the final rule extends to interim periods the annual disclosure requirement of changes in stockholders’ equity. Under the amendments, an analysis of changes in each caption of stockholders’ equity presented in the balance sheet must be provided in a note or a separate statement. The analysis should present a reconciliation of the beginning balance of each period for which a statement of comprehensive income is required to be filed. The Company anticipates its first presentation of changes in stockholders’ equity will be included in its Form 10-Q for the quarter ended March 31, 2019.

**ATRICURE, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(In Thousands, Except Per Share Amounts)

**3. FAIR VALUE**

FASB ASC 820, “Fair Value Measurements and Disclosures” (ASC 820), defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

- Level 1—Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date. An active market for the asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis. The valuation under this approach does not entail a significant degree of judgment.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The valuation technique for the Company’s Level 2 assets is based on quoted market prices for similar assets from observable pricing sources at the reporting date.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date.

The following table represents the Company’s fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2018:

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)	Total
<b>Assets:</b>				
Money market funds	\$ —	\$ 16,193	\$ —	\$ 16,193
Commercial paper	—	40,731	—	40,731
U.S. government agencies and securities	6,734	—	—	6,734
Corporate bonds	—	30,195	—	30,195
Asset-backed securities	—	14,511	—	14,511
<b>Total assets</b>	<b>\$ 6,734</b>	<b>\$ 101,630</b>	<b>\$ —</b>	<b>\$ 108,364</b>
<b>Liabilities:</b>				
Acquisition-related contingent consideration	\$ —	\$ —	\$ 18,773	\$ 18,773
<b>Total liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 18,773</b>	<b>\$ 18,773</b>

**ATRICURE, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(In Thousands, Except Per Share Amounts)

The following table represents the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2017:

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)	Total
<b>Assets:</b>				
Money market funds	\$ —	\$ 12,774	\$ —	\$ 12,774
Commercial paper	—	7,472	—	7,472
U.S. government agencies and securities	2,999	—	—	2,999
Corporate bonds	—	2,920	—	2,920
Total assets	<u>\$ 2,999</u>	<u>\$ 23,166</u>	<u>\$ —</u>	<u>\$ 26,165</u>
<b>Liabilities:</b>				
Acquisition-related contingent consideration	\$ —	\$ —	\$ 37,098	\$ 37,098
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 37,098</u>	<u>\$ 37,098</u>

There were no changes in the levels or methodology of measurement of financial assets and liabilities during the years ended December 31, 2018 and 2017.

**Acquisition-Related Contingent Consideration.** Contingent consideration arrangements under the nContact merger agreement obligate the Company to pay former shareholders of nContact for the following milestones, if achieved:

- *Trial Enrollment Milestone* – \$7,500 upon completion of patient enrollment in the CONVERGE IDE clinical trial. The Company completed patient enrollment on August 21, 2018, and payment was made to former nContact shareholders on September 20, 2018.
- *Regulatory Milestone* – up to \$42,500 upon the completion of the CONVERGE IDE clinical trial and receiving a PMA from FDA for the EPI-Sense AF Guided Coagulation System and/or any other nContact product with an indication for symptomatic persistent Afib or similar or related indication. The full contingent consideration amount of \$42,500 is only earned if such regulatory approvals are received on or before January 1, 2020. The potential contingent consideration is reduced by 8.33% (or one-twelfth) each month following January 2020 and is reduced to zero if the regulatory milestone is achieved after December 31, 2020. Any payment of the regulatory milestone contingent consideration is due within 30 days following the receipt of the related PMA approval.
- *Commercial Milestone* – for calendar years 2016 through 2019, nContact revenues in excess of specified target revenue amounts will result in contingent consideration equal to 1.5 times the revenues in excess of target. Payments of contingent consideration when the commercial milestone is achieved are due within 65 days of each calendar year end. No payments were made for calendar years 2016 through 2018 as revenues did not exceed the targets for these years.

Subject to the terms and conditions of the merger agreement, all contingent consideration must be paid first in shares of AtriCure common stock. The merger agreement limits the total number of shares of AtriCure common stock issued in connection with the acquisition to 5,660, of which 3,757 shares were issued at closing of the nContact acquisition on October 13, 2015. As a result of the achievement of the trial enrollment milestone, the Company made cash payments totaling approximately \$1,221 and issued and delivered 232 shares of common stock to the former shareholders of nContact on September 20, 2018.

The Company measures contingent consideration liabilities using unobservable inputs by applying an income approach, such as the discounted cash flow technique or the probability-weighted scenario method. Various key assumptions, such as the probability and timing of achievement of the agreed milestones, projected revenues and the discount rate, are used in the determination of fair value of contingent consideration arrangements and are not observable in the market, thus representing a Level 3 measurement within the fair value hierarchy. The contingent consideration liability is recorded in other noncurrent liabilities. Subsequent revisions to key assumptions, which impact the estimated fair value of contingent consideration liabilities, are recorded in selling, general and administrative expenses.

The fair value of the nContact contingent consideration was remeasured during 2018, resulting in a decrease in fair value of \$10,825. This decrease in fair value is due to actual 2018 revenues falling below the commercial milestone target, a decrease in forecasted 2019 revenues for the 2019 commercial milestone, and changes in estimates related to the timing of achievement of the

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regulatory milestone as a result of the completion of enrollment in the CONVERGE IDE clinical trial in 2018. Adjustments to fair value are recorded in selling, general and administrative expenses.

The following table represents the company's Level 3 fair value measurements using significant other unobservable inputs for acquisition-related contingent consideration for each of the years ended December 31:

	2018	2017	2016
Beginning Balance – January 1	\$ 37,098	\$ 41,176	\$ 40,207
Settlement of trial enrollment milestone	(7,500)	—	—
Changes in fair value included in selling, general and administrative expenses	(10,825)	(4,078)	969
Ending Balance – December 31	<u>\$ 18,773</u>	<u>\$ 37,098</u>	<u>\$ 41,176</u>

#### 4. INVESTMENTS

Investments as of December 31, 2018 consisted of the following:

	Cost Basis	Unrealized Gains (Losses)	Fair Value
Corporate bonds	\$ 30,223	\$ (28)	\$ 30,195
U.S. government agencies and securities	6,734	—	6,734
Commercial paper	40,731	—	40,731
Asset-backed securities	14,520	(9)	14,511
Total	<u>\$ 92,208</u>	<u>\$ (37)</u>	<u>\$ 92,171</u>

Investments as of December 31, 2017 consisted of the following:

	Cost Basis	Unrealized Gains (Losses)	Fair Value
Corporate bonds	\$ 2,925	\$ (5)	\$ 2,920
U.S. government agencies and securities	3,000	(1)	2,999
Commercial paper	6,723	—	6,723
Total	<u>\$ 12,648</u>	<u>\$ (6)</u>	<u>\$ 12,642</u>

The Company has not experienced any significant realized gains or losses on its investments in the years ended December 31, 2018, 2017 and 2016.

