AtriCure, Inc.
Form 10-K
March 08, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2016

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

Commission File Number 000-51470

AtriCure, Inc.

(Exact name of registrant as specified in its charter)

Delaware	34-1940305
State or other jurisdiction of	(I.R.S. Employer
incorporation or organization	Identification Number)

7555 Innovation Way, Mason, OH 45040
(Address of principal executive offices) (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	Name of each exchange on which registered
Common Stock, $.001 Par Value Per Share	NASDAQ Global Market

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

None

_____

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted 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 and post 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 or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer Accelerated Filer Non-Accelerated Filer Smaller reporting company

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, 2016, as reported on the NASDAQ Global Market, was $440.5 million.

As of February 24, 2017 there were 33,338,700 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 convey our current expectations or forecasts of future events. All statements contained in this Form 10-K other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words “may,” “continue,” “estimate,” “intend,” “plan,” “will,” “believe,” “project,” “expect,” “anticipate” and expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. 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. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise.

(Dollar amounts referenced in this Part 1 are in thousands.)

ITEM 1. BUSINESS

Overview

We are a leading atrial fibrillation (Afib) solutions company providing innovative products, professional education and support for clinical science to reduce the economic and social burden of atrial fibrillation. 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 multiple different types of cardiothoracic surgery. Our AtriClip® Left Atrial Appendage Exclusion System is the most widely sold device worldwide specifically designed to occlude the heart’s left atrial appendage (LAA).

Cardiothoracic surgeons have adopted our radiofrequency (RF) ablation and cryoablation systems to treat Afib in over 222,000 patients since 2004, and we believe that we are currently the market leader in the surgical treatment of Afib. Our products are used by cardiothoracic surgeons during both open-heart and minimally invasive surgical procedures, either on a concomitant or standalone basis. During a concomitant procedure, the surgeon ablates cardiac tissue and/or occludes the LAA secondary, or concomitant, to a primary structural heart procedure such as a valve repair or replacement or coronary artery bypass graft (CABG). 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 such as coronary artery bypass grafting and/or valve replacement or repair. All of our other ablation devices are cleared for sale under FDA 510(k) clearances, including our other RF and cryo ablation products, which are indicated for the ablation of cardiac tissue and/or 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 occlusion of the LAA, under direct visualization, concomitant to other open cardiac surgical procedures. Direct visualization, in this context, requires that the surgeon is able to see the heart directly, without assistance from a

camera, endoscope or any other viewing technology. This includes procedures performed by sternotomy (full or partial) as well as thoracotomy (single or multiple). We also have a line of reusable surgical instruments typically used for cardiac valve replacement or repair. 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, which surgeons use to ablate cardiac tissue, to occlude the left atrial appendage, to perform mitral and aortic valve replacement and repair and/or to ablate peripheral nerves during cardiothoracic surgery.

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 quiver, at rapid rates of 400 to 600 beats per minute. As a result, blood in the atria may become static, increasing the risk that a blood clot will form and cause a stroke or other serious complications. 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.

In the United States of America we sell our products to medical centers through our direct sales force. In certain European markets, such as Germany, France, the United Kingdom and the Benelux region, sales are made directly to medical centers, with the remaining international sales being made through distributors who in turn sell to end users. 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.

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AtriCure, Inc. was incorporated in the State of Delaware on October 31, 2000 in connection with a spin-off transaction from Enable Medical Corporation (Enable) in which shares of our common stock were distributed to Enable shareholders. The spin-off was intended to allow us to focus on the development of products designed to treat Afib and to raise capital for that purpose, while Enable continued its broader research and manufacturing activities. On August 5, 2005, we completed an initial public offering of our common stock. On August 10, 2005, we acquired Enable Medical Corporation, the manufacturer of our Isolator clamps, which are an essential part of our Isolator Synergy System. On December 31, 2013, we acquired Endoscopic Technologies, Inc. (Estech®), a medical device company focused primarily on RF ablation products used in cardiothoracic surgery. On October 13, 2015, we acquired nContact Surgical, Inc. (nContact), a medical device company focused primarily on a minimally invasive epicardial ablation products.

