

AtriCure, Inc.
Form 10-K
March 31, 2011
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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, 2010

.. **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

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(State or other jurisdiction of incorporation or organization) **6217 Centre Park Drive, West Chester, OH**
(Address of principal executive offices)
Registrant's telephone number including area code: (513) 755-4100

(I.R.S. Employer Identification Number) **45069**
(Zip Code)

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

(Title of Class)

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 Web site, 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 ☒

(Do not check if 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, 2010, as reported on the NASDAQ Global Market, was \$69.7 million.

As of March 1, 2011 there were 15,953,682 shares of Common Stock, \$.001 par value, 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 close 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.

ITEM 1. BUSINESS

Overview

We are a medical device company and a leader in developing, manufacturing and selling innovative cardiac surgical ablation systems designed to create precise lesions, or scars, in cardiac, or heart, tissue and devices for the exclusion of the left atrial appendage. We have two primary product lines for the ablation of cardiac tissue. Our primary product line for the ablation of cardiac tissue, which accounts for a majority of our revenue, is the Isolator® Synergy bipolar ablation clamp system, or Isolator system, and related radiofrequency ablation devices. Additionally, we offer a cryoablation product line, which features reusable and disposable cryoablation devices. Additionally, we offer the AtriClip Gillinov-Cosgrove Left Atrial Appendage System, or AtriClip system, which is designed to safely and effectively exclude the left atrial appendage.

Cardiothoracic surgeons have adopted our Isolator and cryoablation systems to treat atrial fibrillation, or AF, in an estimated 100,000 patients since January 2003, and we believe that we are currently the market leader in the surgical treatment of AF. Our products are utilized by cardiothoracic surgeons during concomitant cardiac surgical procedures and also during sole-therapy minimally invasive cardiac ablation procedures. During a concomitant open procedure, the surgeon ablates cardiac tissue and/or treats the left atrial appendage, secondary, or concomitant, to a primary cardiac procedure such as a valve or coronary bypass. Additionally, cardiothoracic surgeons have adopted our products as a standard treatment alternative for AF patients who may be candidates for sole-therapy minimally invasive surgical procedures. To date, none of our products have been approved or cleared by the Food and Drug Administration, or FDA, for the treatment of AF. However, we are conducting clinical trials to investigate the safety and effectiveness of our products for the treatment of AF. 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 generally use to ablate cardiac tissue for the treatment of AF or for the exclusion of the left atrial appendage.

AF 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. AF 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 AF persists, patients often progress from experiencing

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AF intermittently to having AF continuously, a condition that is more difficult to treat. Symptoms of AF 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 AF, the condition is often associated with high blood pressure and other forms of heart disease. In most cases, AF 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, the Middle East and Africa, or EMEA, primarily through distributors, while in certain markets, such as Germany and the Netherlands, we sell 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. Our sales outside of the United States represented 19% of our revenue during 2010 and 2009.

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, in which shares of our common stock were distributed to the Enable shareholders. The spin-off was intended to allow us to focus on the development of products designed to treat AF 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 system. Additionally, in December 2005, we formed AtriCure Europe, B.V.

Market Overview

AF is the most commonly diagnosed sustained cardiac arrhythmia, and affects more than 5 million people worldwide, including more than 2.5 million in the United States, where approximately 160,000 new cases of AF 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 AF doubles with each decade of an adult's life. At age 40, remaining lifetime risk for AF is 26% for men and 23% for women. AF is an under-diagnosed condition due in large part to the fact that patients with AF often have mild or no symptoms and their AF is only diagnosed when they seek treatment for an associated condition, such as a stroke or heart disease. We believe that increasing awareness of AF and improved diagnostic screening will result in an increased number of patients diagnosed with AF. Also, since the prevalence of AF increases with age, there will likely be an increase in the number of diagnosed AF patients in the United States as the population ages.

According to the American Heart Association, people with AF are about five times more likely to have a stroke and AF is thought to be responsible for approximately 15% to 20% of the estimated 700,000 strokes that occur annually in the United States. It is estimated that 90% of cardiac clots in AF patients form in the left atrial appendage. AF-related strokes tend to be severe and approximately 35% of AF patients will have a stroke in their lifetime. Studies suggest that 25% of people who have an AF-related stroke die within the first thirty days following their stroke and over 40% are permanently bedridden. AF accounts for \$6.7 billion in hospitalization-related costs in the United States each year and an estimated 5 million in office visits annually. Additional costs include the cost of drugs and indirect costs, such as the management of AF-related strokes, the costs of which are believed to be significant.

AF is a condition that doctors often find difficult to treat and, historically, there has been no widely accepted long-term cure for AF. Doctors typically begin treating AF with drugs, which are often ineffective, not well-tolerated and may be associated with serious side effects. Patients who cannot effectively be treated with drugs may be candidates to undergo catheter-based procedures to treat their AF. To perform a catheter ablation, an

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electrophysiologist performs the ablation from the inside of the heart using a flexible catheter. The heart is reached via a blood vessel, most commonly 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 AF 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 AF 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 AF, 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 over 80,000 of these patients are potential candidates for surgical ablation using our ablation products. Of the United States population diagnosed with AF, approximately 12%, or 300,000, of these patients are symptomatic and do not respond to drug therapy or are intolerant to the drugs used to treat AF. 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 who would potentially benefit from minimally invasive AF treatment using our Isolator system and related products, and that these patients comprise our largest growth opportunity.

It is estimated that 15% to 20% of all strokes are attributable to AF and that a substantial majority of cardiac clots in patients with AF form in the left atrial appendage, which some physicians believe is associated with AF-related strokes. We believe that the surgical practice of excluding the left atrial appendage has become a growing trend in procedures performed to treat AF and current practice guidelines indicate that the left atrial appendage should be removed, when possible, during cardiac surgery in patients at risk of developing postoperative AF. We also believe that our AtriClip system is potentially safer, more effective and easier to use when permanently excluding the left atrial appendage than other products and techniques. The AtriClip system was cleared in the United States in June 2010 and was commercially released in the United States during July 2010. We believe the market for the AtriClip system is large and represents a significant new growth opportunity for us.

The AtriCure Solution and Products

We believe that traditional surgical and catheter-based ablation devices are not ideal for safely, rapidly and reliably creating the transmural lesions required to block the abnormal electrical impulses that cause AF, particularly for patients with more chronic forms of AF or patients who have failed single or multiple catheter ablations. Reports of clinical studies conducted by doctors at prominent medical centers suggest that our products, including our Isolator system, enable cardiac surgeons to simplify the cut and sew Maze procedure with a faster, less invasive and less technically challenging approach that appears to have comparable effectiveness. Over eighty medical centers in the United States have used our Isolator system over the last year as a sole-therapy minimally invasive treatment for AF.