#### 5. INTANGIBLE ASSETS AND GOODWILL

The following table provides a summary of the Company's intangible assets at December 31:

	Estimated Useful Life	2018		2017	
		Cost	Accumulated Amortization	Cost	Accumulated Amortization
Fusion technology	8 years	\$ 9,242	\$ 4,763	\$ 9,242	\$ 3,697
Clamp & probe technology	3 years	829	829	829	829
SUBTLE access technology	5 years	2,179	1,425	2,179	981
IPR&D		44,021	—	44,021	—
Total		<u>\$ 56,271</u>	<u>\$ 7,017</u>	<u>\$ 56,271</u>	<u>\$ 5,507</u>

Amortization expense related to intangible assets with definite lives, which excludes the IPR&D asset, was \$1,510, \$1,367 and \$1,644 for the years ended December 31, 2018, 2017 and 2016. In 2018, the Company reduced the ten-year estimated useful life of the Fusion technology asset by two years based on changes in estimated periods benefited. This change in estimate resulted in additional amortization expense of \$143 in 2018 and will be applied prospectively.

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Intangible assets with definite lives will be fully amortized in 2021. Future amortization expense is projected as follows:

2019	\$ 1,936
2020	1,804
2021	1,493
Total	<u>\$ 5,233</u>

The following table provides a summary of the Company's goodwill, which is not amortized, but rather tested annually for impairment:

Net carrying amount as of December 31, 2016	\$ 105,257
Additions (impairments)	—
Net carrying amount as of December 31, 2017	105,257
Additions (impairments)	—
Net carrying amount as of December 31, 2018	<u>\$ 105,257</u>

**6. INVENTORIES**

Inventories consisted of the following at December 31:

	2018	2017
Raw materials	\$ 9,100	\$ 7,755
Work in process	1,232	1,299
Finished goods	12,152	13,397
Inventories	<u>\$ 22,484</u>	<u>\$ 22,451</u>

**7. PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following at December 31:

	Estimated Useful Life	2018	2017
Generators and other capital equipment	1-3 years	\$ 18,158	\$ 15,754
Building under capital lease	15 years	14,250	14,250
Computer and other office equipment	3 years	6,360	5,873
Machinery, equipment and vehicles	3-7 years	4,859	4,576
Furniture and fixtures	3-7 years	4,702	4,366
Leasehold improvements	5-15 years	3,943	3,636
Construction in progress	N/A	1,868	1,810
Equipment under capital leases	3-5 years	213	221
Total		54,353	50,486
Less accumulated depreciation		(27,273)	(21,737)
Property and equipment, net		<u>\$ 27,080</u>	<u>\$ 28,749</u>

Property and equipment depreciation expense was \$7,244, \$7,761 and \$7,655 for the years ended December 31, 2018, 2017 and 2016. Depreciation related to generators and other capital equipment was \$3,191, \$3,574 and \$3,591 in 2018, 2017 and 2016. As of December 31, 2018 and 2017, the net carrying value of generators and other capital equipment was \$4,545 and \$4,656.



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**8. ACCRUED LIABILITIES**

Accrued liabilities consisted of the following at December 31:

	2018	2017
Accrued bonus	\$ 9,100	\$ 4,726
Accrued commissions	8,065	6,964
Accrued payroll and employee-related expenses	4,512	4,097
Sales returns and allowances	1,410	1,169
Other accrued liabilities	1,205	695
Accrued taxes and value-added taxes payable	886	634
Accrued royalties	662	626
Total	<u>\$ 25,840</u>	<u>\$ 18,911</u>

**9. INDEBTEDNESS**

**Credit Facility.** The Company has a Loan and Security Agreement (“Loan Agreement”) with Silicon Valley Bank (SVB). The Loan Agreement, as amended, restated and modified effective February 23, 2018 and as further amended on December 28, 2018, includes a \$40,000 term loan and \$20,000 revolving line of credit, with an option to increase the revolving line of credit by an additional \$20,000. The term loan and revolving credit facility both mature or expire, as applicable, in February 2023.

Principal payments of the term loan are to be made ratably commencing September 2019 through the loan’s maturity date. If the Company meets certain conditions, as specified by the Loan Agreement, the commencement of term loan principal payments may be deferred by an additional six months. The term loan accrues interest at the greater of the Prime Rate plus 0.50% or 5.00%. Financing costs related to the term loan of \$620 are netted against the outstanding loan balance in the Consolidated Balance Sheets and amortized ratably over the term of the Loan Agreement.

The revolving line of credit is subject to an annual facility fee of 0.33% of the revolving line of credit, and any borrowings thereunder bear interest at the greater of the Prime Rate or 4.50%. Borrowing availability under the revolving credit facility is based on the lesser of \$20,000 or a borrowing base calculation as defined by the Loan Agreement. As of December 31, 2018, the Company had no borrowings under the revolving credit facility and had borrowing availability of \$20,000. Financing costs related to the revolving line of credit are included in other assets in the Consolidated Balance Sheets and amortized ratably over the twelve-month period of the annual fee.

The Loan Agreement also provides for certain prepayment and early termination fees if repaid before January 2020, as well as establishes a minimum liquidity covenant and dividend restrictions, along with other customary terms and conditions. Specified assets have been pledged as collateral.

**Capital Lease Obligations.** As of December 31, 2018, the Company had capital leases for its corporate headquarters building and computer equipment that expire at various terms through 2030. Capital lease assets are depreciated over their estimated useful lives. As of December 31, 2018, the cost of the leased assets, both building and computer equipment, was \$14,463, and accumulated amortization on the capital lease assets was \$3,198.

In connection with the terms of the Company’s corporate headquarters lease, a letter of credit in the amount of \$1,250 was issued to the landlord of the building in October 2015. The letter of credit is renewed annually and remains outstanding as of December 31, 2018.

Future maturities on debt and capital lease obligations are projected as follows:

2019	\$ 5,303
2020	12,942
2021	12,947
2022	12,968
2023	3,467
2024 and thereafter	11,393
Total payments	<u>\$ 59,020</u>
Imputed interest on capital lease obligations	(6,225)
Net debt obligations, of which \$4,433 is current and \$48,362 is noncurrent	<u>\$ 52,795</u>

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**10. COMMITMENTS AND CONTINGENCIES**

**Lease Commitments.** The Company leases certain office and warehouse facilities and a vehicle under noncancelable operating leases that expire at various terms through 2022. Future minimum lease payments under non-cancelable operating leases are projected as follows:

2019	\$ 1,064
2020	893
2021	648
2022	405
Total	<u>\$ 3,010</u>

Rent expense was \$1,146, \$850 and \$1,250 in 2018, 2017, and 2016.

**Royalty Agreements.** The Company has certain royalty agreements in place with terms that include payment of royalties of 3% to 5% of specified product sales. The current royalty agreements have effective dates as early as 2003 and terms ranging from eighteen years to at least twenty years. Parties to the royalty agreements have the right at any time to terminate the agreement immediately for cause. Royalty expense of \$2,715, \$2,323 and \$1,895 was recorded as part of cost of revenue for the years ended December 31, 2018, 2017 and 2016.

**Purchase Agreements.** The Company enters into standard purchase agreements with certain vendors in the ordinary course of business. Outstanding commitments at December 31, 2018 were not significant.

**Legal.** The Company may, from time to time, become a party to legal proceedings. Such matters are subject to many uncertainties and to outcomes of which the financial impacts are not predictable with assurance and that may not be known for extended periods of time. When management has assessed that a loss is probable and an amount can be reasonably estimated, the Company records a liability in the Consolidated Financial Statements.