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. 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 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 procedures to treat their Afib. To perform a catheter ablation, an electrophysiologist inserts a flexible catheter into the inside of the heart, typically through the femoral vein. Catheter-based procedures, especially for more serious forms of Afib, are generally not indicated for patients with persistent or long-standing persistent Afib because they are often technically challenging, have shown to have lower degrees of efficacy as compared to treating milder forms of Afib and can be associated with serious complications. 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 have increased the level of recommendation for concomitant surgical ablation to Class 1, 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 25-30% of those candidates are being treated, but we believe many of these are not treated properly or fully. Of the population

diagnosed with Afib, a large percentage of these patients are symptomatic and do not respond to pharmacological therapy or are intolerant to the pharmaceuticals used to treat Afib. 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 700,000 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 in procedures performed to treat Afib. In addition, current practice guidelines state that the LAA should be occluded or removed, when possible, during cardiac surgery in patients at risk of developing postoperative Afib. We believe that our AtriClip system is safer, more effective and easier to use than other products and techniques for occluding the LAA, and, because of this, we believe that the market for the AtriClip system represents a significant growth opportunity.

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The AtriCure Solution and Products

We believe competing surgical and catheter-based ablation devices 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 but with a faster, less invasive and less technically challenging approach.

Clinical studies for the use of our products to treat Afib are ongoing. 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 are promising in terms of efficacy, ease of use and safety.

We have two primary product lines for cardiac tissue ablation and a product line for left atrial appendage exclusion:

Product lines for cardiac tissue ablation:

1.) Radio Frequency Ablation Devices. Our Isolator Synergy System and related RF devices, such as our multifunctional pens, represent our primary product line and currently generate the majority of our revenue. Physicians use the Isolator Synergy System and related RF devices in both open and minimally invasive procedures. These devices are powered by an Isolator Synergy Ablation and Sensing Unit (ASU), Electrosurgical Unit (ESU) or nContact RF Generator, which are compact power generators 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. We sell multiple configurations of our Isolator Synergy clamps. All of our clamps are single-use disposables and have jaws that close in a parallel fashion. The parallel closure compresses tissue and evacuates the blood and fluids from the energy pathway in order to make the ablation more effective.
- COBRA Fusion® Surgical Ablation System. The COBRA Fusion Surgical Ablation System's Versapolar™ technology combines bipolar temperature-controlled radio frequency (TCRF) energy control with monopolar energy. The COBRA Fusion System also incorporates a unique suction design that draws tissue into the device to create consistent, full thickness lesions without arresting and opening the heart.
- EPi-Sense® Guided Coagulation System with VisiTrax® Technology. The EPi-Sense Guided Coagulation System with VisiTrax technology is intended for the coagulation of cardiac tissue using RF energy using thoracoscopic, endoscopic and laparoscopic surgical techniques. It may be used for temporary cardiac signal sensing and recording during surgery when connected to an external recording device. The SUBTLE® cannula is an access device and conduit for the ablation device and endoscope to enable a closed chest endoscopic approach. This allows surgeons direct visualization while ablating on the posterior of the heart.
- Multifunctional Pens and Linear Ablation Devices. Multifunctional pens are disposable RF devices that come in two configurations—one that makes linear ablations and one that makes spot ablations. The pens enable surgeons to evaluate cardiac arrhythmias, perform temporary cardiac pacing, sensing, and stimulation and ablate cardiac tissue with the same device. When the multifunctional pens are used, surgeons are able to toggle back and forth between temporary pacing, sensing, stimulation and ablation. Surgeons generally use one or more of our pen devices in combination with Isolator Synergy clamps.

Our linear ablation devices are disposable linear RF ablation devices designed to allow physicians to create an expanded cardiac ablation lesion set. We believe physicians are using these devices in order to improve long-term results for patients who have non-paroxysmal forms of Afib.

2.) cryoICE Cryoablation System. The cryoICE cryoablation system consists of the cryoICE BOX generator along with a range of cryoICE single use and reusable cryosurgery probes. The cryoICE cryoablation system is used to ablate cardiac tissue for the treatment of cardiac arrhythmias and to provide temporary pain relief to thoracic surgery patients via ablation of peripheral nerves. The probes come in a variety of configurations, with the primary difference being flexibility of the distal end of the probe.