Our clinical studies for the use of our products to treat AF 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 system. The results of these studies are promising in terms of efficacy, ease of use and safety.

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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.) **Isolator System and Related Radio-Frequency Ablation Devices.** Our Isolator system and related radio-frequency, or RF, devices, such as our multifunctional pens and Coolrail device, represent our primary product line and currently generate a substantial majority of our revenue. Our Isolator system and related RF devices are used in both open and minimally invasive procedures and primarily consist of the following products:

Isolator Synergy Bipolar Radio-Frequency Ablation Clamps. We sell multiple configurations of our Isolator Synergy clamps. One design is for ablation during open-heart procedures and one design is for ablation during minimally invasive procedures. Our Isolator Synergy clamps are single-use disposables and have jaws that close in a parallel fashion. The parallel closure compresses the tissues and evacuates the blood and fluids from the energy pathway in order to make the ablation more effective. During the fourth quarter of 2009, we introduced and commercially released in Europe a new open-heart configuration of our Isolator Synergy clamps, known as the Isolator Synergy Access clamp. The Isolator Synergy Access clamp features a pivoting clamp head which promotes easier access to challenging anatomy. The Isolator Synergy Access clamp has not yet been cleared for use in the United States. We anticipate clearance and commercial release to occur in the United States during the first half of 2011.

Ablation and Sensing Unit, or ASU. Our ASU is a compact power generator that uses our proprietary software and delivers bipolar radio-frequency, or RF, energy. The ASU provides the RF energy necessary for our clamps, multifunctional pens and 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, or 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 Pen. Our 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 our ASB, surgeons are able to toggle back and forth between temporary pacing, sensing, and stimulation and ablation. Because of their broad range of capabilities, we believe surgeons are generally using one or both of our pen devices in combination with our Isolator clamps during both minimally invasive and open-heart procedures.

Coolrail Linear Ablation Device. During the second quarter of 2008 we released our Coolrail linear ablation device, which 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 AF.

- 2.) **Cryoablation System.** Our cryoablation offering consists of a variety of reusable and disposable devices which use cryotherapy, or extreme cold, to ablate cardiac tissue. In August 2007 we acquired the Frigitronics® CCS-200 product line for cardiac ablation, which included a console and a variety of reusable cardiac ablation probes. During the first half of 2009, we launched our Cryo1 cryoablation device, and during the fourth quarter of 2010 we launched our next generation disposable cryoablation device, cryoIce . Our disposable cryoablation devices are used with the CCS-200 console and are being adopted by physicians for AF ablation treatment during certain open-heart procedures, for which physicians prefer cryoablation over RF ablation. We believe our cryoablation devices provide us with a superior competitive product offering.

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Product line for left atrial appendage exclusion:

AtriClip System. Our AtriClip system is designed to exclude the left atrial appendage by implanting the device during concomitant open surgical procedures from the outside of the heart, avoiding contact with the circulating blood pool while eliminating blood flow between the left atrial appendage and the atria. We believe that our AtriClip system is potentially safer, more effective and easier to use when permanently excluding the left atrial appendage than current products and techniques. The AtriClip system received clearance in the United States in June 2010 and was commercially released in July 2010. It was launched in Europe during the second half of 2009.

In addition to the above product lines we also sell enabling technologies including our Lumitip dissector and MicroPace ORLab system. The Lumitip dissector is used by surgeons to gently separate tissues to provide access to key anatomical structures that are targeted for ablation. Our ORLab system is a stimulating, mapping and recording system which, we believe, when used with a mapping probe, enables physicians to effectively confirm that the ablation lines being created are forming electrical barriers or lines of block.

Current AF Treatment Alternatives

Doctors usually begin treating AF 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 AF cannot be adequately controlled with drug therapy, doctors may perform one of several procedures that vary depending on the severity of the AF symptoms and whether or not the patient suffers from other forms of heart disease. During 2007 the Heart Rhythm Society published an expert consensus statement on catheter and surgical ablation for the treatment of AF. The expert consensus concluded that the current indications for the surgical treatment of AF are the following:

Symptomatic AF patients undergoing other cardiac surgery;

Selected asymptomatic AF patients undergoing cardiac surgery in whom the ablation can be performed with minimal risk; or

Stand-alone (or sole-therapy) AF surgery should be considered for symptomatic AF patients who prefer a surgical approach, have failed one or more attempts at catheter ablation or are not candidates for catheter ablation.

Other treatment alternatives include:

Drugs. Currently available drugs are often ineffective, not well-tolerated and may be associated with severe side effects. For these reasons, drug therapy for AF fails for as many as 50% of patients within one year. Of those who initially respond to drug therapy, only approximately 25% of patients can continue to be managed with drugs after five years.

Implantable Devices. Implantable devices, such as defibrillators and pacemakers, can be effective in reducing the symptoms and frequency of AF episodes, but neither device is intended to treat AF. Patients may continue to experience the adverse effects of AF as well as some of the symptoms and complications, including dizziness, fatigue, palpitations and stroke, because the AF continues.

Catheter-Based Treatment. 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. Catheter-based AF treatments are often technically challenging, can be associated with serious complications and have been known to yield inconsistent results. In proportion to the prevalence of AF, only a small number of catheter-based AF treatments are performed each year in the United States.

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Cut and Sew Maze. The cut and sew Maze procedure is a highly invasive open-heart surgical procedure that involves the use of a heart-lung bypass machine and cutting and sewing back together sections of the heart in order to block the abnormal electrical impulses causing AF. Although this procedure is

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highly effective at treating AF, it is rarely performed because it requires extensive open-heart surgery, is technically challenging and is typically associated with long recovery times. For these reasons, only a limited number of these procedures have been performed by a small number of cardiothoracic surgeons.

