

AtriCure, Inc.  
Form 10-K/A  
May 08, 2008  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K/A**  
**(Amendment No. 1)**

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

For the fiscal year ended December 31, 2007

**.. 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)

Edgar Filing: AtriCure, Inc. - Form 10-K/A

**DELAWARE**  
(State or other jurisdiction of

**34-1940305**  
(I.R.S. Employer

incorporation or organization)

Identification Number)

**6033 Schumacher Park Drive, West Chester, OH**  
(Address of principal executive offices)

**45069**  
(Zip Code)

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

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

Title of each class	Name of each exchange on which registered
Common Stock, \$.001 Par Value Per Share	The NASDAQ Stock Market LLC

**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 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, large accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act (check one):

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, 2007, as reported on the Nasdaq Global Market, was \$78.5 million.

As of February 29, 2008, there were 14,167,664 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.

**Table of Contents**

**EXPLANATORY NOTE**

This Amendment No. 1 to the Annual Report on Form 10-K of AtriCure, Inc. for the year ended December 31, 2007 is being filed to correct a printer error in the Consolidated Statements of Stockholders' Equity (Deficit) on Page 71 of the Form 10-K. The error consisted of (i) two amounts being incorrectly listed by the financial printer in the second column as a Common Stock Amount rather than in the third column as Additional Paid-In Capital, (ii) one amount incorrectly listed by the financial printer in the third column as an Additional Paid-In-Capital amount rather than in the fourth column as Unearned Compensation and (iii) three amounts being incorrectly listed by the financial printer in the sixth column as Other Comprehensive Income rather than in the seventh column as Total Stockholders' Equity (Deficit). The balances included at the bottom of each column were correct.

The foregoing error has been corrected in this Amendment No. 1. We have also included in this Amendment No. 1 a new consent of independent registered accounting firm as Exhibit 23.1 and new officer certifications as Exhibits 31.1, 31.2, 32.1 and 32.2. Except for these changes, this Amendment No. 1 does not make any new disclosures, update prior disclosures or attempt to reflect any events that occurred subsequent to the original filing of the Form 10-K with the Securities and Exchange Commission on March 17, 2008.

**Table of Contents****TABLE OF CONTENTS**

	<b>Page Number</b>
<b><u>PART I</u></b>	1
<u>ITEM 1: Business</u>	1
<u>ITEM 1A: Risk Factors</u>	25
<u>ITEM 1B: Unresolved Staff Comments</u>	47
<u>ITEM 2: Properties</u>	48
<u>ITEM 3: Legal Proceedings</u>	48
<u>ITEM 4: Submission of Matters to a Vote of Security Holders</u>	
<u>Executive Officers of the Registrant</u>	48
<b><u>PART II</u></b>	50
<u>ITEM 5: Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	50
<u>ITEM 6: Selected Financial Data</u>	53
<u>ITEM 7: Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	54
<u>ITEM 7A: Quantitative and Qualitative Disclosures About Market Risk</u>	66
<u>ITEM 8: Financial Statements and Supplementary Data</u>	67
<u>ITEM 9: Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	94
<u>ITEM 9A: Controls and Procedures</u>	94
<u>ITEM 9B: Other Information</u>	96
<b><u>PART III</u></b>	96
<u>ITEM 10: Directors, Executive Officers and Corporate Governance</u>	96
<u>ITEM 11: Executive Compensation</u>	96
<u>ITEM 12: Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	96
<u>ITEM 13: Certain Relationships and Related Transactions and Director Independence</u>	96
<u>ITEM 14: Principal Accountant Fees and Services</u>	96
<b><u>PART IV</u></b>	97
<u>ITEM 15: Exhibits and Financial Statement Schedules</u>	97
<b><u>SIGNATURES</u></b>	100

---

**Table of Contents**

**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. Medical journals have described the adoption by leading cardiothoracic surgeons of our Isolator® bipolar ablation clamp system as a treatment alternative during open-heart surgical procedures to create lesions in cardiac tissue to block the abnormal electrical impulses that cause atrial fibrillation, or AF, a rapid, irregular quivering of the upper chambers of the heart. Additionally, leading cardiothoracic surgeons, treatment guidelines as published by the Heart Rhythm Society and publications in medical journals have described our Isolator® system as a standard treatment alternative for AF patients who may be candidates for sole-therapy minimally invasive surgical procedures.

From our inception in November 2000 through the first half of 2002, our operations consisted primarily of development-stage activities, including the development of our Isolator® system, raising capital, obtaining product clearances, conducting product testing and evaluations, and recruiting personnel. In January 2003 we commenced a full commercial release of our Isolator® system. Revenues reached \$48.3 million in 2007, were \$38.2 million in 2006, and were \$31.0 million in 2005. We anticipate that substantially all of our revenues for the foreseeable future will relate to products we currently sell or are in the process of developing, which surgeons use to ablate cardiac tissue for the treatment of AF and we believe will use in the future for the exclusion of the left atrial appendage in order to potentially reduce the risk of stroke in patients with AF.

Our primary product line, which accounts for a majority of our revenues, is our AtriCure Isolator® bipolar ablation system. Our Isolator® system consists primarily of a compact power generator known as an ablation and sensing unit, or ASU, a switchbox unit, or ASB, which allows physicians to toggle between multiple products and multiple configurations of our Isolator® clamps, including our recently introduced Isolator Synergy™ clamps. We sell two configurations of our clamps, one designed for ablation during open-heart, or open, procedures and one designed for ablation during sole-therapy minimally invasive procedures. We also sell a multifunctional bipolar pen, or multifunctional pen, which is often used by physicians in combination with our Isolator® system to ablate cardiac tissue and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. Additionally, we sell various configurations of enabling devices, such as our Lumitip™ dissection tool. In August 2007, we acquired a cardiac cryoablation product line which uses extreme cold to ablate tissue. Prior to our acquisition of the product line, we sold the product line as a distributor.

---

## **Table of Contents**

In the United States we primarily sell our products through our direct sales force. AtriCure Europe BV, our wholly-owned European subsidiary incorporated and based in the Netherlands, sells our products throughout Europe, primarily through distributors, with the exception of Germany and Austria where we began to sell direct through our sales force during 2007. 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 primarily transacted in Euros. Our sales outside of the United States represented 14% of our 2007 revenues.

Cardiothoracic surgeons have adopted our Isolator<sup>®</sup> system to treat AF in over 40,000 patients since January 2003. Based on this adoption of our products, we believe that we are currently the market leader in the surgical treatment of AF. The Food and Drug Administration, or FDA, has cleared our Isolator<sup>®</sup> system and our multifunctional pen for the ablation of cardiac tissue, but to date, none of our products have been cleared by the FDA for the treatment of AF and accordingly, substantially all of our revenues are currently generated through non-FDA-approved, or off-label, use of our products for the treatment of AF.

AF 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. According to data from the Framingham Study, one in four people over the age of 40 in the United States has a lifetime risk of developing AF, and the incidence of AF increases with age. More than five million people worldwide, including approximately 2.5 million Americans, have been diagnosed with AF and studies expect a 30% increase in the prevalence of AF by 2015. According to the American Heart Association, approximately 15% to 20% of the estimated 700,000 strokes that occur annually in the United States are attributable to AF and people with AF are approximately five times more likely to have a stroke. Further, 35% of AF patients will have a stroke in their lifetime and AF-related strokes tend to be severe. Studies suggest that 25% of the people who have an AF-related stroke die within the first thirty days following their stroke and over 40% are permanently bedridden.

