AtriCure, Inc.
Form 10-K
March 02, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2014

¨ **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 incorporation or organization	(I.R.S. Employer Identification Number)
6217 Centre Park Drive, West Chester, OH	45069
(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 x

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 x

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 x 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 x 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 x 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 x

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, 2014, as reported on the NASDAQ Global Market, was $478.3 million.

As of February 20, 2015 there were 27,590,646 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 similar 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 in this Part I are in thousands.)

ITEM 1. BUSINESS

Overview

We are a medical device company providing innovative atrial fibrillation (Afib) solutions designed to produce superior outcomes that reduce the economic and social burden of atrial fibrillation. We have two primary product lines for the ablation of cardiac tissue. Our Isolator Synergy® Ablation System is the first and only surgical device approved by the United States Food and Drug Administration (FDA) for the treatment of Afib. Our cryoICE cryosurgery product line offers a variety of both single use and reusable cryoablation devices. 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). We believe cardiothoracic surgeons are adopting our ablation and LAA management (LAAM) devices to cure Afib and reduce Afib-related complications such as stroke.

Cardiothoracic surgeons have adopted our radiofrequency (RF) ablation and cryoablation systems to treat Afib in an estimated 170,000 patients since 2004, and we believe that we are currently the market leader in the surgical treatment of Afib. Our products are utilized by cardiothoracic surgeons during both open-heart and minimally invasive procedures, either on a concomitant or sole-therapy basis. During a concomitant procedure, the surgeon ablates cardiac tissue and/or excludes the left atrial appendage, secondary, or concomitant, to a primary cardiac procedure such as a valve replacement or coronary artery bypass graft (CABG). Our Isolator Synergy System, which includes our Isolator Synergy clamps, generator and switchbox, is approved by FDA for the treatment of persistent and long-standing persistent Afib in patients who are undergoing open concomitant coronary artery bypass grafting and/or valve replacement or repair. To date, none of our other products have been approved or cleared by FDA specifically for the treatment of Afib. Our 510k-cleared RF ablation products are indicated for the ablation of cardiac tissue. Our 510k-cleared cryosurgery products are indicated for the treatment of cardiac arrhythmias. Our AtriClip products are 510k-cleared with an indication for occlusion of the LAA, under direct visualization, in conjunction with other open cardiac surgical procedures. 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 treat Afib, exclude the left atrial appendage, or repair or replace mitral and aortic valves.

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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. Afib is a condition wherein 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 of this quivering, blood in the atria may become static, creating an increased risk that a blood clot will form and cause a stroke or other serious complications. If Afib persists, patients often progress from experiencing Afib intermittently to having Afib continuously, a condition that is more difficult to treat. 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. Although there is often no specific cause of Afib, the condition is often associated with high blood pressure and other forms of heart disease. In most cases, Afib is associated with cardiovascular disease, in particular hypertension, congestive heart failure, left ventricular dysfunction, coronary artery disease and valvular disease.

In the United States we primarily sell our products to medical centers through our direct sales force. AtriCure Europe B.V., our wholly-owned subsidiary incorporated and based in the Netherlands, markets and sells our products throughout Europe and the Middle East primarily through distributors, while in certain markets, such as Germany, France and the Benelux region, sales are made directly to medical centers. Additionally, we sell our products to other international distributors, primarily in Asia, South America and Canada. Our business is primarily transacted in U.S. dollars with the exception of transactions with our European subsidiary which are substantially transacted in Euros or British Pounds.

We were incorporated in the State of Delaware as AtriCure, Inc. 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. We have two operating subsidiaries: (i) AtriCure Europe B.V., a company incorporated under the laws of the Netherlands in December 2005 and (ii) AtriCure, LLC, a limited liability company organized under the laws of Delaware in October 2012.