Surgeons have adopted our products for use in open-heart and minimally invasive procedures for the treatment of AF. During elective open-heart surgical procedures, such as bypass or valve surgery, cardiothoracic surgeons use our Isolator and/or cryoablation systems to treat patients with a pre-existing history of AF. Surgeons report that ablation using our products generally adds approximately 20 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 AF and whether the patient's AF is intermittent, known as paroxysmal, or more continuous, known as persistent, long-standing persistent or permanent AF. Patients who have been diagnosed with AF for a longer duration and have non-paroxysmal forms of AF generally receive more extensive ablation procedures than patients who have been diagnosed with AF for a shorter duration or who have paroxysmal AF. Additionally, during an open-heart procedure, physicians are beginning to use our AtriClip system to exclude the left atrial appendage, which has been reported to add less than one minute to a procedure. Surgeons using our Isolator system and/or cryoablation system and related products during an open-heart surgical procedure typically perform the following steps:

Pulmonary Vein Isolation. Regardless of the duration or type of AF, surgeons will create lesions in the heart tissue surrounding the pulmonary veins to create an electrical barrier between the pulmonary veins and the atrium, or upper chambers of the heart. In patients with intermittent AF, those lesions are often the extent of the treatment performed and, in some cases, doctors may also use our multifunctional pens to sense, pace, stimulate or ablate cardiac tissue. Surgeons utilize our Isolator system and/or our cryoablation system to perform pulmonary vein isolation.

Additional Lesions. For those patients who have non-paroxysmal forms of AF, doctors may determine that additional lesions are required to treat their AF. In cases where patients require such additional lesions, surgeons may use our devices during open-heart or concomitant surgical procedures to create lesions in the atrium that are intended to reproduce similar electrical barriers to those created by surgeons during the cut and sew Maze procedure. In some cases, doctors may also use a multifunctional pen to sense, pace, stimulate or ablate cardiac tissues. Additionally, our reusable cryoablation probes are sometimes used to ablate cardiac tissue near the heart valves.

For those patients with AF who do not require a concomitant open-heart surgical procedure, surgeons have used our Isolator system and related products for minimally invasive AF 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 three 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 AF generally require an expanded lesion set that mimics the cut and sew Maze procedure. Our Coolrail device and multifunctional pens are often used during these procedures to enable physicians to perform additional ablations.

Physicians have recently developed and are exploring an emerging minimally invasive stand-alone procedure which combines epicardial ablation (ablation on the outside of the heart) with endocardial ablation and mapping techniques (from the inside of the heart). Physicians are reporting that they are performing this emerging procedure, also known as a hybrid procedure, utilizing our Isolator system and related products in combination with catheter ablation and mapping techniques to primarily treat patients who have non-paroxysmal forms of AF. In December 2010, the first patient was enrolled in a feasibility clinical trial, DEEP AF, which explores the safety and effectiveness of this procedure when utilizing our Isolator system and related products in combination with a commercially available catheter for the treatment of persistent and long-standing persistent AF.

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Product Development

Our product development team develops product enhancements and new products to address unmet procedural and market needs with the goal of 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.

Our product development initiatives have been partially funded by a variety of grant programs. From June 2005 through December 2009, we participated in a grant program whereby we received publicly announced grants from the State of Ohio for, among other things, the creation of the Atrial Fibrillation Innovation Center. We received a total of \$0.9 million for personnel and materials in matching dollars associated with our required \$7.7 million spend for research and development-related operating expenses and The Cleveland Clinic acquired \$2.4 million in matching capital equipment under the grant for our use in support of our performance under the grant, which we earned by spending \$4.8 million in qualifying capital expenditures through the period ended December 31, 2009.

Effective April 2010, we received an additional grant from the State of Ohio through the Global Cardiovascular Innovation Center. Pursuant to the terms of the grant, we are eligible to receive \$0.5 million in support of defined research and development activities through September 2011. During 2010, we earned \$0.1 million pursuant to the grant.

In October 2010, we were awarded two grants totaling \$0.5 million in aggregate under the IRS Qualifying Therapeutic Discovery Program. The grants related to completed research and development activities and were funded in full in November 2010.

Business Strategy

Our mission is to expand the treatment options for patients who suffer from AF through the continued development of our technologies and expansion of our product offerings. The key elements of our strategy include:

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. During 2010 we launched the AtriClip system in the United States, which provides a new growth platform and allows entrance into a new market. Our product development and growth plans include continued innovation to expand on both new and existing market opportunities.

Provide Product 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 cleared indications. Our highly trained sales professionals meet with doctors at leading institutions to provide education and technical training on the technical features and benefits of our products. In addition to our sales activities, we 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 AF, including the use of our products as an AF treatment alternative. As a result of the educational process, we believe that awareness of our technology is growing and will result in the increased use of our products.

Expansion of International Markets and Entrance into New Markets. Our international business represented 19% of our total revenue for 2010. 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.

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Form Investigational Relationships with Key Opinion Leaders at Leading Institutions. We have formed investigational relationships with key opinion leaders at several leading medical centers who have worked with us as consultants to evaluate and develop our products. Additionally, several key opinion leaders have published peer-reviewed data that describes the use of our products as a treatment alternative for AF. These opinion leaders have assisted and continue to assist us with the design and/or evaluation of our products. To date, there have been over 40 peer-reviewed publications that describe our Isolator systems' ability to create transmural lesions or the use of our Isolator system as an AF treatment alternative. Key publications and presentations have highlighted promising results utilizing our products to treat patients with AF during sole-therapy minimally invasive surgical procedures. Further, initial presentations and publications have described our AtriClip system as a means of excluding the left atrial appendage. We believe that these publications and presentations have contributed to and, we expect, will continue to contribute to the expanded adoption 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 AF. 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.

Clinical Trials

During 2007 we worked with the FDA and leading cardiothoracic surgeons to design our pivotal clinical trial, ABLATE, which was approved by the FDA for patients with permanent AF (as defined in the trial's protocol) undergoing concomitant cardiac surgical procedures. The primary efficacy endpoints of the trial were an estimated minimum of 70% of patients treated being free of AF and off of antiarrhythmic drugs at their six-month follow-up. A 24-hour holter monitor was used to determine the rhythm status six months following surgery. The ABLATE clinical trial completed enrollment and preliminary follow-up at 55 patients during 2009 and we believe that the trial met or exceeded the defined endpoints. During 2010 we worked with the FDA to gather and provide supplementary data and follow-up associated with the ABLATE trial. In December 2010, we submitted our final clinical module to the FDA, including the supplementary data, in support of a PMA approval. During February 2011 we were notified by the FDA that our PMA achieved fileable status and received expedited review status. In March 2011 we received a major deficiency letter related to the ABLATE PMA which highlights items that the FDA requests clarification on. We plan to work interactively with the agency to respond to these questions. Additionally, the FDA began its PMA manufacturing review. An approval of the ABLATE PMA would allow us to market our Isolator system for the treatment of patients with permanent AF during open-heart procedures.

In November 2010 we received approval from the FDA for an ABLATE AF Registry, which allows for centers to enroll up to an additional 50 patients in accordance with the ABLATE trial protocol. We anticipate that the data from this registry will be used as additional supporting clinical evidence during the PMA process and at the anticipated FDA advisory panel review meeting.