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 occasionally undergo catheter-based procedures to treat their AF, but catheter-based procedures are often technically challenging, can be associated with serious complications, are 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 was not widely adopted because it is technically challenging, highly invasive and involves long recovery times.

The creation of transmural, or full-thickness, lesions is thought to be a potentially critical factor in the successful treatment of AF when performing ablation treatments. Prominent medical journals, which contain articles that were written, in part, by leading cardiothoracic surgeons, some of whom may be consultants to us, describe how cardiothoracic surgeons have used our Isolator<sup>®</sup> system to create transmural lesions when treating AF either during an elective open-heart surgical procedure or as a sole-therapy minimally invasive procedure. As indicated in these articles, cardiothoracic surgeons using our products have treated AF in approximately 20 minutes during open-heart surgical procedures and in approximately two to three hours as a sole-therapy minimally invasive procedure.

In July 2007, the FDA cleared our Isolator<sup>®</sup> system for the ablation of cardiac tissue. Prior to July 2007, our Isolator<sup>®</sup> system had been cleared in the United States for the ablation of soft tissues during general and thoracic surgical procedures. Our multifunctional pen has been cleared by the FDA for cardiac tissue ablation and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. We may only promote our products to doctors and provide education and training on the use of our devices for their cleared indications, which does not include the treatment of AF. While the FDA does not prevent doctors from using products off-label, we cannot market a product for an off-label use.

---

**Table of Contents**

We are in the process of conducting a clinical trial, known as ABLATE, to evaluate the safety and effectiveness of our Isolator<sup>®</sup> system for the treatment of patients who have AF and are undergoing a concomitant open-heart procedure. If this trial is successful, we intend to seek FDA approval as early as 2010 for the use of our Isolator<sup>®</sup> system during open procedures to treat patients with permanent AF. If the FDA were to require our products to have AF approval in order for us to continue selling them, not only would we no longer receive revenues from the sale of these products, but we also would require significant financing to conduct additional clinical trials and to sustain our operations until such time as sales could resume. We cannot be assured that we can obtain FDA approvals for the treatment of AF, that we would have, or could raise, sufficient financial resources to sustain our operations pending FDA approval, or that, if and when the required approvals are obtained, there will be a market for our products, including our Isolator<sup>®</sup> system and our multifunctional pen.

Although the use of our Isolator<sup>®</sup> system and multifunctional pen to treat AF remains investigational and we are still seeking FDA approval in connection with the use of our Isolator<sup>®</sup> system for the treatment of AF, preliminary clinical studies conducted by doctors at leading medical centers provide support for our Isolator<sup>®</sup> systems' ability to create the lesions needed to block the abnormal electrical impulses that cause AF. We believe that those studies indicate that we have a significant potential competitive advantage in the treatment of AF. Several clinical studies, including a 27-patient study, a 40-patient study, a 47-patient study and a 276-patient study, in which several of our consultants participated and that were published in *The Journal of Thoracic and Cardiovascular Surgery*, found that approximately 90% of study participants treated using our Isolator<sup>®</sup> system were free of AF at their six-month follow-up. Recently, several studies have been completed and results published utilizing our Isolator<sup>®</sup> system and our multifunctional pen during minimally invasive sole therapy surgery for the treatment of AF, in which several of our consultants have participated, including a 20-patient, a 22-patient and an 88-patient study. The success rates for the treatment of paroxysmal, or intermittent, AF patients were in excess of eighty percent and patients who had more continuous, or persistent or permanent, AF experienced success rates ranging from 25% to over 50%. We plan to introduce our new Coolrail<sup>™</sup> Linear Ablation Pen system, or linear ablation pen, during the first half of 2008, which when used in combination with our Isolator<sup>®</sup> system and other products will allow physicians to perform an expanded ablation during a sole-therapy procedure. We believe this expanded ablation, or lesion set, will result in higher success rates when physicians treat patients with more continuous AF. We believe the overall demand for our products will increase, including an increased demand for products for use in minimally invasive procedures, which we believe will ultimately represent our largest growth opportunity.

We have developed the AtriCure Left Atrial Appendage Exclusion System, which is designed to exclude the left atrial appendage by implanting the device during open or minimally invasive 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. It is estimated that 15% to 20% of all strokes are attributable to AF and that a 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. We also believe that our left atrial appendage exclusion system is potentially safer, more effective and easier to use when permanently excluding the left atrial appendage than products and procedures currently being utilized. Our left atrial appendage exclusion system is currently being utilized and has been safely and effectively implanted in humans as part of a clinical evaluation in Europe. The AtriCure Left Atrial Appendage Exclusion System has not yet been approved for human use by the FDA in the United States. However, we have filed a 510(k) notification with the FDA and if the FDA's review is favorable, we expect to have clearance from them for commercial use of the AtriCure Left Atrial Appendage Exclusion System to permanently exclude the left atrial appendage in the second half of 2008 or 2009. We believe the market for the left atrial appendage exclusion system is large and represents a significant new growth opportunity for us.

Information about our operating results and working capital practices is set forth in Item 7 of this Form 10-K.

---

## **Table of Contents**

### **Market Overview**

AF is a condition where 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 becomes 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 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 a patient's 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.

AF is the most commonly diagnosed sustained cardiac arrhythmia, and affects more than five million people worldwide, including more than 2.5 million Americans, where approximately 160,000 new cases of AF are diagnosed each year. According to data from the Framingham Study, 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 was 26% for men and 23% for women.

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. AF accounts for an estimated five million office visits annually and approximately \$6.7 billion in hospitalization-related costs in the United States each year. These costs do not include the costs of drugs or indirect costs, such as the management of AF-related strokes, the costs of which are believed to be significant.

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. Of the patients undergoing open-heart surgery in the United States, we estimate that approximately 80,000 of these patients are potential candidates for surgical ablation using our Isolator® system.

Of the United States population diagnosed with AF, approximately 12% 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 is often not 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 that these patients will ultimately comprise our largest growth opportunity.

Because the FDA has not cleared our products for the treatment of AF, we and others acting on our behalf may not promote our products for the treatment of AF, make any claim that they are safe and effective for the treatment of AF or train doctors to use them for the treatment of AF outside of the clinical trial setting. However, these restrictions do not prevent doctors from choosing to use our Isolator® system and other products for the treatment of AF or prevent us from engaging in sales and marketing efforts that focus only on the general attributes of our products and their FDA-cleared uses and not on the treatment of AF. Although we educate and train doctors as to the general skills involved in the proper use of our products, it is our policy not to educate or train them to use our products for the treatment of AF. We provide information to physicians in response to their unsolicited requests, and also consider requests and often support physician training by providing educational grants to be used for university and physician training programs, the content for which is intended to be developed independently of AtriCure.

## **Table of Contents**

### **Current 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 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 atrial fibrillation 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;

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-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.

*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 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.

### **The AtriCure Solution**

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. Reports of preliminary clinical studies conducted by doctors at prominent medical centers suggest that our products, including our Isolator<sup>®</sup> 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. We believe that these reports have led to our high market penetration and rapid product adoption. Over eighty medical centers in the United States are currently using our Isolator<sup>®</sup> system as a sole-therapy minimally invasive treatment for AF and revenues from our minimally invasive products, including an estimate of revenues from our multifunctional pen, exceeded \$14 million in 2007. Our multifunctional pen is complementary to our Isolator<sup>®</sup> system and we believe it is used in combination with our Isolator<sup>®</sup> system in most sole-therapy procedures. We also believe there has been a trend toward utilizing our multifunctional pen during open-heart procedures.