Product line for left atrial appendage management:

1.) AtriClip System. The AtriClip system is designed to occlude the left atrial appendage by mechanically clamping the appendage from the outside, 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 excluding the left atrial appendage. The AtriClip portfolio includes a range of devices with different size clips, as well as different applier lengths and deployment features.

In addition to the above product lines we also sell enabling technologies including our Lumitip™ dissectors and the Estech line of reusable cardiac surgery (valve) instruments. The Lumitip dissector is used by surgeons to separate tissues to provide access to key

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anatomical structures that are targeted for ablation. The Estech cardiac surgery instruments are used during surgical procedures for repair or replacement of certain 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 procedures that vary depending on the severity of the Afib symptoms and whether or not the patient suffers from other forms of heart disease. In late 2016, the Society of Thoracic Surgeons released their updated Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation.The guidelines state:

- Surgical ablation for Afib can be performed without additional operative risk and is recommended at the time of concomitant mitral valve operations to restore sinus rhythm.
- Surgical ablation for Afib can be performed without additional operative risk and is recommended at the time of concomitant isolated aortic valve replacement, isolated coronary artery bypass graft surgery and aortic valve replacement plus coronary bypass graft operations to restore sinus rhythm.
- Surgical ablation for symptomatic persistent or longstanding persistent Afib in the absence of structural heart disease is reasonable as a primary standalone procedure to restore sinus rhythm.

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 times, 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 and frequency 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.

With the exception of 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-heart procedures, we do not promote our products specifically for Afib. Nevertheless, physicians have adopted our products for use in open-heart and minimally invasive procedures for the treatment of Afib. 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, which has been reported to add less than one minute to a procedure.

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.

Additionally, some physicians are performing various minimally invasive stand-alone procedures which combine epicardial (surgical) ablation (ablation on the outside of the heart) with endocardial ablation and mapping techniques (from the inside of the heart). These combination procedures are often times referred to as “staged” approaches, in that the surgical ablation is performed first, then the catheter ablation is performed second. 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. Physician preference as well as hospital logistics and procedural room availability plays into the decision whether to perform in a single setting or a staged setting. Physicians are reporting that they are performing these procedures, also known as hybrid procedures, utilizing certain of our products to primarily treat patients who have non-paroxysmal forms of Afib.

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Business Strategy

Our mission 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. 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. Our product development and growth plans include continued innovation to expand on both new and existing market opportunities through either leveraging our existing product platform or developing entirely new products to serve new markets.

Invest in Clinical Science and Build Physician 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 who work with us to evaluate and develop our products. Additionally, we have formed advisory boards made up of key opinion leaders (KOLs) in cardiac surgery and other specialties to oversee our training and clinical programs. We are also building relationships with physicians in other specialties, including electrophysiology, interventional cardiology and general thoracic surgery who are involved in the treatment of patients with Afib and thus will provide insight regarding treatment trends, input on future product direction and education for other specialties involved in treating the disease.

Provide Training and Education. We have recruited and trained sales and education professionals to effectively communicate to physicians the unique features and benefits of our technologies as they relate to their indications for use. Our highly trained sales and education professionals meet with physicians at institutions around the world to provide education and technical training on the features and benefits 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 Afib in patients undergoing open-heart surgery. We believe this training and education program has increased and will continue to increase awareness about the surgical treatment of Afib during open-heart procedures. We also provide medical information on our products in response to information requests from physicians, and we have provided educational grants to institutions that have facilitated the education of doctors concerning the treatment of Afib, including the use of our products as an Afib treatment alternative. 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 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 clinical trials, new procedural techniques and anticipated presentations and publications will create an increased demand for our minimally invasive products.

Evaluate Acquisition Opportunities. In the past four years, we have acquired two companies that we believe further expand our ability to establish a platform for long-term revenue growth. We expect to continue to be opportunistic with respect to acquisitions where it makes strategic and financial sense.