In 2008 we received FDA approval for our EXCLUDE clinical trial for our AtriClip system, which was used in support of our 510(k) filing. The primary endpoint for the trial was safe and effective exclusion of the left atrial appendage, which was evaluated at three months for all patients and at six months for 30 patients. The clinical trial was completed with 70 patients treated. 61 patients were followed through the primary endpoint at three months post procedure, and 45 patients were followed through six months post procedure. The clinical data were submitted to the FDA in December 2009 and 510(k) clearance was received in June 2010.

During the third quarter of 2010 we received approval from the FDA for a feasibility trial, DEEP AF. The trial evaluates the safety and efficacy of our minimally invasive products with catheter ablation and mapping technologies for persistent and long-standing persistent patients. DEEP AF is a 30-patient feasibility trial and is

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being conducted at six medical centers in the United States. The trial's primary endpoint is freedom from AF and off of antiarrhythmic drugs at the twelve-month follow-up. Enrollment in the trial was initiated in December 2010 and is anticipated to be completed during the third quarter of 2011.

Sales, Marketing and Medical Education

Our United States sales and marketing efforts focus on educating doctors about our unique technologies and their technical benefits. It is our policy not to market or promote our products for the treatment of AF or a reduction in stroke risk unless and until we receive FDA approval or clearance for those uses. Our sales personnel visit physicians to discuss the general attributes of our products and promote them for their FDA cleared indications. We train our sales force on the use of our products to treat AF so that they are able to respond to unsolicited requests from doctors for information. In addition, medically trained clinical application specialists attend surgical procedures to discuss the use of our products and to respond in a non-promotional manner to unsolicited requests for information on the use of our products.

We have formed a healthcare compliance committee in support of our ongoing compliance efforts with applicable federal and state healthcare laws and regulations. This committee has instituted standard operating procedures relating to our marketing and promotional activities, grant review and funding procedures and the training and education of our sales force. Our training and educational programs include training on federal and state requirements for marketing medical devices. During 2010, we entered into a five-year Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services. The Agreement provides for increased training, monitoring and compliance activities with respect to our healthcare compliance activities.

Our sales team in the United States is led by a Vice President of Sales and has over 60 employees supporting approximately 40 sales territories. We select our sales personnel based on their expertise, sales experience and reputation in the medical device industry and their knowledge of our products and technologies.

We market and sell our products in selected markets outside of the United States through independent distributors and, in EMEA markets, through our European subsidiary which includes a combination of independent distributors and direct sales personnel. During 2010 and 2009, sales outside of the United States accounted for 19% of our total revenue. We have a network of distributors outside of the United States who currently market and sell our products and are located primarily in Europe, Asia, South America and Canada. Our international sales team is led by a Vice President of Sales and has direct sales representatives who sell to customers in markets we sell directly to, such as Germany and the Netherlands. We continue to evaluate opportunities for further expansion into markets outside of the United States.

Competition

Our industry is highly 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 distribution channels that are more established and developed than ours. Our primary competitors include Medtronic, Inc., St. Jude Medical, Inc., nContact, Inc. and Endoscopic Technologies, Inc. We and our competitors provide products that have been adopted by doctors for the off-label treatment of AF. As of December 31, 2010, no company had received FDA approval or clearance to market a surgical ablation system for the treatment of AF. Some of our competitors offer catheter-based treatments, including but not limited to Biosense Webster, Inc. (a subsidiary of Johnson & Johnson), St. Jude Medical, Inc., and Medtronic, Inc. These companies sell products that are used by doctors to treat the population of patients that have AF but are not candidates for open-heart surgery. However, catheter-based treatments often do not effectively treat patients with non-paroxysmal forms of AF, which we believe is a segment of the AF patient population that would benefit from minimally invasive AF procedures.

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We believe that we compete favorably against companies that have products used for the surgical treatment of AF 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 compete favorably when compared to catheter-based treatments for non-paroxysmal forms of AF. Further, we believe our AtriClip system provides an improved treatment alternative for the exclusion of the left atrial appendage.

Due to the size of the AF and left atrial appendage exclusion markets and the unmet need for an AF cure, competitors have dedicated and will continue to dedicate significant resources to aggressively develop and market their products. New product developments that could compete with us more effectively are likely because the AF treatment and left atrial appendage exclusion markets are characterized by extensive research efforts and technological progress. Further, recent publications and industry events are expanding knowledge of the markets and treatment alternatives.

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, brand and name recognition, reputation, service and price. We have encountered and expect to continue to encounter potential customers who, due to existing relationships with our competitors, are committed to or prefer the products offered by competitors. Competitive pressures may result in price reductions and reduced gross profit margins for our products over time. Technological advances developed by one or more of our competitors 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 under the Inpatient Prospective Payment System, or IPPS, which provides a predetermined payment based on the patient's discharge diagnoses. Discharge diagnoses are grouped into Medicare Severity Diagnosis Related Groupings (MS-DRGs). There are several cardiac surgery MS-DRGs associated with the surgical treatment of AF, with and without a concomitant open-heart procedure. When an ablation device and/or LAA exclusion device are 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 AF 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 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, or CPT, codes to receive a professional fee. Surgeons have a choice of CPT codes to report sole-therapy and concomitant therapy cardiac tissue ablation.

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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. It is our understanding that there has recently been an increase in certain payors declining reimbursement for sole-therapy minimally invasive AF ablation treatment. Physicians, in combination with their industry organizations and societies, are responding and working to secure reimbursement for the procedure to the extent the payor has denied reimbursement.

The FDA generally 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 AF, even though the FDA has not approved or cleared our products for that indication. In these circumstances, some government or private payors, including some Medicare carriers, may make coverage and payment determinations on a case-by-case basis. Additionally, some government or private payors may deem the treatment of AF using our products for indications not approved or cleared by the FDA to be experimental or not medically necessary and, as such, may not provide coverage or payment.

Government Regulation

Our products are medical devices and are subject to regulation by the FDA, as well as other federal and state regulatory bodies in the United States and comparable authorities in other countries. We currently market our Isolator system and Coolrail device in the United States under a 510(k) clearance for the ablation of cardiac tissue. Our multifunctional pen and multifunctional linear pen are marketed in the United States under a 510(k) clearance for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias and for the ablation of cardiac tissue. Our cryoablation products are approved for the cryosurgical treatment of cardiac arrhythmias. We currently market the Lumitip dissector in the United States under a 510(k) clearance for use in the dissection of soft tissues during general, ear, nose and throat, thoracic, urological and gynecological surgical procedures. We market our AtriClip system for exclusion of the left atrial appendage under direct visualization in conjunction with other open-heart procedures. Our products may not be marketed for the treatment of AF or the reduction of stroke without obtaining additional approvals from the FDA.