---

## **Table of Contents**

Our clinical studies for the use of our products to treat AF are ongoing. Leading cardiothoracic surgeons and electro-physiologists, including those who are consultants to us, have published results of initial clinical studies utilizing our Isolator<sup>®</sup> system. These studies have been conducted at prominent medical centers, including the Cleveland Clinic, Washington University (St. Louis, Missouri), the Cardiopulmonary Research Science and Technology Institute (Dallas, Texas), Sutter Memorial (Sacramento, California), Oregon Heart and Vascular Institute (Eugene, Oregon), Inova Heart and Vascular Institute (Fairfax, Virginia), University of Zurich (Zurich, Switzerland) and the Nebraska Heart Hospital (Lincoln, Nebraska). The results of these studies were promising in terms of the efficacy, ease of use and safety.

**Efficacy.** We believe that products designed to treat AF must be able to reliably create transmural lesions in order to block the electrical impulses that trigger and sustain AF. Transmurality is considered by many physicians to be necessary for the treatment of AF, since creating lesions with gaps can fail to treat AF and may cause other abnormal heart rhythms. Initial studies have found that between 80% and 95% of the study participants treated for AF during open-heart procedures using our Isolator<sup>®</sup> clamps were free of AF at a minimum of six-month follow-up. Recently, initial studies have been published in leading publications on the clinical outcomes related to the sole-therapy minimally invasive surgical treatment of AF utilizing our products, including our Isolator<sup>®</sup> system. Those studies resulted in over 80% of patients with paroxysmal AF and 25% to 50% of patients with permanent AF being free of AF after a minimum six-month follow-up period. We are conducting longer-term FDA-approved clinical trials in order to confirm these initial promising results. During the first half of 2008, we plan to introduce our new Coolrail<sup>™</sup> Linear Ablation Pen, which will allow physicians to perform an expanded ablation treatment during sole-therapy AF procedures, which we believe will improve the success rates, particularly for persistent and permanent AF patients undergoing a sole-therapy AF procedure. In March 2008, our linear ablation pen was cleared by the FDA for the ablation of cardiac tissue.

**Ease of Use.** In studies, physicians reported that our Isolator<sup>®</sup> system is easy to use, based in part on the design and automated features of our ablation and sensing unit, or ASU. Our ASU does not require the surgeon to make any prior settings or adjustments, and signals the surgeon when conductance drops below a certain threshold indicating that the lesion is transmural. Further, our AtriCure switch box, or ASB allows the physician to easily toggle between multiple devices, such as our clamps and pens. The unique jaws of our Isolator<sup>®</sup> clamps firmly clamp and evenly compress the targeted tissue being ablated, allowing surgeons to rapidly create transmural lesions. During 2007, we introduced our new Isolator Synergy<sup>™</sup> clamps, which incorporate two pulsing pairs of electrodes in the jaws of the clamp. We believe these clamps ensure full thickness ablation of thicker and more diseased tissue. Cardiothoracic surgeons report that they have generally treated AF in only 20 minutes when using our Isolator<sup>®</sup> system during an open-heart procedure, or in approximately two to three hours when using our products to treat AF as a sole-therapy minimally invasive procedure.

**Safety.** Although serious complications, including death, may arise from any type of cardiac surgery, initial studies have concluded that our Isolator<sup>®</sup> system appears to have an excellent safety profile as a treatment alternative for the surgical treatment of AF. Cardiothoracic surgeons participating in these studies concluded that our Isolator<sup>®</sup> system may potentially reduce or eliminate damage to adjacent anatomical structures due to its unique design, which confines the delivery of energy to within the jaws of the clamps and allows the surgeon to control the application of energy to the tissue targeted for ablation.

### **AtriCure Products**

The AtriCure Isolator<sup>®</sup> bipolar ablation system, or Isolator<sup>®</sup> system, primarily consists of the following products:

**Ablation and Sensing Unit, or ASU.** Our ablation and sensing unit, or 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 both our clamps and multifunctional pen. We generally lend our ASU to customers in the United States and sell it to customers outside of the United States.

**AtriCure Switch Box, or ASB.** Our AtriCure switch box, or ASB, is a compact switch box which was introduced with our Isolator Synergy<sup>™</sup> clamps and provides the technology needed for the dual pulsing

---

**Table of Contents**

electrodes as well as the ability to connect and toggle between our multiple devices, including our clamps and multifunctional pen. We generally lend our ASB to customers in the United States and sell it to customers outside of the United States.

**Isolator® Bipolar Radio-Frequency Ablation Clamps.** We sell two configurations of our Isolator® clamps, one designed for ablation during open-heart procedures and one designed for ablation during minimally invasive procedures. All of our Isolator® clamps are disposable 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 2007, we introduced our next generation clamps, Isolator Synergy , which are designed to provide more reliable full thickness lesions in thicker and more diseased tissue. During the first quarter of 2006, we introduced our endoscopic Isolator® bipolar ablation clamps and released a series of Isolator Synergy ablation clamps throughout 2007. Our endoscopic clamps are specifically designed for use in minimally invasive procedures and include our unique glide-path transfer guide. The clamps are designed to simplify minimally invasive procedures, making it more adaptable to a broader number of surgeons and enabling surgeons the ability to perform a completely thoracoscopic (through small incisions in the chest) procedure.

In addition to our AtriCure Isolator® system, we sell a pen-shaped ablation device known as the multifunctional bipolar Pen. This disposable hand piece is powered by the same ASU that powers our Isolator® clamps and is compatible with standard external pacing/stimulating and sensing/recording systems. Because of its broad range of capabilities, we believe surgeons generally are using this device in combination with our Isolator® clamps during minimally invasive procedures and they also have adopted it for use during open-heart procedures. The multifunctional pen enables surgeons to evaluate cardiac arrhythmias, perform temporary pacing, stimulation, sensing, and ablate cardiac tissues with the same device. When the multifunctional pen is used with our ASB, surgeons are able to toggle back and forth between temporary pacing, sensing, stimulation and ablation. We released our multifunctional pen during the third quarter of 2005. During the first half of 2008, we plan to release our Coolrail™ Linear Ablation Pen, which is designed to allow the physician to create an expanded cardiac ablation lesion set during minimally invasive procedures. We believe physicians will utilize our linear ablation pen during minimally invasive procedures in order to improve long-term results for patients who have persistent and permanent AF. Concurrent with the release of our Coolrail™ Linear Ablation Pen, we plan to introduce our new MicroPace ORLab™, a stimulating, mapping and recording system which we believe will enable physicians to more effectively confirm that the ablation lines being created are forming electrical barriers or lines of block.

We also sell a device known as the Lumitip™ dissector, which is used by surgeons to gently separate tissues to provide access to key anatomical structures that are targeted for ablation. The Lumitip™ dissector consists of a shaft with an articulating index finger-shaped tip that illuminates, allowing surgeons to more easily determine the movement, direction and position of the device during procedures. The Lumitip™ dissector is cleared by the FDA for the dissection of soft tissues during general, thoracic and certain other surgical procedures. The Lumitip™ dissector was designed by Dr. Randall Wolf, who is a leader in the field of minimally invasive cardiothoracic surgery.