The Company received a Civil Investigative Demand (CID) from the U.S. Department of Justice (USDOJ) in December 2017 stating that it is investigating the Company to determine whether the Company has violated the False Claims Act, relating to the promotion of certain medical devices related to the treatment of atrial fibrillation for off-label use and submitted or caused to be submitted false claims to certain federal and state health care programs for medically unnecessary healthcare services related to the treatment of atrial fibrillation. The CID covers the period from January 2010 to December 2017 and requires the production of documents and answers to written interrogatories. The Company had no knowledge of the investigation prior to receipt of the CID. The Company maintains rigorous policies and procedures to promote compliance with the False Claims Act and other applicable regulatory requirements. The Company provided the USDOJ with documents and answers to the written interrogatories and is cooperating with its investigation. However, the Company cannot predict when the investigation will be resolved, the outcome of the investigation or its potential impact on the Company.

**11. REVENUE**

The Company adopted FASB ASC 606, "Revenue from Contracts with Customers" (ASC 606) using the modified retrospective method effective January 1, 2018. The adoption of ASC 606 did not have a material impact on the amount and timing of revenue recognized in the Consolidated Financial Statements.

Revenue is generated primarily from the sale of medical devices. The Company recognizes revenue in an amount that reflects the consideration the Company expects to be entitled to in exchange for those devices when control of promised devices is transferred to customers. At contract inception, the Company assesses the products promised in its contracts with customers and identifies a performance obligation for each promise to transfer to the customer a product that is distinct. The Company's devices are distinct and represent performance obligations. These performance obligations are satisfied and revenue is recognized at a point in time upon shipment or delivery of products. Sales of devices are categorized as follows: open-heart ablation, minimally invasive ablation (MIS), appendage management and valve tools. Shipping and handling activities performed after control over products transfers to customers are considered activities to fulfill the promise to transfer the products rather than as separate promises to customers. Revenue includes shipping and handling revenue of \$1,236, \$1,090 and \$1,266 in 2018, 2017 and 2016.

Products are sold primarily through a direct sales force and through distributors in certain international markets. Terms of sale are generally consistent for both end-users and distributors, except that payment terms are generally net 30 days for end-users and net 60 days for distributors, with limited exceptions. The Company does not maintain any post-shipment obligations to customers. No installation, calibration or testing of products is performed by the Company subsequent to shipment in order to render products operational.

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Significant judgments and estimates involved in the Company's recognition of revenue include the determination of the timing of transfer of control of products to customers and the estimation of a provision for returns. The Company considers the following indicators when determining when the control of products transfers to customers: (i) the Company has a right to payment in accordance with the shipping terms set forth in its contracts with customers; (ii) customers have legal title to products in accordance with shipping terms; (iii) the Company transfers physical possession of products either when the Company presents the products to a third party carrier for delivery to a customer (FOB shipping point) or when a customer receives the delivered goods (FOB destination); (iv) customers have the significant risks and rewards of ownership of products; and (v) customers have accepted products in connection with contractual shipping terms.

In the normal course of business, the Company does not accept product returns unless a product is defective as manufactured. The Company establishes estimated provisions for returns based on historical experience. The Company does not provide customers with the right to a refund.

The Company expects to be entitled to the total consideration for the products ordered by customers as product pricing is fixed according to the terms of customer contracts and payment terms are short. Payment terms fall within the one-year guidance for the practical expedient which allows the Company to forgo adjustment of the promised amount of consideration for the effects of a significant financing component. The Company excludes taxes assessed by governmental authorities on revenue-producing transactions from the measurement of the transaction price.

Costs associated with product sales include commissions and royalties. Considering that product sales are performance obligations in contracts that are satisfied at a point in time, commission expense associated with product sales and royalties paid based on sales of certain products is incurred at that point in time rather than over time. Therefore, the Company applies the practical expedient and recognizes commissions and royalties as expense when incurred because the expense is incurred at a point in time and the amortization period is less than one year. Commissions are recorded as selling expense and royalties are recorded as cost of revenue.

See Note 16 for disaggregated revenue by geographic area and by product category.

## **12. INCOME TAXES**

The Company files federal, state, local and foreign income tax returns in jurisdictions with varying statutes of limitations. Income taxes are computed using the asset and liability method in accordance with FASB ASC 740, "Income Taxes", under which deferred income taxes are provided for the temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities. Deferred taxes are measured using provisions of currently enacted tax laws. A valuation allowance against deferred tax assets is recorded when it is more likely than not that such assets will not be fully realized. The Company has recorded a full valuation allowance against substantially all net deferred tax assets as it is more likely than not that the benefit of the deferred tax assets will not be recognized in future periods.

On December 22, 2017, H.R.1, "An Act to Provide for Reconciliation Pursuant to Titles II and V of the Concurrent Resolution on the Budget for Fiscal Year 2018" (the Tax Reform Act) was enacted and amends the Internal Revenue Code to reduce tax rates and modify policies, credits and deductions for businesses. For businesses, U.S. GAAP requires resulting tax effects of accounting for the Tax Reform Act to be recorded in the reporting period of enactment. On December 22, 2017, the SEC staff also issued Staff Accounting Bulletin No. 118 (SAB 118) which allowed businesses to record provisional amounts in the application of U.S. GAAP during a measurement period, not to extend beyond one year from the enactment of the Tax Reform Act, in situations when a registrant did not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of the Tax Reform Act.

We have completed our accounting for the tax effects of enactment of the Tax Reform Act which resulted in the following:

*Reduction of US federal corporate tax rate:* The Tax Reform Act reduces the corporate tax rate from 34 to 21 percent, effective January 1, 2018. Consequently, the Company has recorded a reduction to its federal deferred tax assets of \$29,480 with an offsetting reduction in its valuation allowance at December 31, 2017. In addition, the Company's state deferred tax assets and corresponding valuation allowance have been adjusted to account for the impact of the federal rate change on state deferred taxes.

*Interest Limitation:* The Tax Reform Act limits a Company's interest deduction to 30% of tax earnings before interest, tax, depreciation and amortization beginning in 2018 through 2021. Thereafter, the interest deduction is limited to 30% of tax earnings before interest and taxes. Any disallowed interest in a year becomes a separate deferred tax asset with an indefinite carryforward period that can be utilized by a Company in a future tax year by an amount equal to its interest limitation in excess of its interest expense for that year. In 2018, the Company's net interest expense of \$3,131 was disallowed and became a \$774 deferred tax asset on which a full valuation allowance was recorded.

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*Compensation and Shared-Based Payment Awards:* The Tax Reform Act modifies the deductibility of covered employees' compensation and eliminates the exclusion of performance-based compensation under IRC § 162(m), prospectively. The Tax Reform Act includes a transition rule that permits the continued exclusion of performance-based compensation paid pursuant to a written, binding contract which was in effect on November 2, 2017, and which was not modified in any material respect on or after such date. In 2018, the Company completed its analysis of all of its relevant equity compensation agreements and recorded a reduction to its federal deferred tax assets of \$2,482 with an offsetting reduction in its valuation allowance at December 31, 2018.

*Corporate Alternative Minimum Tax (AMT):* The repeal of AMT provides companies with the ability to obtain refunds of historic AMT credits. In 2018, the Company has recorded a current federal tax refund of \$51 of its historic AMT credits.

*Bonus Depreciation:* The Tax Reform Act provides for 100 percent bonus depreciation on personal tangible property expenditures beginning September 27, 2017 through 2022. The bonus depreciation percentage is phased down from 100 percent beginning in 2023 through 2026. The Company intends to claim 100 percent bonus depreciation for eligible property in 2018.