The FDA requires that premarket approval, or PMA, be obtained for a device before it can be marketed for the treatment of AF. During 2007 we worked with the FDA and leading cardiothoracic surgeons to design our clinical trial, ABLATE, which was approved by the FDA for patients with permanent AF undergoing concomitant open-heart surgical ablation procedures. We filed the final module of our PMA during December 2010 which, if approved by the FDA, would allow us to market our Isolator system for the treatment of patients with AF during open-heart procedures. Since the filing of our ABLATE trial, guidelines with respect to the classification of AF patients has changed. As a result, the approval we may obtain for the type of AF is not likely to be permanent AF and is unknown at this time. We cannot be certain that we will successfully complete ABLATE, receive approval for any additional clinical trials or submit and obtain approval for any of our products for use in treating AF. Submission of a PMA is a much more demanding process than the 510(k) notification process. Further, both 510(k)s and PMAs must now be submitted with a potentially substantial user fee payment to the FDA, although certain exemptions and waivers of the user fee can apply, including certain exemptions and waivers for small businesses.

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;

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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, each medical device distributed commercially in the United States will require either prior 510(k) clearance or approval of a PMA from the FDA. 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, which requires the manufacturer to submit to the FDA a 510(k) notification requesting clearance to commercially distribute the device. Some low risk devices are exempted from this requirement. 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, 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. We have recently been in communication with the FDA regarding our decision not to file a new 510(k) related to a change in indication for our Isolator Synergy clamps. At the time our Isolator clamps received 510(k) clearance for the ablation of cardiac tissue, through our internal and external regulatory review process, we determined that a new 510(k) was not needed for our Isolator Synergy clamps to change their intended use from the ablation of soft tissue to the ablation of cardiac tissue. During 2010, the FDA reviewed this decision and indicated that a 510(k) was required to be filed for us to market our Isolator Synergy clamps for cardiac tissue ablation instead of soft tissue ablation. During 2010 we filed a 510(k) and received clearance in November 2010 to market our Isolator Synergy clamps for the ablation of cardiac tissue.

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 trials, manufacturing and labeling to demonstrate to the FDA's satisfaction, the safety and effectiveness of the device.

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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 Investigational Device Exemption, or IDE, to the FDA for approval. An IDE amendment 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 good clinical practices. We are also required to obtain the patients' written informed consent 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 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. The FDA permits a device manufacturer to provide financial support, including support by way of grants, to third-parties for the purpose of conducting medical educational activities. If these

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funded activities are considered by the FDA to be independent of the manufacturer, then the activities fall outside the restrictions on promotion to which the manufacturer is subject.

The FDA considers several factors in determining whether an educational event or activity is independent from the substantive influence of the device manufacturer and therefore nonpromotional, 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, or 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, or MDR, 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. During 2010 we submitted to the FDA ten MDRs related to complications during procedures utilizing our products. Of these MDRs, six related to our Isolator clamps, two related to our Coolrail device, one related to our reusable cryoablation device and one related to our Lumitip dissector. Included in the above MDR filings was at least one patient death. The death was not categorized as an outcome related to the failure of our devices.

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Additionally, there may have been other incidents, including patient deaths, which have occurred during procedures utilizing our products, although we are not aware of any such incidents during the period noted above.

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. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR 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;

customer notifications, 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 our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;

withdrawing 510(k) clearance or premarket approvals that have already been granted; and

criminal prosecution.

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. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG, has issued a series of regulations, known as the safe harbors. These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable element of a safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

The Federal False Claims Act, or 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

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behalf of the government to recover the civil penalties and treble damages. The U.S. Department of Justice, or DOJ, on behalf of the

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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.

As previously reported, in late 2008 we received a letter from the DOJ informing us that they were conducting an investigation for potential FCA and common law violations relating to our surgical ablation devices for the period beginning January 1, 2005. Other manufacturers of medical devices adopted for the treatment of AF reported receiving similar letters. Specifically, the letter stated that the DOJ was investigating our marketing practices utilized in connection with our surgical ablation system to treat AF, a specific use outside the FDA's 510(k) clearance, and was also investigating whether we instructed hospitals to bill Medicare for cardiac surgical ablation using incorrect billing codes. On February 2, 2010, we entered into a settlement agreement with the DOJ, the Office of Inspector General of the Department of Health and Human Services, or OIG, and Elaine Bennett (also known as Elaine George), the relator in the related *qui tam* complaint (the Relator), which definitively resolved all claims related to the DOJ investigation and *qui tam* complaint, which has been dismissed. We did not and will not admit wrongdoing in connection with the settlement. Additionally, we entered into a five-year corporate integrity agreement with the OIG. For a discussion of the terms of the settlement, see Item 3. Legal Proceedings.

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 doctors. Key to the underlying principles of the AdvaMed Code is the need to focus the relationships between manufacturers and healthcare professionals on matters of training, education and scientific research, and limit payments between manufacturers and healthcare professionals to fair market value for legitimate services provided and payment of modest meal, travel and other expenses for a healthcare professional under limited circumstances. We have incorporated these principles into our relationships with healthcare professionals under our consulting agreements, payment of travel and lodging expenses, grant making procedures and sponsorship of third-party conferences. In addition, we have conducted training sessions 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.

The primary regulatory body in Europe is that of the European Union, which has adopted numerous directives and promulgated voluntary standards regulating the design, manufacture and labeling of and clinical trials and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the European Union and other countries that comply with or mirror these directives. The method for assessing conformity varies depending on the type and class of the product, but normally involves a

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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 may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's device. Such an assessment is required for a manufacturer to commercially distribute the product throughout these countries. We are compliant with the International Organization for Standardization, (ISO) 13485:2003 Quality Management System. Compliance establishes the presumption of conformity with the essential requirements for a CE Marking. We have the authorization to affix the CE Mark to our Isolator clamps and to commercialize our Isolator clamps in the European Union for the treatment of cardiac arrhythmias, including atrial fibrillation.

Intellectual Property

Protection of our intellectual property is a strategic 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 crucial 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 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 cannot provide any assurance that employees and consultants will abide by the confidentiality or assignment terms of these agreements. 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. 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 or for which we have chosen to maintain secrecy rather than file for patent protection. 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.