Additionally, we have developed the AtriCure Left Atrial Appendage Exclusion System, which is designed to exclude the left atrial appendage, the small appendage that is attached to the left atrium. The left atrial appendage is considered by many physicians to be the source of blood clots which may cause a high percentage of AF-related strokes. During 2007, the AtriCure Left Atrial Appendage Exclusion System was used to implant our clip in humans in Europe as part of a clinical study, but has not yet been approved by the FDA for human use in the United States. We have filed with the FDA a 510(k) notification for our AtriCure Left Atrial Appendage Exclusion System to obtain an indication that includes left atrial appendage exclusion. We are currently working with the FDA and, if the FDA review is favorable, we expect clearance during the fourth quarter of 2008 or the first half of 2009.

---

## **Table of Contents**

In August 2007 we acquired the Frigtronics® CCS-200 product line for cardiac ablation, which includes a console that is currently used in combination with a variety of reusable cardiac ablation probes which use cryotherapy, or extreme cold, to ablate tissues. Currently, some surgeons use this reusable device in conjunction with our Isolator® clamps to ablate tissues around heart valves as part of an AF treatment. We are in the process of developing a long, malleable, disposable cryotherapy ablation probe, which will be used with the console and we believe will be adopted by physicians for AF ablation treatment during certain open-heart procedures. We anticipate a potential second half 2008 clearance from the FDA and full commercial product release during the fourth quarter of 2008.

### **Open-Heart Surgical Procedure**

During elective open-heart surgical procedures, such as bypass or valve surgery, cardiothoracic surgeons use our Isolator® system to treat patients with a pre-existing history of AF. Surgeons report that ablation using our Isolator® system generally adds approximately 20 minutes to an open-heart surgical procedure. Surgeons use our Isolator® clamps 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, or paroxysmal, or more continuous, known as persistent or permanent AF. Patients who have been diagnosed with AF for a longer duration and have more continuous AF generally receive more extensive ablation procedures than patients who have been diagnosed with AF for a shorter duration or who have paroxysmal AF. Surgeons using our Isolator® 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 required. Cardiothoracic surgeons report that using our Isolator® system for open-heart procedures enables them to create lesions to achieve electrical isolation of the pulmonary veins from the atrium. In order to perform this procedure, surgeons position the jaws of our clamps on the cardiac tissue surrounding the pulmonary veins. The jaws are closed and the ablation is activated. Moments later, an audible tone from the ASU alerts the surgeon that the conductance has dropped below a certain threshold, indicating that the lesion has become transmural, or full thickness, and that the pulmonary veins have been electrically isolated.

*Additional Lesions.* For those patients who have more continuous AF, doctors may determine that additional lesions may be required to treat their AF. In cases where patients require such additional lesions, surgeons may use our Isolator® clamps for open-heart 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 our multifunctional pen to sense, pace, stimulate or ablate cardiac tissues. Additionally our reusable cryotherapy probes are often used to ablate cardiac tissues near the heart valves.

### **Sole-Therapy Minimally Invasive Procedure**

For those patients with AF who do not require a concomitant open-heart surgical procedure, surgeons have used our endoscopic Isolator® system 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 been two to five days. Similar to the open-heart surgical procedure, patients who have more continuous AF generally require an expanded lesion set that mimics the cut and sew Maze procedure. During the first half of 2008, we plan to introduce our Coolrail™ Linear Ablation Pen which is designed to enable physicians to perform an expanded ablation procedure.

---

## **Table of Contents**

### **Business Strategy**

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

***Form Investigational Relationships with Key Opinion Leaders at Leading Institutions.*** We have formed investigational relationships with key opinion leaders at several leading medical centers including the Cleveland Clinic, Washington University, Medical College of Virginia, the Cardiopulmonary Research Science and Technology Institute (Dallas, Texas), Inova Heart and Vascular Institute (Fairfax, Virginia), Oregon Heart and Vascular Institute, Nebraska Heart Hospital, the University of Oklahoma, the University of Zurich and the University Community Hospital of Tampa. These key opinion leaders and others have worked with us as consultants to evaluate and develop our products. Additionally, several key opinion leaders at these institutions have published peer-review data that describes the use of our products as a treatment alternative for AF. These opinion leaders continue to assist us with the design and/or evaluation of our products. To date, there have been over 20 peer-review publications that describe our Isolator<sup>®</sup> systems' ability to create transmural lesions or the use of our Isolator<sup>®</sup> system as an AF treatment alternative. Recently, several key publications were published highlighting promising results utilizing our products to treat patients with AF during sole-therapy minimally invasive surgical procedures. We believe that these publications, and the presentations given by key opinion leaders, have contributed to the adoption of our Isolator<sup>®</sup> system for the treatment of AF.

***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 technology as they relate to their cleared indications. Our highly trained sales professionals meet with doctors at leading institutions to provide education and technical training limited to 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.

***Expand Adoption of Our Minimally Invasive Products.*** We believe that the catalysts for expanded adoption of our minimally invasive products include the publication of peer-review articles, which we believe will help validate the successful long-term use of our products for patients with AF, and our new innovative product introductions, such as our Coolrail<sup>™</sup> Linear Ablation Pen.

Our consultants have received grant monies to support certain research activities and they have presented and published their results of an initial series of studies relating to the use of our minimally invasive products. As results of these peer-review studies are accepted, we believe that this will increase the demand for our minimally invasive products. We believe our consultants are continuing their efforts to investigate, present and publish results from the use of our products to perform minimally invasive procedures and that the results from these research activities will continue to demonstrate that our products can be used to offer certain AF patients an improved treatment alternative. We believe that these ongoing research activities and anticipated presentations and publications will create an increased demand for our minimally invasive products.

***New Product Innovation.*** During 2007 we released our new Isolator Synergy<sup>®</sup> ablation clamps. The unique ablation technology used in our Isolator Synergy<sup>®</sup> clamps provides more reliable full thickness lesions in thicker and more diseased tissues. We believe that physicians view the capability of the Isolator Synergy<sup>®</sup> clamps to more reliably create transmural lesions in thicker and more diseased tissues, increasing patient outcomes and providing us with an important competitive advantage. During the first half of 2008 we plan to release our Coolrail<sup>™</sup> Linear Ablation Pen, allowing for the expansion of the ablation procedure during minimally invasive cases and an integrated mapping system, MicroPace ORLab<sup>™</sup>. We are also developing a long, malleable disposable cryotherapy ablation probe that will be used in combination with our recently acquired

---

## **Table of Contents**

AtriCure Frigitronics® CCS-200 console for use primarily during open-heart procedures. We believe that during certain open-heart procedures physicians prefer cryotherapy ablation to RF ablation. We expect that our new disposable cryotherapy probe will broaden our open-heart technology platform and also allow us to capitalize on a growing market opportunity. We plan to release this disposable probe during the second half of 2008. Additionally, we have developed the AtriCure Left Atrial Appendage Exclusion System, which is designed to exclude the left atrial appendage by implanting a clip device during a surgical procedure 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 have filed a 510(k) notification with the FDA and if the FDA review is favorable, we expect to have clearance in the United States for commercial use of the AtriCure Left Atrial Appendage Exclusion System to permanently exclude the left atrial appendage in the fourth quarter of 2008 or first half of 2009.