Clinical Trials

The December 2011 FDA approval of our Isolator Synergy System included the requirement to implement a 350-patient post-approval study (PAS). The PAS was designed to evaluate the long-term safety and efficacy of our Isolator Synergy System in the treatment of persistent and long-standing persistent Afib in patients undergoing open-heart procedures. Enrollment in the trial was completed in October 2014 with 365 patients at 40 medical centers. We expect to release preliminary data from the study in 2017, with a complete report expected to be published in 2018.

We submitted an Investigational Device Exemption (IDE) application for the Staged Dual Epicardial Endocardial Persistent (DEEP) AF pivotal trial to FDA in May 2014. The Staged DEEP AF 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. FDA approval to enroll up to 220 subjects at 23 domestic medical centers and two international medical centers was received during the third quarter of 2014. Enrollment began during the first quarter of 2015, and there are currently 41 patients enrolled and thirteen sites initiated. Enrollment has been temporarily suspended while we evaluate changes to the trial protocol with FDA.

We are conducting the CONVERGE IDE clinical trial. The CONVERGE pivotal trial evaluates 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. We currently have FDA approval to enroll up to 153 subjects at 27 domestic medical centers and three international medical centers. Enrollment began during the first quarter of 2014, and there are currently 54 patients enrolled and seventeen domestic medical centers initiated.

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We are also conducting the ATLAS study, which 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. At full capacity, we expect to enroll approximately 2,000 patients at up to 40 medical centers. We began enrollment in February 2016, and there are currently 159 patients enrolled and ten medical centers initiated.

Our cryoanalgesia study (FROST) is a non-IDE randomized pilot study evaluating whether intraoperative intercostal cryoanalgesia in conjunction with standard of care provides improved analgesic efficacy in patients undergoing unilateral thoracotomy cardiac procedures as compared to current standard of care. The study involves treatment arm subjects who receive intercostal cryoanalgesia in conjunction with standard post-operative pain management and control arm subjects who receive standard post-operative pain management only. At full capacity, we expect to enroll up to 100 patients at up to five medical centers. We began enrollment in June 2016, and there are currently 20 patients enrolled and three medical centers initiated.

We are also pursuing a non-IDE trial in Europe, CEASE AF, 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 across twelve medical centers. There are currently 58 patients enrolled and eleven medical centers initiated.

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 regulatory agency approved or cleared labeling. We train our sales force on the use of our products to treat Afib to the extent the products are cleared for the treatment of Afib.

Our sales team in the United States has approximately 120 employees supporting approximately 53 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 independent distributors and through our European subsidiary which includes a combination of independent distributors and direct sales personnel. We have a network of distributors outside of the United States who market and sell our products. They are located primarily in Asia, South America and Canada, as well as certain countries in Europe. Our international sales team includes sales representatives focused on our direct markets, such as Germany, France, the United Kingdom and the Benelux region. 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. Our competitors have significantly 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. We and our competitors provide products that have been adopted by physicians for the treatment of Afib and related conditions. Several of our competitors offer intracardiac catheter devices that are commonly used by electrophysiologists to treat Afib. Some of these catheter devices are FDA-approved to treat the paroxysmal form of Afib, but they are not FDA-approved to treat persistent or long-standing persistent Afib. AtriCure's Isolator Synergy System is the only medical device FDA approved to treat Afib in a surgical setting, and the only medical device approved to treat persistent or long-standing persistent Afib.

We believe that our products compare favorably against competing products that are commonly used for the surgical treatment of Afib during both open-heart and sole-therapy minimally invasive procedures, although we cannot assume that we will be able to continue to do so in the future or that new devices that perform better than our products will not be introduced. We also believe 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 superior to all other medical devices indicated for exclusion of the left atrial appendage.

Due to the size of the Afib and left atrial appendage exclusion markets, and the unmet need for an Afib cure, competitors have dedicated and will continue to dedicate resources to develop and market their products. New product developments could compete with us more effectively because the Afib treatment and left atrial appendage exclusion markets are characterized by extensive research efforts and technological progress.