As of December 31, 2010, we had the following portfolio of patents or patent applications covering our proprietary technologies and products:

38 issued or approved United States patents expiring between 2015 and 2028;

27 United States non-provisional patent applications;

2 United States provisional patent applications;

9 issued foreign patents; and

16 pending foreign patent applications that are in various national stages of prosecution.

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Additionally, as of December 31, 2010, we had ten registered and two pending trademark registrations covering our product branding.

Manufacturing

We manufacture a substantial majority of the disposable and implantable products we sell and generally purchase items that would be deemed capital equipment, including our ASU, ASB and ORLab. We inspect, assemble, test and package our products in West Chester, Ohio and our products are sterilized by third-party outside sterilizers at their facilities. Purchased components are generally available from more than one supplier. However some products, such as our ASU and ASB, are critical components of our Isolator system, and there are relatively few alternative sources of supply available. We generally carry a six month supply of these products, however, obtaining a replacement supplier for the ASU and ASB, if required, may not be accomplished quickly or at all and could involve significant additional costs. Generally, our suppliers have no contractual obligations to supply us with, and we are not contractually obligated to purchase from them, any of our supplies. During 2007, we entered into a development, manufacturing and supply agreement with MicroPace Pty Ltd of Australia to develop, manufacture and supply our ORLab system. Under the terms of the agreement, as amended, we are obligated to meet certain minimum purchase commitments in order to retain exclusive distribution rights.

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. There are no unique or proprietary processes required in manufacturing our components. We generally do not have contractual obligations that preclude us from developing products or sourcing components from new suppliers.

We and our component suppliers are required to manufacture our products in compliance with the FDA's QSR. The QSR regulates extensively the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. The FDA enforces the QSR through periodic inspections that may be announced or unannounced and may include the manufacturing facilities of our suppliers. Our failure or the failure of our suppliers to maintain compliance with the QSR requirements 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 our quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result. We also could be subject to injunctions, product seizures, or civil or criminal penalties.

We regularly audit our suppliers for compliance with QSR and applicable ISO standards. We have been a FDA-registered medical device manufacturer since November 2002. We obtained our CE Mark in June of 2002 and our quality systems and facility practices are certified to ISO 13485:2003; MDD 93/42/EEC, or CE Mark, and CMDCAS, or Canadian regulations. We believe that we are currently in good standing with the FDA and are subject to pre-announced inspections. Our current quality system is developed to comply with QSR and ISO standards. During June 2010 a representative from the FDA visited our facility to investigate an issue related to one of our third-party sterilizers who had received a warning letter from the FDA. AtriCure had already been notified of the sterilizer's warning letter and had taken corrective actions accordingly. The FDA completed their review of the matter as it related to our response to the warning letter and related corrective actions and no further action was needed.

During February 2011 the FDA conducted an inspection of our West Chester, Ohio facility and manufacturing processes. As a result of the inspection, we received a Form FDA 483, Inspectional Observations, which outlined deficiencies observed by the FDA inspectors. We have taken corrective and preventive actions with respect to the findings and have formally responded in writing to the FDA. While our actions are subject to FDA's verification, we believe we have addressed FDA's findings and we will remain in good standing with the FDA.

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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. We may incur significant costs to comply with those laws and regulations now or in the future, but, as we currently 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.

Consulting Relationships

We have developed consulting relationships with a number of leading scientists and doctors throughout the world to give our research and development team additional technical and creative breadth. We work closely with these thought leaders to understand unmet needs and emerging applications for the treatment of AF. Until October 2010, we typically entered into a written agreement with our consultant pursuant to which the consultant was obligated to provide services such as advising us regarding the design and development of our products, educating doctors on the cleared or approved use of our technologies, conducting clinical trials, and providing supporting data for clinical trials and providing advice concerning grants and regulatory submissions. These agreements were generally for a term of one year and generally could be terminated by us or by the consultant upon written notice. Generally, we own the rights to any inventions or ideas made or conceived by our consultants during the performance of the consulting services.

In October 2010, we elected to cancel and restructure all of our physician contracts to include more specific language on proctoring and preceptor training, which can be performed only in conjunction with our FDA-regulated clinical trials. This change in physician consulting has significantly reduced the number of current physician consulting contracts.

Most of our consulting agreements provide for payment of compensation in cash only and on a per diem basis (in addition to travel and other expenses), upon determination by us that services have been provided to our satisfaction. In addition, under agreements entered into prior to the fourth quarter of 2005, some of our consultants were entitled to receive stock options. 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. See **Risk Factors** **Risks Relating To Our Business** We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our product for non-FDA-approved, or off-label, uses.

Royalty Agreements

We have certain royalty agreements in place with terms that include payment of royalties based on product revenue from sales of current products, certain other inventions, improvements or ideas. During 2010 we had royalty agreements with rates of 5% of product revenue related to our AtriClip system and 1.5% of product revenue related to our Lumitip dissector. The agreement for the Lumitip dissector also calls for minimum royalty payments and limits the maximum aggregate in royalties during the term of the agreement. Parties to royalty agreements have the right at any time to terminate the agreement immediately for cause. Royalty expense for each of the years ended December 31, 2010, 2009 and 2008 was \$0.3 million, \$0.2 million and \$0.2 million, respectively.

Employees

As of December 31, 2010, we had approximately 220 full-time employees. 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.

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Available Information

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 possible after they are filed with the SEC. Our charters for our Audit, Compensation and Nominating and Corporate Governance 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 AF is dependent upon, among other factors, the level of screening for AF and the awareness and education of the medical community about the surgical treatment of AF, in general, and the existence, effectiveness and, in particular, the safety of our products. Market acceptance and adoption of our products for the treatment of AF also depends on the level of reimbursement to doctors and hospitals for 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 the Isolator system and related 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.

Currently, our Isolator system and related RF products generate a large majority of our revenue. We expect that sales of our Isolator system and related products will 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 Isolator system and related products as a standard treatment alternative for the surgical treatment of AF 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 Isolator system and related products for a number of additional reasons, including those set forth elsewhere in this Risk Factors section. In addition, our Isolator system and related 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 instruments and/or write off their value or accelerate their depreciation. Since we believe that doctors are using our Isolator system only for the surgical treatment of AF, if doctors do not use our Isolator system and other products to treat AF, we would lose substantially all of our revenue.

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Current worldwide economic conditions may have reduced demand for procedures using our products or otherwise resulted in adverse implications on our business, operating results and financial condition.

General worldwide economic conditions deteriorated beginning in late 2007 due to the effects of, among other developments, the subprime lending crisis, general credit market crisis, 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. Although there are signs of an improving economic environment, the deteriorated economic environment continues. Because many procedures using our products are elective, they can be deferred by patients. In addition, patients may not be as willing under current 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 continuing worldwide economic crisis, including in particular its effect 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.