### **Clinical Trials**

During 2007 we worked closely 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 undergoing concomitant open-heart surgical ablation procedures. We anticipate we will need to enroll approximately 75 patients in the trial, which is being conducted at ten centers throughout the United States. As of February 29, 2008, we have treated two patients in the trial. The primary endpoints of the trial are an estimated 70% of patients treated being free of AF and off of antiarrhythmic drugs at their six-month follow-up. A 24-hour holter monitor will be used to determine the rhythm status six months following surgery. If the ABLATE trial is successful, we anticipate filing a Pre-Market Approval application, or PMA, which if approved by the FDA would allow us to market our Isolator® system for the treatment of patients with permanent AF during open-heart procedures.

Additionally, we have two clinical trials, RESTORE-SR and RESTORE-SRII, both of which are in their final stages. Data and results from these 39-patient and 25-patient trials were utilized in support of our 510(k) filing with the FDA to obtain clearance for the use of our Isolator® systems for the ablation of cardiac tissue, which we received in July 2007. During 2007, we received approval for a new 25-patient, 5 center clinical trial, RESTORE-SRIIB. This feasibility trial, which is the second arm of RESTORE-SRII, is designed to demonstrate the potential safety and efficacy of our Isolator Synergy™ system during a sole-therapy minimally invasive procedure to treat patients with permanent AF.

### **Regulatory Clearances**

#### *United States*

In July 2007 we were notified by the FDA that our Isolator® system received 510(k) clearance for the ablation of cardiac tissue. From August 2001 until July 2007, the system had been cleared for the ablation and coagulation of soft tissues during general, ear, nose and throat, thoracic, gynecologic and urologic surgical procedures.

In July 2004 the FDA granted us clearance to market our Lumitip™ dissector for its intended use of dissection of soft tissues during general, thoracic and certain other surgical procedures.

In June 2005 the FDA granted us a 510(k) clearance to market our multifunctional bipolar Pen for its intended use of ablation of cardiac tissue during cardiac surgery, and in July 2006, the FDA granted us 510(k) clearance to market our multifunctional pen for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias.

In October 2005 the FDA granted us 510(k) clearance to market our endoscopic Isolator® bipolar ablation clamps and the Glide-path transfer guide for the ablation and coagulation of soft tissues during general, ear, nose and throat, thoracic, gynecologic and urologic surgical procedures, which in conjunction with our July 2007 FDA notification, are now cleared for the ablation of cardiac tissue.

## **Table of Contents**

In March 2008 the FDA granted us 510(k) clearance to market our Coolrail™ Linear Ablation Pen for the ablation of cardiac tissue.

During 2007 we filed a 510(k) notification for the AtriCure Left Atrial Appendage Exclusion System for a left atrial appendage exclusion indication. We are currently working with the FDA and believe we will have clearance for the system in the later half of 2008 or 2009.

### *International*

We received our original CE Mark for our Isolator® bipolar ablation clamp system in July 2002, which allows us to market and sell these clamps throughout the European Union for the same uses for which they may currently be marketed in the United States. In September 2006, we expanded our CE Mark indication to market our Isolator® system for the treatment of cardiac arrhythmias, including atrial fibrillation. We have also received certifications to market and sell our Isolator® clamp system in several other foreign markets, including Canada, Japan and China.

We received our original CE Mark for the Lumitip™ dissector in February 2005, which allows us to market and sell the Lumitip™ dissector throughout the European Union for the same uses for which it may currently be marketed in the United States. In October 2005, we also received approvals to market and sell the Lumitip™ dissector in Canada, Japan and China.

We received our original CE Mark for our multifunctional pen in July 2005, which allows us to market and sell our multifunctional pen throughout the European Union. We have also received approvals to market and sell our multifunctional pen in Japan, Canada and China.

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

Our United States sales and marketing efforts focus on educating doctors concerning our unique technologies and the technical benefits of our Isolator® system for the ablation of cardiac tissue. It is our policy not to market or promote our products for the treatment of AF. Our sales personnel visit cardiac surgeons, electrophysiologists and other doctors to discuss the general attributes of our Isolator® system to ablate cardiac tissue, and they also promote our multifunctional pen for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias during cardiac surgical ablation procedures and our Lumitip™ dissector for the dissection of soft tissues during general, thoracic and certain other surgical procedures. We train our sales force on the use of our Isolator® system to treat AF so that they are able to respond to unsolicited requests from doctors for information on the use of our Isolator® system for the treatment of AF. In addition, medically trained clinical applications specialists attend surgical procedures to discuss the use of our Isolator® system to ablate cardiac tissue and to respond in a non-promotional manner to unsolicited requests for information on the use of our Isolator® system for the treatment of AF.

We have entered into consulting agreements with leading scientists, cardiothoracic surgeons and electrophysiologists who assist us with the design, clinical testing and evaluation of our products, education of doctors on the use of our technologies and provide advice concerning regulatory submissions. We work closely with these thought leaders to understand unmet needs and emerging applications related to the ablation of cardiac tissues and the treatment of AF. We also provide educational grants to several leading medical centers. These institutions have used these grants to sponsor activities to evaluate the effectiveness of our Isolator® system and our other products and technology, which has increased the number of peer-review publications that cite the use of our Isolator® system. These grants have also been used by these institutions to sponsor independent educational programs relating to AF, including programs which focus on the surgical treatment of AF using our Isolator® system. We provide some guidance to physicians and medical institutions regarding what physicians are available and qualified for training other physicians in the use of our Isolator® system in the treatment of AF.

## **Table of Contents**

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 and we maintain continuous oversight of our grant application and funding procedures and requirements.

Our sales team in the United States is led by a vice president of sales and four area sales directors. As of December 31, 2007, our sales force in the United States had a total of approximately 55 employees, including approximately 30 full-time regional sales representatives. In addition to our regional sales representatives, we have approximately 15 sales personnel, or market development managers, who are focused on developing relationships between cardiothoracic surgeons and electrophysiologists. We select our sales personnel based on their expertise in the medical device industry, sales experience, reputation in the medical device industry, and their knowledge of our products and technologies. We believe at this time that our sales organization is appropriately sized and do not anticipate significant increases in the foreseeable future.

We market and sell our products in selected markets outside of the United States through independent distributors and in Europe through our European subsidiary, which includes a combination of independent distributors and direct sales personnel. During 2007, sales outside of the United States accounted for 14% of our total revenues. We have a network of distributors outside of the United States who currently market and sell our products and are located primarily in Asia, Europe, South America and Canada. During 2007, we hired a direct sales representative who sells to customers in Germany and Austria and we plan to expand in those markets by adding additional sales representatives during 2008. We continue to expand our presence in markets outside of the United States and revenues from outside of the United States grew from 11% of total revenues in 2006 to 14% of total revenues in 2007. See Risk Factors Risks Relating To Our Business We sell the AtriCure Isolator<sup>®</sup> bipolar ablation system outside of the United States and are subject to various risks relating to international operations, which could harm our international revenues and profitability.

We have one reporting segment. For information regarding revenues from customers, operating losses and total assets for each of our last three fiscal years, please refer to our consolidated financial statements, which are included in Item 8 of this Form 10-K.

### **Seasonality**

During the third quarter, we historically experience a decline in revenues that we attribute to the elective nature of the procedures in which our products are typically used, which we believe arises from fewer people choosing to undergo elective procedures during the summer months.