*International Tax:* The Tax Reform Act provides for a one-time "deemed repatriation" of accumulated foreign earnings for the year ended December 31, 2017. In addition, beginning in 2018 the Tax Reform Act imposes a new tax on global intangible low taxed income of foreign subsidiaries and provides a new deduction for foreign derived intangible income of a domestic company. The Company did not incur a tax on the deemed repatriation or its current year foreign earnings as a result of its foreign deficits and previously taxed foreign earnings. The Company also did not receive a deduction for its foreign derived income due to its net operating losses.

The Tax Reform Act provided companies with the ability to elect to reclassify the income tax effects of the Tax Cuts and Jobs Act on items within accumulated other comprehensive income (loss) to retained earnings. The Company will not make this election due to its full valuation allowance.

The detail of deferred tax assets and liabilities at December 31 is as follows:

	2018	2017
Deferred tax assets (liabilities):		
Net operating loss carryforward	\$ 68,563	\$ 64,776
Research and development and AMT credit carryforwards, net	6,206	5,339
Deferred interest	774	—
Equity compensation	4,750	6,955
Accruals and reserves	802	874
Inventories	726	588
Intangible assets	(11,448)	(11,297)
Property and equipment, net	(608)	(339)
Other, net	135	179
Subtotal	69,900	67,075
Less valuation allowance	(69,849)	(66,973)
Total	\$ 51	\$ 102

The Company's provision for income taxes for each of the years ended December 31 is as follows:

	2018	2017	2016
Current Tax Expense			
Federal	\$ (51)	\$ —	\$ —
State	28	44	32
Foreign	198	72	8
Total current tax expense	175	116	40
Deferred Tax Expense			
Federal	\$ (3,048)	\$ 18,485	\$ (7,333)
State	178	(1,337)	210
Foreign	45	(2,241)	(1,177)
Change in valuation allowance	2,876	(15,009)	8,300
Total deferred tax expense	51	(102)	—
Total tax expense	\$ 226	\$ 14	\$ 40

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The Company has federal net operating loss carryforwards of \$239,162 which have expirations between 2021 and 2038 and \$18,228 which has no expiration as a result of the Tax Reform Act. The Company has state and local net operating loss carryforwards of \$154,370 with varying expirations from 2019 to 2039. A portion of the Company's federal and state net operating loss carryforwards are subject to certain limitations under Internal Revenue Code Sections 382 and 383. The Company has federal research and development credit carryforwards of \$6,154 which have expirations between 2023 and 2039. Additionally, the Company has foreign net operating loss carryforwards of approximately \$37,694 which have expirations between 2019 and 2028. At December 31, 2016, there were \$2,816 of unrecognized deferred tax assets that arose from tax deductions for equity compensation in excess of compensation recognized for financial reporting during years when net operating losses were created. On January 1, 2017, the Company adopted ASU 2016-09, "Improvements to Employee Share-Based Payment Accounting" and recognized \$2,816 of previously unrecognized deferred tax assets with a corresponding increase in its valuation allowance.

The Company's 2018, 2017 and 2016 effective income tax rates differ from the federal statutory rate as follows:

	2018		2017		2016	
Federal tax at statutory rate	21.00 %	\$ (4,391)	34.00 %	\$ (9,139)	34.00 %	\$ (11,322)
Federal and Foreign tax rate change	(6.84)	1,430	(109.68)	29,480	—	—
Federal R&D credit	4.39	(918)	(0.40)	107	2.89	(962)
Federal deferred adjustment	(10.77)	2,253	—	—	—	—
Federal NOL adjustment for ASU	—	—	10.48	(2,816)	—	—
Valuation allowance	(13.75)	2,876	55.84	(15,009)	(24.93)	8,300
State income taxes	(0.99)	206	4.81	(1,292)	(0.69)	231
Foreign NOL adjustment	(1.22)	256	1.30	(348)	(1.36)	452
Foreign tax rate differential	(0.60)	125	(2.45)	658	(1.62)	539
Permanent differences and other	7.70	(1,611)	6.05	(1,627)	(8.41)	2,802
Effective tax rate	<u>(1.08) %</u>	<u>\$ 226</u>	<u>(0.05) %</u>	<u>\$ 14</u>	<u>(0.12) %</u>	<u>\$ 40</u>

The Company's pre-tax book loss for domestic and international operations was \$(13,443) and \$(7,468) for 2018, \$(19,409) and \$(7,469) for 2017 and \$(27,271) and \$(6,027) for 2016.

The Company had undistributed earnings of foreign subsidiaries of approximately \$234 at December 31, 2018. The Company does not consider these earnings as permanently reinvested and thus has recognized appropriate U.S. current and deferred taxes on such amounts.

Federal, state and local tax returns of the Company are routinely subject to examination by various taxing authorities. Federal income tax returns for periods beginning in 2015 are open for examination. Generally, state and foreign income tax returns for periods beginning in 2014 are open for examination. However, taxing authorities have the ability to adjust net operating loss and tax credit carryforwards from years prior to these periods. The Company has not recognized certain tax benefits because of the uncertainty of realizing the entire value of the tax position taken on income tax returns upon review by the taxing authorities.

A reconciliation of the change in federal and state unrecognized tax benefits for 2018, 2017 and 2016 is presented below:

	2018	2017	2016
Balance at the beginning of the year	\$ 1,157	\$ 3,175	\$ 1,982
Increases (decreases) for prior year tax positions	—	(2,018)	1,193
Increases (decreases) for current year tax positions	—	—	—
Increases (decreases) related to settlements	—	—	—
Decreases related to statute lapse	—	—	—
Balance at the end of the year	<u>\$ 1,157</u>	<u>\$ 1,157</u>	<u>\$ 3,175</u>

The Internal Revenue Service completed its review of the Company's 2014 federal income tax return in February 2017. In 2017, the Company also completed a detailed analysis of R&D credit carryforwards for the tax years 2008 through 2016. As a result of this analysis, as well as completion of the IRS audit of the 2014 credit, the Company has reduced both the R&D credit carryforward and related unrecognized tax benefits by \$2,018. The Company has not had to accrue any interest and penalties related to unrecognized income tax benefits as a result of offsetting of net operating losses. However, if the situation occurs, the Company will recognize interest and penalties within income tax expense and the related tax liability.

There are no amounts included in the balance of unrecognized tax benefits at December 31, 2018, 2017 and 2016 that, if recognized, would affect the effective tax rate. Included in the balance of unrecognized tax benefits at December 31, 2018 are \$1,157



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of tax benefits that, if recognized, would result in adjustments to other tax accounts, primarily deferred taxes and valuation allowance. The Company does not expect that its unrecognized tax benefits for research credits will significantly change within twelve months of December 31, 2018.

**13. CONCENTRATIONS**

During 2018, 2017 and 2016, approximately 10.8%, 13.2% and 14.4% of the Company's total net revenue was derived from its top ten customers. During 2018, 2017 and 2016 no individual customer accounted for more than 10% of the Company's revenue.

As of December 31, 2018 and 2017, 11.8% and 19.7% of the Company's total accounts receivable balance was derived from its top ten customers. No individual customer accounted for more than 10% of the Company's accounts receivable as of December 31, 2018 and 2017.

The Company maintains cash and cash equivalents balances at financial institutions which at times exceed FDIC limits. As of December 31, 2018, \$31,955 of the cash and cash equivalents balance was in excess of the FDIC limits.