Existing or new competitors may develop technologies and products that are safer, more effective, easier to use or less expensive than our products. To compete effectively, we have 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. We

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have encountered and expect to continue to encounter potential customers who prefer products offered by our competitors. Competitive pressures may result in price reductions and reduced gross profit margins for our products over time. Technological advances may render our products obsolete or uneconomical.

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 (IPPS), 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 is used during a concomitant open-heart procedure, Medicare's hospital reimbursement is based upon the patient's primary surgical procedure. Reimbursement for sole-therapy minimally invasive Afib ablation treatment is also influenced by the patient's severity of illness. We believe hospital reimbursement rates for sole therapy and concomitant therapy cardiac surgical tissue ablation are adequate to cover the cost of our products. Medicare's coding, coverage, and payment policies are subject to change. As a result, the continuance of current coverage, coding or payment determinations cannot be guaranteed, and any change may have an adverse impact on our business.

Physicians are reimbursed for their services separately under the Medicare Part B physician fee schedule. When surgically performing a cardiac ablation with and without a concomitant open-heart procedure, surgeons report Current Procedural Terminology (CPT) codes to receive a professional fee. Surgeons have a choice of CPT codes to report sole-therapy and concomitant therapy cardiac tissue ablation. At this time, there are no CPT codes for the physician to report surgical exclusion of the left atrial appendage.

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.

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 payers. In addition, some private third-party payers require that certain procedures or the use of certain products be authorized in advance as a condition of reimbursement. In certain markets outside of the United States, 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. 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.

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 (CABG) 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;

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- 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, design or manufacture, requires a new 510(k) clearance or, possibly, in connection with safety and effectiveness, approval of a PMA. FDA requires every manufacturer to make the determination regarding a new 510(k) submission in the first instance, but FDA may review any manufacturer's decision. We have made modifications to elements of our products which we believe did not require us to seek additional 510(k) clearance.

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. New PMAs or PMA supplements are required for significant modification to the 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;

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- 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 MedWatch 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, only a small portion of which 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 unable to determine whether our product caused or contributed to a death or serious injury in the particular case, or that a malfunction of the type reported would not 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 to determine our compliance with the QSR, the European Union's Medical Device Directive (MDD) and other regulations, and these inspections may include the manufacturing facilities of our suppliers.

Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by FDA or other federal or state authorities, which are described in Item 1A "Risk Factors".

Fraud, Abuse and False Claims. We are directly and indirectly subject to various federal and state laws governing our relationship with healthcare providers and pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs.

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 can be significant and consist of the imposition of fines and penalties. 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 included the off-label promotion of products or the payment of prohibited kickbacks to doctors violated the FCA resulting in the submission of improper claims to federal and state healthcare entitlement programs such as 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 by a medical device manufacturer is voluntary, and while the OIG 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

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on these principles. However, we cannot provide any assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws.

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) 13485:2003 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, 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. For example, 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 certain proprietary trade secrets that may not be patentable. With respect to proprietary know-how 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 available from more than one supplier. However, some products, such as our RF generators and Fusion and Epi-Sense products, are critical components of our RF ablation lines and there are 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 are required to manufacture our products in compliance with FDA’s Quality System Regulation (QSR) and International Organization for Standardization standard 13485 (ISO 13485). The QSR and ISO 13485 regulate the methods and documentation of the design, testing, acceptance, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products.

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FDA enforces the QSR through periodic inspections that may be announced or unannounced and may include appropriate manufacturing facilities of some of our suppliers. Our failure to maintain compliance with the QSR could result in the shutdown of our manufacturing operations or the recall of our products, which would have a material adverse effect on our business. In the event that one of our suppliers fails to maintain compliance with AtriCure's quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result. We also could be subjected to injunctions, product seizures and/or civil or criminal penalties.

We regularly audit our suppliers for compliance with AtriCure's quality system requirements, the QSR and/or applicable ISO standards. We are an FDA-registered medical device manufacturer and certified to ISO 13485:2003. In addition, AtriCure has successfully participated in the Medical Device Single Audit Program (MDSAP) and has been certified accordingly. Our quality system meets the regulatory requirements for Australia, Brazil, Canada, Europe, Japan and the U.S.