### **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., MedicalCV, Inc., and ATS Medical, Inc. We believe that our Isolator<sup>®</sup> system is the only bipolar radio frequency ablation clamp system that has received FDA clearance for the ablation of cardiac tissue. We and our competitors provide products that have been adopted by doctors for the off-label treatment of AF. As of December 31, 2007, no company had received FDA approval or clearance to market an ablation system for use as a treatment for AF.

We and many of our competitors have developed surgical ablation devices that have been used to treat AF during open-heart surgical procedures and in some cases sole-therapy minimally invasive AF treatment. We and

---

## **Table of Contents**

these competitors utilize a variety of different technologies as energy sources for the ablation devices, including laser technology, microwave, cryotherapy, high-intensity focused ultrasound, and radio frequency technologies. Some of our competitors offer catheter-based treatments, including but not limited to Biosense Webster, Inc., EP Technologies, St. Jude Medical, Inc., and CryoCath Technologies, 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, which is a segment of the AF patient population that we believe would benefit from minimally invasive AF procedures. However, catheter-based treatments often do not treat patients with more continuous forms of AF. Some of these catheter-based treatments already have FDA clearance or approval for cardiac use, including the treatment of certain arrhythmias, although we believe none have approval for the treatment of AF at this time.

We believe that we compete favorably against companies that have products that are used for the surgical treatment of AF during both open-heart surgical 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 Isolator<sup>®</sup> system will not be introduced. We also believe that our Isolator<sup>®</sup> system competes favorably when compared to catheter-based treatments.

Because of the size of the AF market and the unmet need for an AF cure, competitors have 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 surgical AF treatment market is characterized by extensive research efforts and technological progress. Further, recent publications and industry events are expanding knowledge of the market and treatment alternatives and have identified the surgical treatment of AF as a treatment alternative for AF patients.

Existing or new competitors may develop technologies and products that are safer, more effective, easier to use or less expensive than our Isolator<sup>®</sup> system and other 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 Isolator<sup>®</sup> system 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 or 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, or 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 Part B of Medicare includes doctors' services. Because Medicare beneficiaries comprise a large percentage of the populations for which our Isolator<sup>®</sup> system is used, and private insurers may follow the coverage and payment policies for Medicare, Medicare's coverage and payment policies are significant to our operation.

Medicare's Part A program pays hospitals for inpatient services under the Inpatient Prospective Payment System, which provides a pre-determined payment based on the patient's discharge diagnosis. Discharge diagnoses are grouped into Diagnosis Related Groups, or DRGs. Effective October 2007, Medicare hospital reimbursement moved to a severity-adjusted DRG system. This severity-based DRG system considers a patient's co-morbidities and procedural complications in determining the DRG assignment, or code. We do not expect these changes to have a material impact on our business or revenues. There are several cardiac surgery DRGs associated with the surgical treatment of AF with and without a concomitant open-heart procedure. When an ablation device is used during a concomitant open-heart procedure, its reimbursement is included in the primary

---

**Table of Contents**

open-heart DRG. Reimbursement for sole-therapy minimally invasive AF treatment is represented by unique cardiac surgery DRGs. Each year, Medicare's inpatient 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 operations.

Doctors are reimbursed for their services separately under the Medicare Part B physician fee schedule. When surgically treating AF with and without a concomitant open-heart procedure, surgeons must select the appropriate Current Procedural Terminology, or CPT, codes to receive payment. These billing codes identify the procedure or procedures performed and are relied upon to determine third-party payor amounts. In terms of physician reimbursement for surgical ablation procedures, on January 1, 2007 several new CPT codes for sole-therapy surgical ablation procedures were published by the American Medical Association, or AMA, in the CPT coding book for 2007. The one-size fits all maze CPT code was deleted effective December 31, 2006. In its place, surgeons now have the choice of five different CPT codes for sole-therapy ablation procedures depending on the extent of the procedure and ablation performed.

During 2007 when an ablation was performed during an open-heart concomitant procedure, per AMA guidelines, surgeons were directed to use the miscellaneous CPT code for cardiac surgery. Generally, payors require surgeons to submit documentation that establishes the medical necessity for the ablation procedure when a miscellaneous CPT code is used. However, reimbursement is determined solely by the payor. Based on this change, we expected and believe that the reimbursement for open-heart concomitant procedures was less during 2007 when compared to the preceding year and we believe this had a negative impact on the demand for our open-heart products during 2007. Effective January 1, 2008, three new CPT codes were introduced for cardiac ablation when performed concomitantly. The 2008 codes are add-on codes and will allow the physician to obtain full reimbursement for the ablation procedure and the primary procedure. Prior to 2007, the reimbursement for the ablation under the one-size fits all maze CPT code was reduced by at least 50% when the ablation was performed concomitantly during open-heart surgery. We believe this change could have a positive impact on the demand for our products which are used during open-heart procedures during 2008.

Currently, we believe that the AF treatment reimbursement rates are adequate for hospitals to cover the use of our Isolator<sup>®</sup> system. In 2007, we estimate that the national Medicare average hospital payment rate for an open-heart procedure, whether or not the AF treatment was included, was approximately \$17,500 to \$40,000 depending on the type of open-heart procedure being performed, the geographic region and the type of facility. The cost of AF treatment performed during open-heart surgical procedures is not reimbursed separately by the Medicare program. For example, reimbursement for open-heart surgical procedures include supplies, such as an ablation device, but exclude doctor's fees for these procedures, which payors remit to doctors in addition to the amounts paid to hospitals. We estimate that Medicare's national average reimbursement to hospitals for AF treatment performed as a sole-therapy minimally invasive treatment was approximately \$28,000 in 2007. Effective October 2007, Medicare hospital reimbursement moved to a severity-adjusted DRG system. Although we currently expect a modest decline in the average reimbursement for hospitals as a result of this change, we do not expect these changes to have a material impact on our business or revenues. Reimbursement rates from other third-party payors may be the same as or higher or lower than Medicare rates, depending on their particular reimbursement methodology.

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 the payment rates they make 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 affect coverage and reimbursement determinations by many private payors. Additionally, some private payors do not follow the Medicare guidelines, and those payors may reimburse only a portion of the cost of AF treatment, or not at all.

Our Isolator<sup>®</sup> system and multifunctional pen have received FDA clearance for the ablation of cardiac tissue. However, because the FDA generally does not regulate the practice of medicine, doctors may use our

## **Table of Contents**

Isolator<sup>®</sup> system and other products in circumstances where they deem it medically appropriate, 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.

### **Acquisitions**

On August 8, 2007, we acquired the Frigitronics<sup>®</sup> CCS-200 product line for use in cardiovascular cryosurgery and certain related assets from Cooper Surgical, Inc. for an aggregate purchase price of \$3.7 million. The acquired product line includes the Frigitronics<sup>®</sup> CCS-200 console, which is currently used in combination with a variety of reusable cardiac ablation probes. Prior to the acquisition, we were a worldwide distributor of the product line. At closing, we paid \$3.3 million, and issued an unsecured note for \$0.4 million, which was paid in full in January of 2008, upon Cooper's successful completion of defined manufacturing services and delivery of all acquired tangible assets to AtriCure. Prior to the acquisition, we were a distributor of the acquired product line.