**14. EMPLOYEE BENEFIT PLANS**

The Company sponsors the AtriCure, Inc. 401(k) Plan (401(k) Plan), a defined contribution plan covering substantially all U.S. employees of the Company. Eligible employees may contribute pre-tax annual compensation up to specified maximums under the Internal Revenue Code. During 2018, 2017 and 2016 the Company made matching contributions of 50% on the first 6% of employee contributions to the 401(k) Plan. The Company's matching contributions expensed during 2018, 2017 and 2016 were \$1,560, \$1,367 and \$1,222. Additional amounts may be contributed to the 401(k) Plan at the discretion of the Company's Board of Directors, however, no such discretionary contributions were made during 2018, 2017 or 2016. The Company also provides retirement benefits for employees of AtriCure Europe and other foreign subsidiaries. Total contributions to retirement plans for these employees were \$243, \$205 and \$101 in 2018, 2017 and 2016.

**15. EQUITY COMPENSATION PLANS**

The Company has two share-based incentive plans: the 2014 Stock Incentive Plan (2014 Plan) and the 2018 Employee Stock Purchase Plan (ESPP).

***Stock Incentive Plan***

Under the 2014 Plan, the Board of Directors may grant incentive stock options to Company employees and may grant restricted stock awards, restricted stock units, collectively "RSAs", nonstatutory stock options, performance share awards (PSAs) or stock appreciation rights to Company employees, directors and consultants. The administrator (the Compensation Committee of the Board of Directors) has the authority to determine the terms of any awards, including the number of shares subject to each award, the exercisability of the awards and the form of consideration. As of December 31, 2018, 11,099 shares of common stock had been reserved for issuance under the 2014 Plan and 1,319 shares were available for future grants.

Effective March 1, 2018, the Compensation Committee of the Board approved the grant of performance share awards (2018 PSAs) to the Company's named executive officers and certain other executive employees pursuant to the Company's 2014 Plan. The form of award agreement for the 2018 PSAs (2018 PSA Grant Form) provides, among other things, that (i) each 2018 PSA that vests represents the right to receive one share of the Company's common stock; (ii) the 2018 PSAs vest based on the Company achieving specified performance measurements over a performance period of three years, beginning January 1, 2018; (iii) the performance measurements include revenue CAGR as defined in the 2018 PSA Grant Form; (iv) threshold, target and maximum payout opportunities established for the 2018 PSAs will be used to calculate the number of shares that will be issuable when the award vests, which may range from 0% to 200% of the target amount; (v) any 2018 PSAs that are earned are scheduled to vest and be settled in shares of the Company's common stock at the end of the performance period; and (vi) all or a portion of the 2018 PSAs may vest following a change of control or a termination of service by reason of death or disability (each as described in greater detail in the 2018 PSA Grant Form).

With respect to the 2018 PSAs, the number of shares that vest and are issued to the recipient is based upon the Company's performance as measured against the specified targets at the end of the three-year performance period as determined by the Compensation Committee of the Board. The Company estimated the fair value of the 2018 PSAs based on its closing stock price on the grant date and will adjust compensation expense over the performance period based on its estimate of performance target achievement.

Stock options granted prior to 2018 under the 2014 Plan generally expire ten years from the date of grant and generally vest at a rate of 25% on the first anniversary date of the grant and ratably each month thereafter over the following three years. Restricted stock

**ATRICURE, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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awards granted prior to 2018 generally vest between one and four years from the date of grant. Beginning in 2018, stock options, restricted stock awards, and restricted stock units granted generally vest in one-third increments on the first, second and third anniversaries of the grant date.

Activity under the plans during 2018 was as follows:

	Number of Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
<b>Time-Based Stock Options</b>				
Outstanding at January 1, 2018	2,026	\$ 13.30		
Granted	52	26.05		
Exercised	(474)	12.70		
Cancelled	(22)	18.14		
Outstanding at December 31, 2018	1,582	\$ 13.83	5.02	\$ 26,587
Vested and expected to vest	1,574	\$ 13.78	5.00	\$ 26,525
Exercisable at December 31, 2018	1,419	\$ 12.99	4.63	\$ 24,991

	RSA Shares Outstanding	Weighted Average Grant Date Fair Value	PSA Shares Outstanding	Weighted Average Grant Date Fair Value
<b>Restricted Stock Awards and Performance Share Awards</b>				
Outstanding at January 1, 2018	1,845	\$ 18.22	—	\$ —
Awarded	630	18.71	90	17.71
Released	(638)	18.87	—	—
Forfeited	(91)	17.97	—	—
Outstanding at December 31, 2018	1,746	\$ 18.19	90	\$ 17.71

	Number of Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
<b>Performance Stock Options</b>				
Outstanding at January 1, 2018	450	\$ 13.48		
Granted	—	—		
Exercised	—	—		
Cancelled	—	—		
Outstanding at December 31, 2018	450	\$ 13.48	4.45	\$ 5,555
Exercisable at December 31, 2018	350	\$ 13.48	4.45	\$ 4,321

Activity under the plans during 2017 was as follows:

	Number of Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
<b>Time-Based Stock Options</b>				
Outstanding at January 1, 2017	2,454	\$ 12.51		
Granted	65	20.22		
Exercised	(458)	9.61		
Cancelled	(35)	19.08		
Outstanding at December 31, 2017	2,026	\$ 13.30	5.62	\$ 11,730
Vested and expected to vest	2,004	\$ 13.23	5.58	\$ 11,717
Exercisable at December 31, 2017	1,766	\$ 12.48	5.20	\$ 11,471

**ATRICURE, INC. AND SUBSIDIARIES**  
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<u>Restricted Stock Awards</u>	Number of Shares Outstanding	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2017	1,416	\$ 17.40
Awarded	771	19.38
Released	(331)	17.43
Forfeited	(11)	18.52
Outstanding at December 31, 2017	<u>1,845</u>	<u>\$ 18.22</u>

<u>Performance Stock Options</u>	Number of Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2017	450	\$ 13.48		
Granted	—	—		
Exercised	—	—		
Cancelled	—	—		
Outstanding at December 31, 2017	<u>450</u>	<u>\$ 13.48</u>	<u>5.45</u>	<u>\$ 2,774</u>
Exercisable at December 31, 2017	<u>250</u>	<u>\$ 13.48</u>	<u>5.45</u>	<u>\$ 1,541</u>

The total intrinsic value of options exercised during the years ended December 31, 2018, 2017 and 2016 was \$5,343, \$5,121 and \$3,550. As a result of the Company's full valuation allowance on its net deferred tax assets, no tax benefit was recognized related to the stock option exercises. The exercise price per share of each option is equal to the fair market value of the underlying share on the date of grant. For 2018, 2017 and 2016, \$6,012, \$4,402 and \$3,337 in cash proceeds were included in the Company's Consolidated Statements of Cash Flows as a result of the exercise of stock options. The total fair value of restricted stock vested during 2018, 2017 and 2016 was \$11,864, \$6,235 and \$5,102. The Company issues registered shares of common stock to satisfy stock option exercises and restricted stock grants.