Market Overview

Afib is the most commonly diagnosed sustained cardiac arrhythmia, and affects more than 30 million people worldwide, including more than 5 million in the United States, where approximately 160,000 new cases of Afib are diagnosed each year. According to data from the Framingham Heart Study, a study originally undertaken by the National Heart Institute (now known as the National Heart, Lung and Blood Institute), 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 stroke or heart disease. 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.

According to the American Heart Association, people with Afib are about five times more likely to have a stroke, and Afib is thought to be responsible for approximately 15% to 20% of the estimated 700,000 strokes that occur annually in the United States. In a major study of patients with a stroke and Afib, over 90% of the clots identified by imaging were found to exist within the LAA providing evidence that Afib-related stroke is significantly linked with clots arising from the LAA. Afib-related strokes tend to be severe, and approximately

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35% of Afib patients will have a stroke in their lifetime. Studies suggest that 25% of people who have an Afib-related stroke die within the first thirty days following their stroke and over 40% are permanently bedridden. In addition, Afib accounts for $6,700,000 in hospitalization-related costs in the United States. Additional costs include the cost of drugs and indirect costs, such as the management of Afib-related strokes, the costs of which are believed to be significant. Because of this significant cost burden on the healthcare system, we believe that the surgical practice of excluding the LAA has become a growing trend in procedures performed to treat Afib, and current practice guidelines indicate that the LAA should be removed, when possible, during cardiac surgery in patients at risk of developing postoperative Afib. We also believe that our AtriClip system is potentially safer, more effective and easier to use when permanently excluding the LAA than other products and techniques, and, because of this, we believe that the market for the AtriClip system is large and represents a growth opportunity for us.

Afib is a condition that doctors often find difficult to treat and, historically, there has been no widely accepted long-term cure for Afib. Doctors typically begin treating Afib with drugs, 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 drugs 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 are often technically challenging, can be associated with serious complications, are generally not indicated for a certain population of Afib patients, and have been known to yield inconsistent results. 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, but this procedure has not been widely adopted because it is technically challenging, highly invasive and involves long recovery times.

Of the patients undergoing open-heart surgery in the United States, we estimate that 80,000-90,000 are potential candidates for surgical ablation using our ablation products. Of the United States population diagnosed with Afib, a large percentage of these patients are symptomatic and do not respond to drug therapy or are intolerant to the drugs used to treat Afib. For these patients, the cut and sew Maze procedure is typically too invasive and catheter ablation may not be indicated. Accordingly, we believe that there is a large population of under-treated patients for whom their physicians may decide that they would potentially benefit from a minimally invasive or hybrid Afib treatment using our Synergy System and related products, and that these patients comprise our largest growth opportunity.

The AtriCure Solution and Products

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 cardiac surgeons to achieve comparable results to the cut and sew Maze procedure but with a faster, less invasive and less technically challenging approach.

Our 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.

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

Product lines for cardiac tissue ablation:

1.) **Isolator s Synergy Ablation System and Related 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 a substantial majority of our revenue. Physicians may elect to use the Isolator Synergy System and related RF devices in both open and minimally invasive procedures. These devices primarily consist of the following products:

Isolator Synergy and Isolator Synergy Access Clamps. We sell multiple configurations of our Isolator Synergy clamps. One configuration is optimized for is for ablation during open-heart procedures and others for minimally invasive procedures. 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.

Isolator Synergy Ablation and Sensing Unit (ASU). The ASU is a compact generator that delivers bipolar radio frequency energy to our Isolator Synergy clamps, pens and the Coolrail linear ablation device. We generally lend our ASU, free of charge, to our direct customers and sell it to our distributors.

AtriCure Switch Box (ASB). Our ASB is a compact switch box which provides the technology needed for the dual pulsing electrodes in our Isolator Synergy clamps as well as the ability to connect and toggle between our multiple RF devices. We generally lend our ASB, free of charge, to our direct customers and sell it to our distributors.

Isolator Multifunctional Pens. Isolator 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 with the ASB, 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 during both minimally invasive and open-heart procedures.