On August 10, 2005, we acquired Enable Medical Corporation, the manufacturer of our disposable Isolator<sup>®</sup> clamps, which are an essential component of our Isolator<sup>®</sup> system, for an aggregate purchase price of \$7.0 million (\$6.4 million net of cash acquired). In addition, under the terms of the merger agreement that we entered into with Enable, if certain Enable assets unrelated to our Isolator<sup>®</sup> system are sold prior to the third anniversary of the closing of our acquisition of Enable, we will be required to pay the former shareholders of Enable 50% of the consideration from that sale that is in excess of \$1 million, subject to a maximum payment of \$2 million. Prior to the acquisition, Enable was engaged in the research and development of radio-frequency energy-based surgical products and provided contract design, research and development and manufacturing services to us and other medical device companies.

### **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<sup>®</sup> system in the United States under a 510(k) clearance for the ablation of cardiac tissue. Currently, our Isolator<sup>®</sup> system may not be marketed for the treatment of AF without obtaining additional approvals from the FDA. Our multifunctional bipolar multifunctional pen is 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. The Lumitip<sup>™</sup> dissector is also a medical device 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 the Lumitip<sup>™</sup> 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.

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 closely 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 anticipate we will need to enroll approximately 75 patients in the trial, which is being conducted at ten centers throughout the United States. If the clinical trial is successful, we anticipate filing a PMA, no sooner than 2010, which if approved by the FDA would allow us to market our Isolator<sup>®</sup> system for the treatment of patients with permanent AF during open-heart procedures. We cannot assure you that we will successfully complete ABLATE, receive approval for any additional clinical trials or submit and obtain approval for any of the products comprising our Isolator<sup>®</sup> system for use in treating AF.

## Table of Contents

During the second half of 2007, we filed a 510(k) notification for the AtriCure Left Atrial Appendage Exclusion System for an indication of left atrial appendage exclusion. FDA regulations govern nearly all of the activities that we perform, or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses. The activities that the FDA regulates include the following:

product design, development and manufacture;

product safety, testing, labeling and storage;

pre-clinical testing in animals and in the laboratory;

clinical investigations in humans;

premarketing clearance or approval;

record keeping and document retention procedures;

advertising and promotion;

the import and export of products;

product marketing, sales and distribution;

post-marketing surveillance and medical device reporting, including reporting of deaths, serious injuries, device malfunctions or other adverse events; and

corrective actions, removals and recalls.

***FDA's Premarket Clearance and Approval Requirements.*** Unless an exemption applies, each medical device distributed commercially in the United States will require either prior 510(k) clearance or 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 placed in Class III, requiring submission of a PMA supported by clinical trial data.

In July 2007, the FDA determined that our Isolator<sup>®</sup> system is a Class II device and granted us 510(k) clearance to market our Isolator<sup>®</sup> system for the ablation of cardiac tissue. During 2007, the FDA approved our clinical trial, ABLATE. Notwithstanding the FDA's decision, in order to market our Isolator<sup>®</sup> system for the treatment of AF, the FDA will require that we seek approval through submission to the FDA of a PMA. Submission of a PMA is a much more demanding process than the 510(k) notification process. 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 can apply, including certain exemptions

and waivers for small businesses.

**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

## **Table of Contents**

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, but we do not believe that such modifications will require us to seek additional 510(k) clearance. The FDA may not agree with our decisions regarding whether new 510(k) clearances are required. If the FDA disagrees with us and requires us to submit a new 510(k) or PMA, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval. In addition, we could be subject to significant regulatory fines or penalties. Furthermore, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. 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.

**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. The PMA process is much more demanding than the 510(k) notification process. 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.

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 onerous 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 also be submitted before initiating a new clinical study under an existing IDE, such as initiating a pivotal trial following the conclusion of a feasibility trial. The IDE application 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 or IDE supplement is approved by the FDA and the appropriate institutional review boards, or IRBs, 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 patients' informed consent and IRB approval are required. Under its regulations, the agency responds to an IDE or an IDE amendment for a new trial within 30 days. The FDA may approve the IDE or amendment, grant an approval with certain conditions, or identify deficiencies and request additional information. It is common for the FDA to require additional information before approving an IDE or amendment for a new trial, and thus final FDA approval on a submission may extend 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

## **Table of Contents**

feasibility trial, the FDA limits the number of patients, sites and investigators that may participate. Feasibility trials are typically structured to obtain information on safety and to help determine how large a pivotal trial should be to obtain statistically significant results.

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' 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 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 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:

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;

---

**Table of Contents**

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. From January 1, 2007 through February 29, 2008, we submitted to the FDA 14 MDRs related to complications during procedures utilizing our products. Of these MDRs, four related to our Isolator<sup>®</sup> clamps, four related to the Lumitip<sup>™</sup> dissector and six related to our multifunctional pen. Included in the above MDR filings were two patient deaths, which we included in our MDR filings; however, they were categorized as outcomes based on physician judgment, not on the failure of one of our devices. Additionally, there have also been other incidents, including patient deaths that have occurred using our Isolator<sup>®</sup> system and other products that we have not, and we 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.

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:

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;

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

Edgar Filing: AtriCure, Inc. - Form 10-K/A

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

---

**Table of Contents**

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 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 Federal False Claims Act also allows a private individual or entity with knowledge of past or present fraud on the federal government to sue on behalf of the government to recover the civil penalties and treble damages. The U.S. Department of Justice on behalf of the government has successfully enforced the FCA against pharmaceutical and medical device manufacturers. The federal government suit has alleged that pharmaceutical manufacturers whose marketing and promotional practices were found to have included the off-label promotion of drugs or the payment of prohibited kickbacks to doctors violated the FCA on the grounds that these prohibited activities resulted in the submission of improper claims to federal and state healthcare entitlement programs such as Medicaid. Such 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.

We seek to structure our marketing practices such that they are not in violation of the Federal False Claims Act or state equivalents and other applicable laws, but we cannot assure you that the federal authorities will not take action against us and, if such action were successful, we could be required to pay significant fines and penalties and change our marketing practices. Such enforcement could have a significant adverse effect on our ability to operate. We engage in a variety of activities that are subject to these laws and that have come under particular scrutiny in recent years by federal and state regulators and law enforcement entities. These activities have included consulting arrangements with cardiothoracic surgeons, grants for training and other education, grants for research, and other interactions with doctors.

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 payment of 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 can not provide any assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws.

---

## **Table of Contents**

**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 has 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 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. International Standards Organization, or ISO 9001 and ISO 13845 certifications are voluntary standards. 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 our Isolator® system and other important technologies 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 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 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 Isolator® bipolar ablation system 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. We have already obtained patents or filed patent applications on a number of our technologies, including patents and patent applications relating to our Isolator® system and ancillary devices. 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

## **Table of Contents**

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, 2007, we had issued United States patents that will expire between 2015 and 2023.

As of December 31, 2007, we had the following portfolio of patents or patent applications covering our proprietary technologies and products:

28 issued United States patents;

23 United States non-provisional patent applications;

9 United States provisional patent applications;

4 issued foreign patents; and

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

## **Manufacturing**

We manufacture the majority of the disposable products we sell and generally purchase items that would be deemed capital equipment, including our ASU and ASB. 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<sup>®</sup> system, and there are relatively few alternative sources of supply available. We generally carry at least 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 new integrated mapping system, ORLab<sup>™</sup>. Under the terms of the agreement, we are obligated to certain minimum purchase commitments during through 2009.

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 an 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;



## **Table of Contents**

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. In December 2004, Stellartech, the manufacturer of our ASU and ASB, was inspected by the FDA as part of a not-for-cause, general QSR inspection. The FDA issued a notice with three observations requiring responses. Stellartech addressed those observations and sent their responses to the FDA.