The Company has awarded 450 performance options to its President and Chief Executive Officer. The options expire ten years from the date of grant and vest in increments of 25 shares when the volume adjusted weighted average closing price of the common stock of the Company as reported by NASDAQ (or any other exchange on which the common stock of the Company is listed) for 30 consecutive days equals or exceeds each of \$10.00 per share, \$12.50 per share, \$15.00 per share, \$17.50 per share, \$20.00 per share, \$25.00 per share, \$30.00 per share, \$35.00 per share and \$40.00 per share. In accordance with FASB ASC 718, a Monte Carlo simulation was performed to estimate the fair values, vesting terms and vesting probabilities for each tranche of options. Expense calculated using these estimates is being recorded over the estimated vesting terms. The Company recognized expense related to the performance options during 2018, 2017 and 2016 of \$0, \$43 and \$269. As of December 31, 2017, compensation costs related to non-vested performance options were fully recognized.

***Employee Stock Purchase Plan***

The ESPP is available to eligible employees as defined in the plan document. Under the ESPP, shares of the Company's common stock may be purchased at a discount (currently 15%) of the lesser of the closing price of the Company's common stock on the first trading day or the last trading day of the offering period. The offering period (currently six months) and the offering price are subject to change. Participants may not purchase more than \$25 of the Company's common stock in a calendar year and may not purchase a value of more than 3 shares during an offering period. As of December 31, 2018, there were 595 shares available for future issuance under the ESPP.

**ATRICURE, INC. AND SUBSIDIARIES**  
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**Valuation and Expense Information Under FASB ASC 718**

The following table summarizes share-based compensation expense related to employees, directors and consultants under FASB ASC 718 for 2018, 2017 and 2016. The expense was allocated as follows:

	2018	2017	2016
Cost of revenue	\$ 1,545	\$ 610	\$ 420
Research and development expenses	1,987	2,052	1,825
Selling, general and administrative expenses	12,963	11,953	9,452
Total	<u>\$ 16,495</u>	<u>\$ 14,615</u>	<u>\$ 11,697</u>

Share-based compensation expense with respect to the ESPP was \$697, \$664 and 556 for 2018, 2017 and 2016. The Company recognized expense related to time-based stock options, restricted stock awards, and restricted stock units for 2018, 2017, and 2016 of \$15,032, \$13,908 and \$10,872. The Company recognized expense of \$766 related to performance share awards in 2018. As of December 31, 2018 there was \$20,198 of unrecognized compensation costs related to non-vested stock options and restricted stock arrangements (\$1,432 relating to stock options and \$18,766 relating to restricted stock). This cost is expected to be recognized over a weighted-average period of 2.0 years for stock options and 1.5 years for restricted stock. As of December 31, 2018 there was \$1,869 of unrecognized compensation costs related to non-vested performance share awards, and this cost is expected to be recognized over a weighted-average period of 1.9 years.

In calculating compensation expense, the fair value of the options is estimated on the grant date using the Black-Scholes model including the following assumptions:

	2018	2017	2016
Risk-free interest rate	2.31 - 3.01%	1.75 - 2.12%	1.06 - 2.02%
Expected life of option (years)	5.14 to 5.71	5.21 to 5.76	5.27 to 7.10
Expected volatility of stock	41.00 - 42.00%	43.00 - 48.00%	46.00 - 51.00%
Weighted-average volatility	41.51 %	44.50 %	48.87 %
Dividend yield	0.00 %	0.00 %	0.00 %

The Company's estimate of volatility is based solely on the Company's trading history over the expected option life. The risk-free interest rate assumption is based upon the U.S. treasury yield curve at the time of grant for the expected option life. The Company estimates the expected terms of options using historical employee exercise behavior.

The fair value of restricted stock awards, restricted stock units and performance share awards is based on the market value of the Company's stock on the date of the awards.

Based on the assumptions noted above, the weighted average estimated grant date fair value per share of the stock options, restricted stock awards and performance share awards granted for 2018, 2017 and 2016 was as follows:

	2018	2017	2016
Stock options	\$ 10.97	\$ 8.60	\$ 8.25
Restricted stock awards	18.71	19.38	16.35
Performance share awards	17.71	—	—

In calculating compensation expense for performance options, the fair value of the options was estimated on the grant dates using a Monte Carlo simulation including strike prices of \$5.91 and \$21.04, contractual terms of 10 years, expected volatility of 69.60% and 60.50% and interest rates of 1.75% and 2.73%. The contractual term assumes that the performance options issued to the CEO of the Company will be held until expiration. Expected volatility was estimated based on the Company's trading history over the expected option life. The expected rate of return assumption was based upon the U.S. treasury yield curve at the time of grant for the expected option life.

**ATRICURE, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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Based on the assumptions noted above, the estimated grant date fair value per share of the performance options granted were as follows:

	Price Target	Fair Value of 2012 Grant	Fair Value of 2014 Grant
Tranche 1	\$ 10.00	\$ 4.32	\$ 14.74
Tranche 2	12.50	4.30	14.74
Tranche 3	15.00	4.27	14.74
Tranche 4	17.50	4.23	14.74
Tranche 5	20.00	4.19	14.73
Tranche 6	25.00	4.10	14.73
Tranche 7	30.00	4.01	14.71
Tranche 8	35.00	3.92	14.67
Tranche 9	40.00	3.83	14.61

**16. SEGMENT AND GEOGRAPHIC INFORMATION**

The Company evaluates reporting segments in accordance with FASB ASC 280, "Segment Reporting". The Company develops, manufactures and sells devices designed primarily for the surgical ablation of cardiac tissue and systems designed for the exclusion of the left atrial appendage. These devices are developed and marketed to a broad base of medical centers globally. Management considers all such sales to be part of a single operating segment. Revenue attributed to geographic areas is based on the location of the customers to whom products are sold.

Revenue by geographic area was as follows:

	2018	2017	2016
United States	\$ 162,146	\$ 138,387	\$ 122,385
Europe	25,912	21,901	19,772
Asia	12,687	13,616	12,223
Other international	885	812	729
Total international	39,484	36,329	32,724
Total revenue	<u>\$ 201,630</u>	<u>\$ 174,716</u>	<u>\$ 155,109</u>

United States revenue by product type was as follows:

	2018	2017	2016
Open-heart ablation	\$ 72,250	\$ 64,517	\$ 58,050
Minimally invasive ablation	35,053	34,421	31,169
Appendage management	52,891	37,281	30,321
Total ablation and appendage management	160,194	136,219	119,540
Valve tools	1,952	2,168	2,845
Total United States	<u>\$ 162,146</u>	<u>\$ 138,387</u>	<u>\$ 122,385</u>

International revenue by product type was as follows:

	2018	2017	2016
Open-heart ablation	\$ 21,118	\$ 20,718	\$ 20,189
Minimally invasive ablation	9,176	8,007	8,065
Appendage management	8,988	7,251	3,986
Total ablation and appendage management	39,282	35,976	32,240
Valve tools	202	353	484
Total international	<u>\$ 39,484</u>	<u>\$ 36,329</u>	<u>\$ 32,724</u>

The Company's long-lived assets are located primarily in the United States, except for \$1,296 as of December 31, 2018 and \$957 as of December 31, 2017, which are located primarily in Europe.