Coolrail Linear Ablation Device. Our Coolrail linear ablation device is a disposable linear RF ablation device designed to allow physicians to create an expanded cardiac ablation lesion set during minimally invasive procedures. We believe physicians are using our Coolrail device during minimally invasive procedures in order to improve long-term results for patients who have non-paroxysmal forms of Afib.

2.) **Estech Radio Frequency Ablation Devices.** Physicians use the Estech ablation devices in both open and minimally invasive procedures. These devices primarily consist of the following products:

Fusion Surgical Ablation System. The Fusion Surgical Ablation System s Versapolatechnology combines bipolar temperature-controlled radio frequency (TCRF) energy control with monopolar energy. The 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.

Estech Electrosurgical Unit (ESU). The Estech ESU is a compact power generator for use with Fusion ablation products. We generally lend our ESU, free of charge, to our direct customers and sell it to our distributors.

AFfirm Bipolar Pacing Probe. The AFfirm Bipolar Pacing Probe is used to test lesions created in surgically treating the patient s arrhythmia.

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3.) **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.

Product line for left atrial appendage management:

AtriClip System. The AtriClip system is designed to exclude 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 currently 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 Estech s line of reusable cardiac surgery instruments. The Lumitip dissector is used by surgeons to separate tissues to provide access to key 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. A 2014 report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society set forth guidelines for the management of patients with Afib. The guidelines state:

An Afib surgical ablation procedure is reasonable for selected patients with Afib undergoing cardiac surgery for other indications;

A stand-alone Afib surgical ablation procedure may be reasonable for selected patients with highly symptomatic Afib not well managed with other approaches.

Treatment alternatives 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 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 an ablation 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.

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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 report that ablation using our products generally adds approximately 10 to 30 minutes to an open-heart surgical procedure. 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 exclude 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 Isolator clamps and related 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. Surgeons have reported that the procedure takes approximately two to four hours and that the average hospitalization period has typically been two to five days. Similar to the open-heart surgical procedure, patients who have non-paroxysmal forms of Afib generally require an expanded lesion set that mimics the cut and sew Maze procedure. Our multifunctional pens are often used during these procedures to enable physicians to perform additional ablations.

Physicians are performing an emerging minimally invasive stand-alone, staged procedure which combines epicardial (surgical) ablation (ablation on the outside of the heart) with endocardial ablation and mapping techniques (from the inside of the heart). This procedure involves having the epicardial procedure performed on the first day of hospitalization and the catheter ablation and mapping performed at a later time. Physicians are reporting that they are performing this procedure, also known as a hybrid procedure, utilizing our Isolator clamps and related products in combination with catheter ablation and mapping techniques to primarily treat patients who have non-paroxysmal forms of Afib.

Product Development

Our product development team develops product enhancements and new products to address unmet procedural and market needs with the goal of improving patient care, increasing revenue and optimizing procedural outcomes. Our current product development activity includes projects extending and improving our existing products, the creation of new enabling devices and research into new technologies.

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:

Provide Training and Education. We have recruited and trained sales professionals who have strong backgrounds in the medical device industry to effectively communicate to doctors the unique features and benefits of our technologies as they relate to their indications for use. Our highly trained sales professionals meet with doctors at leading institutions around the world to provide education and training on the technical 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 will

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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 International Markets and Enter into New Markets. Sales to international customers represented 25% of our total revenue for 2014. Many of the international markets in which we currently do business are underpenetrated markets which present high growth opportunities for our products. Further, we plan to continue to evaluate expansion opportunities in new geographic markets and capitalize on new product introductions.

New Product Innovation. 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.

Engage with Key Opinion Leaders. We have formed consulting relationships with cardiothoracic surgeons who work with us to evaluate and develop our products. Additionally, we have formed an advisory board made up of key opinion leaders (KOLs) in cardiac surgery to oversee our surgical training programs. We are also building relationships with physicians in other specialties, including electrophysiology and interventional cardiology, 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.