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 Eucomed Codes. As such, they provide for payment of a fair market value fee only for legitimate services actually 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 U.S. physicians are disclosed by us in annual reports submitted to CMS under the federal "Open Payments" law and implementing regulations and under similar U.S. state and international laws, rules and regulations.

Employees

We had approximately 500 full-time employees as of January 31, 2017. 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 good although we cannot provide any assurance that we will not experience such work stoppages in the future.

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, or 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 and Compliance, Regulatory and Risk Committees and our Code of Ethics are available on our website. In the event that we grant a waiver under our Code of Ethics to any of our officers and directors, we will publish it on our website. Information contained in any of our websites is not deemed to be a part of this Form 10-K.

ITEM 1A. RISK FACTORS

Risks Relating To Our Business

If our products do not achieve widespread market acceptance in the United States, our operating results will be harmed and we may not achieve 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 as compared to other 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, in particular, the safety of our products. Market acceptance and adoption of our products

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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 isolated incidents involving our products or other products related to those we sell could have a significant adverse effect on the overall acceptance of our products. If we encounter difficulties developing a market for our products in the United States, we may not be able to increase our revenue enough to achieve profitability, and our business and operating results will be seriously harmed.

We rely on our ablation, ablation-related and AtriClip products as our primary sources of revenue. If we are not successful in selling these products, or if these products become obsolete, 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 during open-heart surgical procedures and as a sole-therapy minimally invasive procedure. 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. In addition, 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. Since we believe that physicians are using our ablation and ablation-related products only for the surgical treatment of Afib, if physicians do not use our products to treat Afib, we would lose substantially all of our revenue.

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, 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 (Patient Act), as amended, as well as other healthcare reform have a significant impact on our business. The impact of the Patient Act 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

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citizens and mandating basic healthcare benefits. The Patient Act 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. The increased tax burden significantly impacts our results of operations and cash flows. It is possible that, due to the new Presidential Administration in the United States, legislation will be introduced and passed by the Republican-controlled Congress repealing the Patient Act in whole or in part and signed into law. Because of the continued uncertainty about the implementation of the Patient Act, 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 Patient Act or its repeal on our business model, prospects, financial condition or results of operations.

Any healthcare reforms enacted in the future may, like the Patient Act, 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 Patient Act and changes under any federal or state legislation adopted in the future.

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

Due to current worldwide economic conditions, 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, particularly because our sales prospects are uncertain. These fluctuations may also affect our annual operating results and may cause those results to fluctuate unexpectedly from year to year.

Restrictions in our ability to train surgeons in the use of our products could reduce the market acceptance of our products or result in injuries to patients or other adverse events that could possibly lead to litigation that could harm us or could reduce our revenue.

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. 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. In December 2011 our Isolator Synergy System was 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 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 you that a sufficient number of surgeons will become aware of training programs.

Surgeons may not commit enough time to sufficiently learn 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. 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 and cash flow.

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 many 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.

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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, 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 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 through physicians who use the product off-label.

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 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 the 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.

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, including death, are commonly encountered in connection with the surgical treatment of Afib. If products we sell are defectively designed, manufactured or labeled, contain inadequate warnings, contain defective components or are misused, 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

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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 earnings and financial condition.

Competition from existing and new products and procedures may decrease our market share and cause our revenue to decline.

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 exclude the left atrial appendage, or other surgical Afib treatments, which may be more well-established among doctors and hospitals. 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. Some of our competitors have greater financial, manufacturing, marketing and research and development capabilities than we have or may obtain FDA approval for the use of their products before we do. The introduction of new products, procedures, clinical solutions or our competitors obtaining FDA approvals may result in price reductions, reduced margins or loss of market share and may render our products obsolete, which could adversely affect our revenue and future profitability.

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.

Furthermore, 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 earnings and 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, 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. 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

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products could require us to conduct additional clinical trials and to revise our filings with the 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 doctors and hospitals or the lack of malpractice insurance coverage due to the use of our products by doctors for an off-label indication may cause certain doctors or hospitals to decide not to use our products and may damage our ability to grow and maintain 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 doctors 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 $33,338 in 2016, $27,212 in 2015 and $16,211 in 2014. As of December 31, 2016, we had an accumulated deficit of $198,974.