**ATRICURE, INC. AND SUBSIDIARIES**  
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**17. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

	For the Three Months Ended								
	March 31,		June 30,		September 30,		December 31,		
	2018	2017	2018	2017	2018	2017	2018	2017	
Operating Results:									
Revenue	\$ 46,994	\$ 41,273	\$ 51,802	\$ 45,231	\$ 49,941	\$ 42,150	\$ 52,893	\$ 46,062	
Gross profit	34,503	30,008	38,079	32,554	35,948	30,918	38,590	32,683	
Income (loss) from operations	(9,430)	(9,642)	958	(6,355)	(6,048)	(6,847)	(2,607)	(2,135)	
Net loss	(10,134)	(10,183)	(338)	(6,883)	(7,235)	(7,246)	(3,430)	(2,580)	
Net loss per share (basic and diluted)	\$ (0.31)	\$ (0.32)	\$ (0.01)	\$ (0.21)	\$ (0.22)	\$ (0.22)	\$ (0.09)	\$ (0.08)	

Amounts may not sum to consolidated totals for the full year due to rounding. Basic and diluted net loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly per share amounts will not necessarily equal the total for the year.

**SCHEDULE II**  
**VALUATION AND QUALIFYING ACCOUNTS**

	Beginning Balance	Additions	Deductions	Ending Balance
<b>Reserve for sales returns and allowances</b>				
Year ended December 31, 2018	\$ 1,169	\$ 312	\$ 71	\$ 1,410
Year ended December 31, 2017	834	441	106	1,169
Year ended December 31, 2016	207	634	7	834
<b>Allowance for inventory valuation</b>				
Year ended December 31, 2018	\$ 889	\$ 718	\$ 578	\$ 1,029
Year ended December 31, 2017	1,080	1,004	1,195	889
Year ended December 31, 2016	843	1,692	1,455	1,080
<b>Valuation allowance for deferred tax assets</b>				
Year ended December 31, 2018	\$ 66,973	\$ 2,876	\$ —	\$ 69,849
Year ended December 31, 2017	81,982	—	15,009	66,973
Year ended December 31, 2016	73,682	8,300	—	81,982

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

None.

### **ITEM 9A. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

The Company's management, with the participation of the President and Chief Executive Officer (the Principal Executive Officer) and Senior Vice President and Chief Financial Officer (the Principal Accounting and Financial Officer), has evaluated the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13(a) – 15(e) of the Securities Exchange Act of 1934 (Exchange Act), as of the end of the period covered by this report. Based on this evaluation, we concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's forms and rules, and the material information relating to the Company is accumulated and communicated to management, including the President and Chief Executive Officer and the Senior Vice President and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Control systems, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that control objectives are met. Because of inherent limitations in all control systems, no evaluation of controls can provide assurance that all control issues and instances of fraud, if any, within a company will be detected. Additionally, controls can be circumvented by individuals, by collusion of two or more people or by management override. Over time, controls can become inadequate because of changes in conditions or the degree of compliance may deteriorate. Further, the design of any system of controls is based in part upon assumptions about the likelihood of future events. There can be no assurance that any design will succeed in achieving its stated goals under all future conditions. Because of the inherent limitations in any cost-effective control system, misstatements due to errors or fraud may occur and not be detected.

#### **Changes in Internal Control over Financial Reporting**

In the ordinary course of business, we routinely enhance our information systems by either upgrading current systems or implementing new ones. There were no changes in our internal control over financial reporting that occurred during the three months ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **Management's Annual Report on Internal Control Over Financial Reporting**

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control over financial reporting includes policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements. The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2018. No matter how well designed, because of inherent limitations in all control systems, internal control over financial reporting may not prevent or detect misstatements should they occur. 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 the control procedures may deteriorate. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework (2013)*. Based on such assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2018.

Deloitte & Touche LLP, the Company's independent registered public accounting firm, has audited the consolidated financial statements included in this Annual Report on Form 10-K and, as part of its audit, has issued an attestation report on the effectiveness of the Company's internal control over financial reporting. The attestation report can be found on the following page as part of this Item 9A.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of  
AtriCure, Inc.  
Mason, Ohio

### Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of AtriCure, Inc. and subsidiaries (the “Company”) as of December 31, 2018, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2018, of the Company and our report dated March 1, 2019, expressed an unqualified opinion on those financial statements.

### Basis for Opinion

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

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 the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

Cincinnati, Ohio  
March 1, 2019

## ITEM 9B. OTHER INFORMATION

None.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2019 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of 2018 (the “Proxy Statement”).

### ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the Proxy Statement.

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

The following table summarizes information about our equity compensation plans as of December 31, 2018.

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights (1)</u> (a)	<u>Weighted-average exercise price of outstanding options, warrants and rights (2)</u> (b)	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u> (c)
Equity compensation plans approved by security holders (3)	3,868,445	\$ 14	1,319,287
Equity compensation plans not approved by security holders	—	—	—
<b>Total</b>	<b>3,868,445</b>	<b>\$ 14</b>	<b>1,319,287</b>

(1) Represents outstanding stock options, restricted stock and performance shares as of December 31, 2018.

(2) The weighted average exercise price is calculated without taking into account restricted stock that will become issuable, without any cash consideration or other payment, as vesting requirements are achieved.

(3) Amounts include awards under our 2005 Equity Incentive Plan and 2014 Stock Incentive Plan but exclude shares purchased under our 2018 Employee Stock Purchase Plan.

The remaining information required by this Item is incorporated by reference to the Proxy Statement.

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

The information required by this Item is incorporated by reference to the Proxy Statement.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to the Proxy Statement.



## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

- (1) The financial statements required by Item 15(a) are filed in Item 8 of this Form 10-K.
- (2) The financial statement schedules required by Item 15(a) are filed in Item 8 of this Form 10-K.
- (3) The following exhibits are included in this Form 10-K or incorporated by reference in this Form 10-K:

<u>Exhibit No.</u>	<u>Description</u>
3.1	Second Amended and Restated Certificate of Incorporation (incorporated by reference to our Current Report on Form 8-K, filed on May 27, 2016).
3.2	Fourth Amended and Restated Bylaws (incorporated by reference to our Current Report on Form 8-K filed on February 16, 2017).
4.1	Warrant to purchase AtriCure, Inc. common stock issued to Silicon Valley Bank on May 1, 2009 (incorporated by reference to our Quarterly Report on Form 10-Q, filed on August 10, 2009).
10.1#	Employment Agreement, dated as of November 1, 2012, between AtriCure, Inc. and Michael H. Carrel (incorporated by reference to our Current Report on Form 8-K, filed on November 1, 2012).
10.2#	2005 Equity Incentive Plan, as amended on September 19, 2007 and on March 6, 2013 (incorporated by reference to our Annual Report on Form 10-K filed on March 8, 2013).
10.3#	2018 Employee Stock Purchase Plan (incorporated by reference to our Current Report on Form 8-K filed on May 23, 2018).
10.4#	Form of Change in Control Agreement between AtriCure and AtriCure Executive Officers (incorporated by reference to our Annual Report on Form 10-K filed on March 8, 2013).
10.5	Loan and Security Agreement dated as of February 23, 2018 by and among Silicon Valley Bank, AtriCure, Inc., AtriCure, LLC, Endoscopic Technologies, LLC and nContact Surgical, LLC (incorporated by reference to our Current Report on Form 8-K, filed on February 26, 2018).
10.6	Lease Agreement Dated August 20, 2014 between LM-VP AtriCure, LLC, as Landlord, and AtriCure, Inc., as Tenant (incorporated by reference to our Current Report on Form 8-K, filed on August 25, 2014).
10.7#	AtriCure, Inc. 2014 Stock Incentive Plan (Amended and Restated as of May 22, 2018) (incorporated by reference to our Current Report on Form 8-K, filed on May 23, 2018).
10.8#	Form of Restricted Stock Award Agreement under the Amended and Restated AtriCure, Inc. 2014 Stock Incentive Plan (incorporated by reference to our Quarterly Report on Form 10-Q, filed on October 31, 2014).
10.9#	Form of Stock Option Award Agreement for Executive Officers under the Amended and Restated AtriCure, Inc. 2014 Stock Incentive (incorporated by reference to our Quarterly Report on Form 10-Q, filed on October 31, 2014).
10.10#	Form of Stock Option Award Agreement for Non-Employee Directors under the Amended and Restated AtriCure, Inc. 2014 Stock Incentive Plan (incorporated by reference to our Quarterly Report on Form 10-Q, filed on October 31, 2014).
10.11	Merger Agreement dated as of October 4, 2015 among nContact Surgical, Inc., AtriCure, Inc., Portal Merger Sub, Inc., Second Portal Merger Sub, LLC and WRYP Stockholder Services, LLC, as Representative of nContact stockholders (incorporated by reference to our Current Report on Form 8-K, filed on October 5, 2015).
10.12	First Loan Modification Agreement dated December 28, 2018 among AtriCure, Inc., Silicon Valley Bank, the lenders named therein, AtriCure, LLC, Endoscopic Technologies, LLC and nContact Surgical, LLC (incorporated by reference to our Current Report on Form 8-K filed on January 3, 2019).
10.13#	2018 Form of Performance Share Award Grant (incorporated by reference to our Current Report on Form 8-K, filed on March 2, 2018).
10.14#	2019 Form of Performance Share Award Grant.
14	Code of Conduct.
21	Subsidiaries of the Registrant.
23.1	Consent of Deloitte & Touche LLP.
31.1	Rule 13a-14(a) Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Rule 13a-14(a) Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification pursuant to 18 U.S.C. Section 1350 by the Chief Executive Officer, as adopted, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification pursuant to 18 U.S.C. Section 1350 by the Chief Financial Officer, as adopted, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