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 health care providers in the U.S. have adopted or are considering a managed care system in which the providers contract to provide comprehensive health care for a fixed cost per person. Health care 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 recently-enacted amended Patient Protection and Affordable Care Act (the "Patient Act") as well as other healthcare reform may have a significant impact on our business. The impact of the Patient Act on the health care industry is extensive and includes, among other things, the federal government assuming a larger role in the health care system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits. In addition, any health care 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

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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 doctors 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 doctors familiar with, trained on and proficient in the use of our products. While we educate and train doctors as to the skills involved in the proper use of our products, it is not our policy to educate or train them to use any products for the surgical treatment of AF. Doctors learn to use our products for the treatment of AF through independent training programs sponsored by hospitals and universities and through independent peer-to-peer training among doctors. We cannot assure you that a sufficient number of doctors will become aware of training programs, or that doctors will dedicate the time, funds and energy necessary to obtain training for themselves or to train others in the use of our products. In addition, our inability to directly train doctors in off-label use exposes us to a risk that our products may not be used correctly and may also expose us to a greater risk of product liability for injuries sustained during procedures utilizing our products.

Unless and until we obtain FDA approval for our products, we will not be able to promote our products to treat AF, and our ability to maintain and grow our business could be harmed.

We have not received FDA clearance or approval to promote any of our products for the treatment of AF. See Business Government Regulation. Unless and until we obtain FDA clearance or approval for the use of our products for the treatment of AF we, and others acting on our behalf, may not promote our products for such uses, make any claim that our system is safe and effective for such uses, or proactively discuss or provide information on the use of our system in connection with such uses. We cannot assure you 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.

Unless and until we are able to complete the clinical trials required to support future submissions to the FDA, and unless and until the data generated by such trials supports the use of our products as safe and effective for the treatment of AF, we may not be able to secure additional FDA clearances or approvals and our ability to maintain and grow our business could be harmed.

In order to obtain FDA approvals to promote our products for the treatment of AF, we will need to demonstrate in clinical trials that our products are safe and effective for such use. 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 the FDA. 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, the FDA may not approve our products for the treatment of AF, adoption of the use of our products for the treatment of AF may suffer and our business would be harmed.

We have experienced and may continue to experience unfavorable publicity relating to our business and our industry. This publicity has had and may continue to 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 believe that we experienced a negative impact on our business from newspaper articles relating to, among other things, concerns of conflicts of interest between the Cleveland Clinic and us, our compliance with FDA regulations for medical device reporting, concerns that certain of our consultants who are involved with clinical studies and the publication of articles concerning our products failed to adequately disclose their

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financial relationships with us and our previously settled Department of Justice investigation. We believe that this publicity has had and may continue to have a negative impact on our clinical studies, business, results of operations and financial condition. We also believe that future unfavorable publicity could 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 non-FDA approved, or off-label, uses.

Our business and future growth depend on the continued use of our products for the treatment of AF, which is considered an off-label use of our products. Under the Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products for off-label uses. We may not make claims about the safety or effectiveness of our products for the treatment of AF and may not proactively discuss or provide information on the use of our products for the treatment of AF, except in certain limited scientific and other settings.

These limitations present a material risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales, marketing and/or product support activities, though designed to comply with all FDA requirements, constitute the promotion of our products for a non-FDA approved use in violation of the law. 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 off-label uses and related issues, including our settlement with the DOJ (see further discussion in Item 3, Legal Proceedings of this Form 10-K), 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 non-FDA approved use, which effectively would bar all sales of our products in the United States until we receive FDA clearances or approval, if ever. 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. Also, our failure to comply with the terms of the settlement agreement with the DOJ or the related corporate integrity agreement could result in additional action by the DOJ or the OIG, in fines or penalties or in restrictions on our sales, promotion, grant or educational activities.

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, have been encountered in connection with the surgical treatment of AF, including in connection with a limited number of sole-therapy minimally invasive procedures in which our products were used. 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 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.

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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 AF, is highly competitive, subject to rapid technological change and significantly affected by new product introductions and promotional activities of its participants. We cannot assure you 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 AF 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. Some 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 in the treatment of AF before we obtain approval for any of our products. The introduction of new products, procedures, clinical solutions or our competitors obtaining an AF approval may result in price reductions, reduced margins or loss of market share and may render our products obsolete, which could adversely affect our net 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.

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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.

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 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 system.

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 net losses of \$3.8 million in 2010, \$16.5 million in 2009, \$10.2 million in 2008, \$11.3 million in 2007, \$13.7 million in 2006 and \$12.7 million in 2005. As of December 31, 2010, we had an accumulated deficit of \$97.8 million.

Our net losses have resulted principally from costs and expenses relating to sales and promotional efforts, research and development, seeking regulatory clearances and approvals, goodwill impairment, litigation and settlement costs associated with the DOJ investigation 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 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 stockholders' deficit and we may never become profitable.

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Our federal tax net operating loss 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 percentage points upon the initial public offering of our common stock.

In connection with our initial public offering in August 2005, 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. The Section 382 limitation 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 had federal income tax net operating loss and general business credit carryforwards at August 5, 2005 that, if not utilized to reduce our taxable income, will begin to expire in 2021. In addition, if the company were to experience a second ownership change of more than 50 percentage points in a future period, the company's NOL carryforward at the date of the original ownership change would be subject to a second Section 382 limitation. In addition, the company's NOLs generated subsequent to the original ownership change would be subject to the second Section 382 limitation. Since December 31, 2005 the company has generated additional net operating loss and general business credit carryforwards of \$30.1 million and \$2.1 million, respectively, which, if not utilized to reduce our taxable income, will begin to expire in 2026.

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 will be sufficient to meet our projected capital requirements for at least the next 12 months. Our current loan agreement (the Agreement) with Silicon Valley Bank (the Bank) as amended includes a term loan and a revolving credit facility under which we can borrow a maximum of \$17.5 million. We have borrowed the maximum amount of approximately \$7.5 million under the term loan. We can borrow the lesser of the amount available pursuant to a borrowing base formula and \$10.0 million under the revolving loan facility. Based on our current borrowing base, we have availability of approximately \$8.0 million. The Agreement is secured by all of our assets, including intellectual property, and the term loan and revolving loan mature on March 15, 2016 and April 30, 2014, respectively. Interest on the term loan accrues at a rate of 6.75% per year, and interest on the revolving loans will accrue at a fluctuating rate equal to the Bank's announced prime rate of interest plus between 0.25% and 0.75%, depending on our Adjusted Quick Ratio (as defined in the Agreement).