Leverage Product Portfolio, Labeling and Cross-Selling Opportunities. We believe we have the most comprehensive offering of cardiac ablation and left atrial appendage exclusion products in the market. We plan to leverage our leading product portfolio to facilitate cross-selling of our products as well as to drive market share gains through competitive account conversions.

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 describing long term results from their use in minimally invasive procedures. We also expect that successful completion of several company-sponsored clinical trials, along with FDA approval of expanded indications for the products in those trials, will create increased demand for our minimally invasive products.

Invest in Clinical Trials. 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.

Clinical Trials

We received pre-market approval (PMA) for our Isolator Synergy System in December 2011, following successful completion of the ABLATE clinical trial. FDA approved the Isolator Synergy System for the treatment of patients with persistent and long-standing persistent Afib during open-heart concomitant coronary artery bypass grafting and/or valve replacement or repair procedures. The approval included a requirement to conduct a 350-patient post-approval study (PAS). The PAS was designed to evaluate the long-term results of cases using the Isolator Synergy System to treat persistent and long-standing persistent Afib in patients undergoing open-heart procedures. We submitted a protocol for the PAS to FDA in February 2012, and it was approved in September 2012. We submitted a protocol amendment to increase enrollment by up to 40 patients to FDA in April 2014. The amendment was approved in June 2014. 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 early 2016, with a complete report expected to be published in 2017.

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We conducted the Dual Epicardial Endocardial Persistent Atrial Fibrillation (DEEP AF) Feasibility clinical trial to evaluate use of the Isolator Synergy System for the treatment of Afib in a two-part procedure where a minimally invasive surgical ablation procedure is performed first, and an intracardiac catheter mapping and ablation procedure is then performed on a different day during the same hospitalization. The Staged DEEP AF Feasibility trial protocol was submitted to FDA in February 2012, and FDA approval to conduct the trial was received in June 2012. Enrollment in the Staged DEEP trial began during the third quarter of 2012 and was completed during the fourth quarter of 2013, with 30 patients enrolled at six medical centers.

We submitted an Investigational Device Exemption (IDE) application for the Staged DEEP pivotal trial to FDA in May 2014. The Staged DEEP 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 conditional approval was received in July 2014. FDA full approval was received in September 2014. We have approval to enroll up to 220 subjects at 23 domestic medical centers and two international medical centers.

We are also conducting a Stroke Feasibility clinical trial with the AtriClip System. The Stroke Feasibility trial protocol was initially approved by FDA in December 2011. An amendment to the protocol was submitted to FDA and approved in October 2013. The Stroke trial evaluates the initial safety and efficacy of the AtriClip System for stroke prophylaxis (prevention of stroke) in patients with non-valvular Afib in whom long term oral anticoagulation therapy is medically contraindicated. We have approval to enroll up to 30 patients at seven medical centers during the course of the trial. Enrollment began in the first quarter of 2014 and currently stands at eleven patients.

Sales, Marketing and Medical Education

Our United States sales and marketing efforts focus on educating doctors about our unique technologies and their technical benefits. We only promote our products in the United States for uses described in their FDA 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 is led by a Chief Operating Officer and has approximately 85 employees supporting approximately 45 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.

Our sales team in the United States has approximately 85 employees supporting approximately 45 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. During 2014 and 2013 sales to customers outside of the United States accounted for 25% and 24% of our total revenue, respectively. We have a network of distributors outside of the United States who currently market and sell our products. They are located primarily in Europe, Asia, South America and Canada. Our international sales team includes sales representatives who sell to customers in markets we sell directly to, 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. Many of our competitors have significantly greater financial and human resources than we do and have established reputations with our target customers, as well as worldwide

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distribution channels that are more established and developed than ours. Our primary competitor is Medtronic, Inc. We and our competitors provide products that have been adopted by doctors 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 in any form.