<u>Exhibit No.</u>	<u>Description</u>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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# Compensatory plan or arrangement.

**ITEM 16. FORM 10-K SUMMARY**

Not provided.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Form 10-K to be signed on our behalf by the undersigned, thereunto duly authorized.

AtriCure, Inc.  
(REGISTRANT)

Date: March 1, 2019

/s/ Michael H. Carrel

\_\_\_\_\_  
**Michael H. Carrel**  
**President and Chief Executive Officer**  
**(Principal Executive Officer)**

Date: March 1, 2019

/s/ M. Andrew Wade

\_\_\_\_\_  
**M. Andrew Wade**  
**Senior Vice President and Chief Financial Officer**  
**(Principal Accounting and Financial Officer)**

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael H. Carrel and M. Andrew Wade, his attorney-in-fact, with the power of substitution, for him in any and all capacities, to sign any and all amendments to this Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, and any of them or his substitute or substitutes, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Form 10-K has been signed by the following persons on behalf of the registrant and in the capacities indicated on March 1, 2019.

<u>Signature</u>	<u>Title(s)</u>
_____ /s/ Scott W. Drake <b>Scott W. Drake</b>	<b>Scott W. Drake</b> <i>Chairman of the Board</i>
_____ /s/ Michael H. Carrel <b>Michael H. Carrel</b>	<b>Michael H. Carrel</b> <i>Director, President and Chief Executive Officer</i> <i>(Principal Executive Officer)</i>
_____ /s/ M. Andrew Wade <b>M. Andrew Wade</b>	<b>M. Andrew Wade</b> <i>Senior Vice President and Chief Financial Officer</i> <i>(Principal Accounting and Financial Officer)</i>
_____ /s/ Mark A. Collar <b>Mark A. Collar</b>	<b>Mark A. Collar</b> <i>Director</i>
_____ /s/ Regina E. Groves <b>Regina E. Groves</b>	<b>Regina E. Groves</b> <i>Director</i>
_____ /s/ B. Kristine Johnson <b>B. Kristine Johnson</b>	<b>B. Kristine Johnson</b> <i>Director</i>
_____ /s/ Mark R. Lanning <b>Mark R. Lanning</b>	<b>Mark R. Lanning</b> <i>Director</i>
_____ /s/ Sven A. Wehrwein <b>Sven A. Wehrwein</b>	<b>Sven A. Wehrwein</b> <i>Director</i>
_____ /s/ Robert S. White <b>Robert S. White</b>	<b>Robert S. White</b> <i>Director</i>

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# CORPORATE INFORMATION

## BOARD OF DIRECTORS

**Scott W. Drake**  
Chairman of the Board  
President and Chief Executive Officer  
ViewRay

**Michael H. Carrel**  
President and Chief Executive Officer  
AtriCure, Inc.

**Mark A. Collar**  
Former Division President  
The Procter & Gamble Co.

**Regina E. Groves**  
Former Chief Executive Officer  
REVA Medical, Inc.

**B. Kristine Johnson**  
President  
Affinity Capital Management

**Mark R. Lanning**  
Principal  
Lanning CPA Group

**Sven A. Wehrwein**  
Independent Financial Consultant

**Robert S. White**  
Former President and Chief  
Executive Officer  
Entellus Medical, Inc.

## MANAGEMENT

**Michael H. Carrel**  
President and Chief Executive Officer

**M. Andrew Wade**  
Senior Vice President and  
Chief Financial Officer

**Tonya A. Austin**  
Senior Vice President, Human Resources

**Karl S. Dahlquist**  
Senior Vice President, General Counsel  
and Chief Legal & Compliance Officer

**Vinayak (Vini) Doraiswamy**  
Senior Vice President of Clinical,  
Regulatory, and Scientific Affairs

**Justin J. Noznesky**  
Senior Vice President, Marketing and  
Business Development

**Salvatore (Sam) Privitera**  
Chief Technology Officer

**Douglas J. Seith**  
Chief Operating Officer

## INVESTOR RELATIONS CONTACT

**M. Andrew Wade**  
Senior Vice President and  
Chief Financial Officer

## ANNUAL MEETING

May 22, 2019  
9:00 a.m. (EDT)  
AtriCure, Inc.  
7555 Innovation Way  
Mason, Ohio 45040

## CORPORATE HEADQUARTERS

AtriCure, Inc.  
7555 Innovation Way  
Mason, Ohio 45040  
T 513.755.4100  
F 513.755.4108  
[www.AtriCure.com](http://www.AtriCure.com)

## FORWARD LOOKING STATEMENTS

Our public communications and other reports may contain “forward-looking statements” – that is, statements related to future events that by their nature address matters that are uncertain. For details on the uncertainties that may cause our actual results to be materially different than those expressed in our forward-looking statements, visit [www.AtriCure.com/FLS](http://www.AtriCure.com/FLS) as well as our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q which contain risk factors. We do not undertake to update our forward-looking statements. Our public communications and other reports may also include forward-looking projected financial information that is based on current estimates and forecasts. Actual results could differ materially.

## FORM 10-K

Our Annual Report on Form 10-K is available on the internet by accessing AtriCure’s website at [AtriCure.com](http://AtriCure.com). A copy of the Company’s most recent Form 10-K, as filed with the US Securities and Exchange Commission, or SEC, (including consolidated financial statements and the notes and schedule thereto), will be provided to stockholders upon written request to the Company’s Investor Relations Contact.

# AtriCure

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NASDAQ:ATRC