Our net losses have resulted principally from costs and expenses relating to sales and promotional efforts, research and development, seeking regulatory clearances and approvals and general operating expenses. We expect to continue to make substantial expenditures and to potentially incur additional operating losses in the future as we further develop and commercialize our products, including completing clinical trials and seeking regulatory clearances and approvals. 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 12 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, 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. Our Loan and Security Agreement with Silicon Valley Bank (SVB), as amended, restated, and modified effective April 25, 2016 (Loan Agreement) provides for a $25,000 term loan and a revolving credit facility under which we may borrow up to a maximum of $15,000. The term loan and revolving credit facility both mature in April 2021. According to the Loan Agreement, principal payments on the term loan are to be made ratably commencing twelve months after the inception of the loan through to the loan’s maturity date. We have met certain conditions, as specified by the Loan Agreement, to defer the commencement of term loan principal payments by an additional six months. The term loan accrues interest at the Prime Rate and is subject to an additional 4.0% fee on the original $25,000 term loan principal amount at maturity or prepayment of the term loan. Borrowing availability under the revolving credit facility is based on the lesser of $15,000 or a borrowing base calculation as defined by the Loan Agreement. As of December 31, 2016, we had no borrowings under the revolving credit facility, and we had borrowing availability of $15,000. The applicable borrowing rate on advances outstanding under the revolving credit facility is the Prime Rate. The Loan Agreement also provides for certain prepayment and early termination fees, as well as establishes covenants related to liquidity, sales growth and a minimum cash balance, and includes other customary terms and conditions.

The nContact acquisition provides for contingent consideration to be paid upon attaining specified regulatory approvals and clinical and revenue milestones over the next four years. Subject to the terms and conditions of the nContact merger agreement, such contingent consideration is paid in AtriCure common stock and cash. Over the next twelve months, we do not expect our cash requirements to include 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 our existing stockholders.

If we need to raise additional funds, 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.

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Our Loan Agreement with SVB contains covenants that include, among others, covenants related to liquidity, sales growth and a minimum cash balance. 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 prior to the initial public offering of our common stock will be limited or may expire, which could result in greater future income tax expense and adversely impact future cash flows because we experienced an ownership change of more than 50 percent on June 30, 2001. Additionally, we acquired net operating losses through acquisitions which may be limited or may expire.

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. 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 $222,816 and $5,344.

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 currently rely on single and limited source third-party vendors for the manufacture of many of the components used in our products. For example, we rely on one vendor to manufacture our ASU, ESU and ASB, as well as separate vendors to manufacture our COBRA Fusion Surgical Ablation Systems, EPi-Sense Guided Coagulation System with VisiTrax technology, nContact RF generators and ORLab™. 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 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 our goodwill or other intangible assets become impaired, it could materially reduce the value of our assets and increase our net loss for the year in which the impairment occurs.

As of December 31, 2016, 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 write off the impaired portion, 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 write off occurs and increase our accumulated deficit, which could contribute to difficulty in raising additional funds.

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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 to 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, which could contribute to difficulty in raising additional funds.

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 excess inventory of our products or component parts. Managing our inventory levels is important to our cash position and results of operations and is more 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.

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. The 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 the FDA taking administrative or enforcement actions. Among these may be the FDA's issuance of a Warning Letter to a manufacturer, which informs it that the 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 the FDA's review of product applications and the 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 profitability.

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.

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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 reasonably are the cause of or contribute to an adverse event, death, serious injury or, in the event of product malfunction, that if it were to recur, would likely cause or contribute to a death or serious injury. We have a history of submitting medical device reports to FDA involving our products, including patient deaths, which were categorized as outcomes based on physician judgment, not on the failure of our devices. There have also been other incidents, including patient deaths, which have occurred during procedures using our products that we have not, and believe were not required to be, reported to FDA because we and our physician consultants 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 FDA or us 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.