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 significant resources to develop and market their products. New product developments that could compete with us more effectively are likely 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 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. Reimbursement under Part A of the Medicare program includes hospitals and other institutional services, while Medicare Part B covers physician services. 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. Currently, 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

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result, the continuance of current coverage, coding or payment determinations cannot be guaranteed, and any change may have an adverse impact on our business.

Doctors 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. If CMS or other agencies decrease or limit reimbursement payments to doctors and hospitals, this may negatively impact our business. Additionally, some private payors do not follow the Medicare guidelines and those payors may reimburse only a portion of the cost of cardiac ablation, or not at all. Physicians, in combination with their professional organizations and societies, are responding and working to secure reimbursement for the procedure to the extent the payor has denied reimbursement.

FDA does not regulate the practice of medicine. Doctors may use our products in circumstances where they deem it medically appropriate, such as for the treatment of Afib or the reduction in stroke risk, even though FDA may not have approved or cleared our products to be marketed specifically for those indications. Some payors may deem the use of our products for indications not specifically approved or cleared by FDA to be experimental and, as such, may deny coverage or payment.

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.

Government Regulation

Our products are medical devices and are subject to regulation in the United States by FDA and other federal agencies, and comparable authorities in other countries. In December 2011, following FDA approval of the new indication, we began to market the Isolator Synergy System for the treatment of patients with persistent and long-standing persistent Afib during open-heart concomitant surgical procedures such as coronary artery bypass grafting (CABG) and valve replacement or repair. The Isolator Synergy System was previously 510(k) cleared for the ablation of cardiac tissue, and continues to be marketed in the United States under both the 510(k) clearance and PMA approval. Our minimally invasive clamps are 510(k) cleared for the ablation of cardiac tissue. Our multifunctional pen and multifunctional linear pen are 510(k) cleared for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias and for the ablation of cardiac tissue. Our cryoablation products are 510(k) cleared for the treatment of cardiac arrhythmias. Our CRYO2 probes received an additional 510(k) clearance in December 2014 for blocking pain by temporarily ablating peripheral nerves. The Lumitip dissector is 510(k) cleared for use in the dissection of soft tissues during general, ear, nose and throat, thoracic, urological and gynecological surgical procedures. The AtriClip system is 510(k) cleared for occlusion of the left atrial appendage under direct visualization in conjunction with other open cardiac surgical procedures. The Estech Fusion Ablation System is 510(k) cleared to ablate cardiac tissue and for temporary cardiac pacing, sensing, recording and stimulation during the evaluation of cardiac arrhythmias. The AFfirm

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Bipolar Pacing Probe is 510(k) cleared to provide transient cardiac pacing or recording for the assessment of electrical isolation/conduction block of ablation lesions in the surgical treatment of arrhythmias.

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 the 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;
- premarketing clearance or approval;
- record keeping and document retention procedures;
- advertising and promotion;
- the import and export of products;
- product marketing, sales and distribution;
- post-marketing surveillance and medical device reporting, including reporting of deaths, serious injuries, device malfunctions or other adverse events; and
- corrective actions, removals and recalls.

FDA s Premarket Clearance and Approval Requirements. Unless an exemption applies, most medical devices distributed commercially in the United States will require either prior 510(k) clearance or PMA from the FDA. Other premarket pathways, such as the humanitarian device exemption (HDE) or a request for classification under section 513(a)(1) of the FDCA, commonly known as a de novo request, are also available in certain situations. Medical devices are classified into one of three classes Class I, Class II, or Class III depending on the degree of risk and the level of control necessary to assure the safety and effectiveness of each medical device. Devices deemed to pose lower risks are placed in either Class I or II. While most Class I devices are exempt from the requirement to submit a 510(k) notification requesting clearance to commercially distribute the device, most Class II devices are subject to the 510(k) premarket notification process. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device or predicate device, are generally placed in Class III, requiring submission of a PMA supported by clinical trial data.