We may be unable to comply with the covenants of our credit facility.

Our Agreement contains covenants that include, among others, covenants that limit our ability to dispose of assets, enter into mergers or acquisitions, incur indebtedness, incur liens, pay dividends or make distributions on our capital stock, make investments or loans, and enter into certain affiliate transactions, in each case subject to customary exceptions for a credit facility of this size and type. Additional covenants apply when we have outstanding borrowings under the revolving loan facility or when we achieve specific covenant milestones. 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 under the Agreement, an obligation to repay all obligations in full, and a right by the Bank to exercise all remedies available to it under the Agreement and related agreements including the Guaranty and Security Agreement. If we are unable to pay those amounts, the Bank could proceed against the collateral granted to it pursuant to the credit facility.

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 may 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

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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 depend 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 and ASB. 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, or no, 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 EMEA 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 locating and qualifying alternative suppliers;

switching components may require product redesign and new submissions to the FDA which could significantly delay production or, if the 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 or at all 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.

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 information technology systems for inventory management and to effectively manage accounting and financial functions, our 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.

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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 the FDA's Quality System regulation, or 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 our Isolator system and other products we sell. The 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, FDA investigators observe conditions or practices believed to violate the QSR, the investigators 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.

During February 2011, in connection with an inspection of our West Chester, Ohio facility, the FDA issued a Form FDA-483, which outlined deficiencies observed by the FDA inspectors. We have formally responded in writing to the FDA and taken other corrective and preventative actions. While we believe we have addressed the findings in the Form 483 and will remain in good standing with the FDA, our actions are subject to the FDA's verification, and, if the FDA does not verify our actions, we could receive a warning letter and/or be subject to any of the sanctions described above, among others. These sanctions, if imposed, could materially harm our operating results and financial condition.

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

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

Our products are classified by the FDA as medical devices and, as such, are subject to extensive regulation in the United States by the 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, among other things:

product design, development, manufacturing and labeling;

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product testing, including electrical testing, transportation testing and sterility testing;

pre-clinical laboratory and animal testing;

clinical trials in humans;

product safety, effectiveness and quality;

product manufacturing, storage and distribution;

pre-market clearance or approval;

record keeping and document retention procedures;

product advertising, sales and promotion;

post-market surveillance and medical device reporting of events where our device caused or contributed to a death or other serious injury, or malfunctioned in such a way that if it were to recur would likely cause or contribute to a death or serious injury;

product corrective actions, removals and recalls; and

product import and export.

Compliance with FDA, state and other regulations can be complex, expensive and time-consuming. The 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 were determined, it could result in enforcement action by the 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;

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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 the 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 the 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 the FDA because we and our physician consultants determined that our products did not cause or contribute to the outcomes in these incidents. If the 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

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reports we make, or the magnitude of the problems reported, could cause the 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.

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 the 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, possibly, submission and FDA approval of a PMA. The FDA requires every medical device company to make the determination as to whether a new 510(k) is to be filed, but the 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). The FDA may not agree with our decisions regarding whether new clearances or approvals were required. We have recently been in communication with the FDA regarding our decision not to file a new 510(k) related to a change in indication for our Isolator Synergy clamps. At the time our Isolator clamps received 510(k) clearance for the ablation of cardiac tissue, through our internal and external regulatory review process, we determined that a new 510(k) was not needed for our Isolator Synergy clamps to change their intended use from the ablation of soft tissue to the ablation of cardiac tissue. The FDA reviewed this decision and indicated that a 510(k) was required to be filed for us to market our Isolator Synergy clamps for cardiac tissue ablation instead of soft tissue ablation. During 2010 we filed a 510(k) and received clearance in November 2010 to market our Isolator Synergy clamps for the ablation of cardiac tissue.

If the FDA disagrees with us and requires us to submit a new 510(k) or PMA for then existing modifications, we may 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 the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Delays in receipt or failure to receive clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects.

We 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 the states and foreign countries in which we conduct our business. The laws that affect our ability to operate our business in addition to the Federal Food, Drug, and Cosmetic Act and FDA regulations include, but are not limited to, the following:

state food and drug laws, including laws regulating the manufacture, promotion and distribution of medical devices;

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;

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the federal doctor self-referral prohibition, commonly known as the Stark Law, which, in the absence of a statutory or regulatory exception, prohibits the referral of Medicare patients by a doctor to an entity for the provision of certain designated healthcare services including inpatient and outpatient hospital services, if the doctor or a member of the doctor's immediate family has a direct or indirect financial relationship, including an ownership interest in, or a compensation arrangement with, the entity and also prohibits that entity from submitting a bill to a federal payor for services rendered pursuant to a prohibited referral;

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, and, although we are not a covered entity under HIPAA, as a business associate of covered entities through our contractual agreements with them, we are required to implement and maintain policies, procedures and reasonable and appropriate security measures to protect individually identifiable health information we receive from covered entities;

the Federal Trade Commission Act and similar laws regulating advertising and consumer protection; and

similar and other regulations outside the United States.

Certain federal and state laws regarding Medicare, Medicaid and physician self-referrals are broad and we may be required to change one or more of our practices to be in compliance with these laws. Healthcare fraud and abuse regulations are complex and even minor, inadvertent irregularities in submissions can potentially give rise to claims that a statute 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. In October 2008, the DOJ initiated an investigation of our marketing and promotional practices. Although we admitted to no wrongdoing and believe there was no wrongdoing on the part of us or our employees, during 2010 this investigation resulted in a financial settlement of \$4.4 million (which includes interest based on payment terms). Additionally, we incurred substantial legal costs through the investigation and settlement process.

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

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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 AF treatment would harm our ability to promote and sell our Isolator system and other products.

Third-party payors are increasingly exerting pressure on medical device companies to reduce their prices. Even to the extent that the treatment of AF using our products is reimbursed by private payors and governmental payors, adverse changes in payors' policies toward coverage and reimbursement for surgical AF 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. Alternatively, government or private payors may deem the treatment of AF utilizing our products experimental or not medically necessary and, as such, not provide coverage. Adverse changes in coverage and reimbursement for surgical AF treatment could harm our business and reduce our revenue.

We have 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 continue to experience AF following treatment with our products and the number of patients that have serious complications resulting from AF treatment using our products. Our clinical trials may produce limited data regarding the efficacy of our products for the treatment of AF or may 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 system procedures are not 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 laws and 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 they 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;

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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