FDA conducted an inspection in our Cincinnati, Ohio facility in August 2016. This audit resulted in the issuance of a Form FDA 483, Inspectional Observations, which outlined certain nonconformance items within our Medical Device Reporting (MDR) and risk mitigation processes. We responded to the observations and have taken corrective actions where appropriate. We take these matters seriously, and we will respond timely and fully to any additional FDA requests. We believe that FDA’s concerns will be resolved without a material impact on our financial results.

Modifications to our products may require new clearances or approvals or 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 510(k) clearance or procedure or, possibly, submission and FDA approval of a PMA. FDA requires every medical device company to make the determination as to whether a new 510(k) is to be filed, but FDA may review any medical device company's decision. We have made modifications to our products but do not believe such modifications required us to submit an additional 510(k). FDA may not agree with our decisions regarding whether new clearances or approvals were required.

If FDA were to disagree with us and require us to submit a new 510(k), PMA or a different type of 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.

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We will 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, or 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;
- 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.

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.

Adverse changes in payors' policies toward coverage and reimbursement for surgical Afib treatment 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 Afib treatment 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 Afib treatment 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

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not specifically approved or cleared by FDA to be experimental and, as such, may deny coverage or payment. Often times, these denials can be overcome through an appeals process, but there is no guarantee of success in these cases.

We have traditionally had limited long-term clinical data regarding the safety and efficacy of our products. Any long-term data that is generated may not be positive or consistent with our limited short-term data, 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 long-term 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 long-term data regarding the safety and efficacy of our products going forward, such data could, nevertheless, 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. In addition, the long-term effects of ablation procedures and left atrial appendage exclusion are not well-known. Negative long-term data would affect the use of our products and harm our business and prospects.

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 international 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.

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

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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 in these markets 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 increase or maintain our level of international revenue. Over the long term, 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 personnel. Fluctuations in foreign currency exchange rates including, in particular, any strengthening of the U.S. dollar may cause our independent sales distributors to seek longer payment terms to offset the higher prices they are paying in local currency for our products. 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.

If coverage and adequate levels of reimbursement from governmental and third-party payors outside of the United States are not attained 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. In general, foreign healthcare payors do not provide reimbursement for sole-therapy minimally invasive procedures utilizing ablation devices and related products. 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 clamps 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.

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.

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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 our key personnel. Our officers and key employees, with the exception of our President and Chief Executive Officer and Senior Vice President, Operations and Quality, 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 doctors that involve procedure, product, market and clinical development. If any of these doctors 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 doctor relationships necessary to grow and expand our business and operations. If we fail to identify, attract, retain and motivate these highly skilled personnel and doctors, 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 all the 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 in the past four years 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.

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

We 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 product sales, which include sales within European countries that are currently experiencing economic turmoil.

The majority of our accounts receivable arise from product sales in the United States. However, we also have significant receivable balances from customers within the European Union, Asia and other countries. 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 and sub-dealers operate in certain countries where economic conditions continue to present challenges to their businesses, and, thus, could place in risk the amounts due to us from them. These distributors are owed amounts from public hospitals that are funded by their governments. Adverse financial conditions in these countries may continue, thus negatively affecting the length of time that it will take us to collect associated accounts receivable or impact the likelihood of ultimate collection.

Compliance with environmental laws and regulations may be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability.

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. In addition, 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. As we believe we are in compliance with such laws and regulations, we do not expect that continued compliance will have a material impact on our business.

Risks Relating To Our Common Stock

The price and trading volume of our common stock may experience extreme fluctuations and you could lose some or all of your 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:

- doctor 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;
- 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;

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- 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;
- variations in our quarterly financial and operating results;
- 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. If our quarterly or annual operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. 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 product 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 particular companies. These market prices generally are not sustainable and are highly volatile. 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. 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.

Sales of common stock by us in a capital raising transaction may dilute your 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. If we raise funds by issuing equity securities, our stock price may decline and our existing shareholders may experience significant dilution. Furthermore, we may enter into financing 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. In February 2014 we raised funds through a public offering of 3,660,525 shares of common stock. In October 2015 we issued 3,757,028 shares of common stock in connection with the acquisition of nContact.

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 you 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 you with a premium to the market price of your 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;

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- 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 to remove directors;
- limiting the ability of stockholders