510(k) Clearance Pathway. When 510(k) clearance is required, we must submit a notification to the 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 the FDA has not yet called for the submission of a PMA. The FDA is required to respond to a 510(k) notification within 90 days of submission, but the response may be a request for additional information or data, including clinical data. As a practical matter, 510(k) clearance often takes significantly longer than 90 days and may take up to a year or more. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously cleared device or use, the device is automatically placed into Class III, requiring 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. The FDA requires every manufacturer to make the determination regarding a new 510(k) submission in the first instance, but the 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.

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Premarket Approval Pathway. A PMA must be submitted to the 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 the FDA has determined that the application is sufficiently complete to permit a substantive review, the FDA will accept the application for filing. The FDA has 180 days to review an accepted PMA, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the 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. In the United States, clinical trials for a significant risk device require the prior submission of an application for an IDE to the FDA for approval. An IDE application must be submitted before initiating a new clinical study. Some trials require a feasibility study followed by a pivotal trial. An IDE supplement is utilized as a means of obtaining approval to initiate a pivotal trial following the conclusion of a feasibility trial. IDE applications must be supported by appropriate data, such as animal and laboratory testing results, and any available data on human clinical experience, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The animal and laboratory testing must meet the FDA s good laboratory practice requirements.

The IDE and any IDE supplement for a new trial must be approved in advance by the FDA. Clinical trials for significant risk devices may not begin until the IDE application is approved by the FDA and each center s Institutional Review Board (IRB) overseeing the welfare of the research subjects and responsible for that particular clinical trial. If the product is considered a non-significant risk device under FDA regulations, only the center s IRB approval is required. Under its regulations, the agency responds to an IDE application (amendment or supplement) for a new trial within 30 days. The FDA may approve the IDE unconditionally, grant an approval with certain conditions, or identify deficiencies that must be addressed prior to the approval of the study. It is common for the FDA to require additional information before approving an IDE, and thus final FDA approval on a submission commonly extends beyond the initial 30 days. The FDA may also require that a small-scale feasibility study be conducted before a pivotal trial may commence. In a feasibility trial, the FDA limits the number of patients and centers that may participate. Feasibility trials are typically structured to obtain information on safety and to evaluate the clinical efficacy to determine the number of subjects required to demonstrate statistical significance in a pivotal trial.

Clinical trials are subject to extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an 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. We, the 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. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the

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product in the United States. 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.

FDA considers several factors in determining whether an educational event or activity is independent from the substantive influence of the device manufacturer, including, but not necessarily limited to, the following:

- whether the intent of the funded activity is to present clearly defined educational content, free from commercial influence or bias;
- whether the third-party grant recipient and not the manufacturer has maintained control over selecting the faculty, speakers, audience, activity content and materials;
- whether the program focuses on a single product of the manufacturer without a discussion of other relevant existing competitive products or treatment options;
- whether there was meaningful disclosure to the audience, at the time of the program, regarding the manufacturer s funding of the program, any significant relationships between the provider, presenters, or speakers and the supporting manufacturer and whether any unapproved uses will be discussed; and
- whether there are legal, business, or other relationships between the supporting manufacturer and the provider or its employees that could permit the supporting manufacturer to exert influence over the content of the program.

We seek to ensure that the activities we support pursuant to our educational grants program are in accordance with these criteria for independent educational activities. However, we cannot provide an assurance that the 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:

- the FDA s Quality System Regulation (QSR) which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the false or misleading promotion or the promotion of products for uncleared, unapproved or off-label use or indication;
- requirements to obtain clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use;

medical device reporting regulations which require that manufacturers comply with reporting requirements of the 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.

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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 the FDA as a medical device manufacturer and listed our devices. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the 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 the FDA or other federal or state authorities, which may include any of the following sanctions, among others:

- warning letters, fines, injunctions, consent decrees and civil penalties;