In June 2006, the FDA conducted a Bioresearch Monitoring Inspection of the conduct of our FDA-regulated clinical trials and a Quality Systems Inspection of the manufacture of our products. We were notified that these inspections were part of a for-cause inspection. At the close of the inspections and in subsequent communications, the FDA advised us that it would not be issuing us a Form 483 documenting formal inspectional observations. We received a final Establishment Inspection Report from the FDA on November 9, 2006. The report included two recommendations for continuous improvements, which were brought to our attention during the inspection and were implemented and reviewed by the close of the inspection.

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 we do not expect that such compliance will have a material impact on our business.

We are currently increasing our manufacturing capabilities as our business grows and as we introduce and obtain approvals for new products. Manufacturers can experience difficulties in significantly scaling up production capacities, which may include problems with capacity, production yields and quality control. If we are unable to manufacture our products to keep up with demand, we may not meet expectations for growth of our business.

## **Product Development**

Our product development group develops product enhancements and new products to address unmet procedural and market needs with the goal of increasing revenues 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. Product extensions and improvements of our Isolator<sup>®</sup> system include the 2007 releases of our Isolator Synergy<sup>™</sup> clamps and our ASB. Product extensions and improvements of our multifunctional bipolar pen include the development of our Coolrail<sup>™</sup> Linear Ablation Pen, which we plan to release during the first half of 2008 and we believe will be adopted by physicians to create an expanded lesion set during minimally invasive procedures. Enabling devices, such as our multifunctional pen and our Lumitip<sup>™</sup> dissector are becoming an increasingly larger portion of our development portfolio and revenues. Examples of devices which extend our product line into new markets include the development of the AtriCure Left Atrial Appendage Exclusion System. Our product lines have also been advanced through software improvements, cost savings and support for increased production capacity.

The Cleveland Clinic Foundation and Case Western Reserve University and collaborating businesses, including us, received publicly announced grants from the State of Ohio for, among other things, the creation of the Atrial Fibrillation Innovation Center. Pursuant to the terms of the agreement, effective as of June 2005, we are required to supply personnel and materials to accomplish certain research-related activities in connection with the grant and, over a three and one-half-year period, we will receive up to a total of \$0.9 million for personnel and materials and The Cleveland Clinic will acquire up to \$2.4 million in capital equipment for our use in support of our performance of the agreement. Over the same period, we are required to expend up to \$7.7 million for operating expenses and up to \$4.8 million for capital expenditures in support of the agreement. We believe these represent ordinary course expenditures that we would have otherwise anticipated making. Through December 31, 2007, we have earned \$0.6 million under the grant in support of operating expenses and \$1.3 million in acquired capital equipment. The agreement terminates in December 2008, however it may be terminated at any time by either party by giving 30 days' prior written notice.

---

## **Table of Contents**

In November 2003, we entered into a license and related agreements with the Cleveland Clinic and a third party engineering company for the development of the AtriCure Left Atrial Appendage Exclusion system. Under this arrangement, we granted 33,157 options at fair market value to each of the Cleveland Clinic and the engineering company upon satisfaction of a milestone tied to the technical feasibility and commercial viability of the licensed intellectual property, in addition to payment of royalties to each of the Cleveland Clinic and the engineering company equal to 2.5% of net sales of any commercialized products using the licensed technology. During 2007, 13,157 of the 33,157 options each expired and were not exercised by either party. As of December 31, 2007, 20,000 options each were outstanding with an exercise price of \$13.95 per share.

### **Consulting Relationships**

We have developed consulting relationships with a number of leading scientists and doctors 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. We typically enter into a written agreement with the consultant pursuant to which the consultant is obligated to provide services such as advising us as to the design and development of our products, educating doctors on the FDA-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 are generally for a term of one year and may generally be terminated by us or by the consultant upon written notice. We own the rights to any inventions or ideas made or conceived by our consultants during performance of the consulting services.

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.

We entered into a Consulting Agreement, dated as of January 1, 2007, with Michael D. Hooven, our Co-Founder and also one of our directors. Under the terms of the agreement, Mr. Hooven provided consulting services and advice to us with respect to the creation and development of new products and product platforms relating to cardiac arrhythmias and the prevention or reduction of strokes using cardiac devices. As consideration for his services and for assigning the rights to certain intellectual property as provided for in the agreement, Mr. Hooven was paid \$12,000 per month. The term of the agreement was one year, with the exception of certain non-compete and non-solicitation provisions which expire on December 31, 2009.

### **Royalty Agreement**

On November 21, 2005, we entered into a Royalty Agreement, effective as of October 1, 2005, with Randall K. Wolf, M.D., the co-inventor of the Lumitip™ dissector. Pursuant to the terms of the agreement, we will pay to Dr. Wolf royalties based on product revenues from sales of the Lumitip™ dissector and certain other inventions, improvements or ideas, at royalty rates which range from 1.5% to 15% of such revenues. During the term of the agreement we are required to pay Dr. Wolf a minimum of \$50,000 in royalties per quarter and up to a maximum aggregate of \$2,000,000 in royalties during the term of the agreement. The agreement terminates on December 31, 2009; however, we and Dr. Wolf each have the right at any time to terminate the agreement immediately for cause. Royalties to Dr. Wolf related to 2007 sales of the Lumitip™ dissector were \$0.2 million.

---

## **Table of Contents**

### **Employees**

As of December 31, 2007, we had approximately 200 full-time employees. None of the employees was represented by a labor union or was covered by a collective bargaining agreement. We have never experienced any employment-related work stoppages and consider our employee relations to be good.

### **Corporate History**

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 given 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<sup>®</sup> clamps, which are an essential part of our Isolator<sup>®</sup> system. Additionally, in December 2005, we formed AtriCure Europe, B.V., our wholly-owned subsidiary incorporated in the Netherlands.

### **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 charter 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**

**We expect to derive a majority of our future revenues from the sale of our Isolator<sup>®</sup> bipolar ablation system. If our Isolator<sup>®</sup> system fails to gain or loses market acceptance for the treatment of AF, we may not generate sufficient revenues to continue our operations.**

Currently, our primary product line is our Isolator<sup>®</sup> bipolar ablation system. We expect that sales of our Isolator<sup>®</sup> system will account for a majority of our revenues for the foreseeable future and that our future revenues will depend on the increasing acceptance by the medical community of our Isolator<sup>®</sup> system as a standard treatment alternative for the surgical treatment of AF during open-heart surgical procedures and as a sole-therapy minimally invasive procedure.

Acceptance of our Isolator<sup>®</sup> system 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 Isolator<sup>®</sup> system. Our Isolator<sup>®</sup> system and the procedures involved with the treatment of AF using our system are relatively new. We cannot assure you that doctors will continue to use our Isolator<sup>®</sup> system or that demand for the surgical treatment of AF will not decline or will not increase as quickly as we expect.

## Table of Contents

We may not be able to maintain or increase market acceptance of our Isolator<sup>®</sup> system for a number of additional reasons, including:

our inability to promote our Isolator<sup>®</sup> system or any of our products for the treatment of AF until we obtain FDA approval;

our inability to train doctors in the use of our Isolator<sup>®</sup> system or any of our products for the treatment of AF until we obtain FDA approval;

our inability to sustain acceptance of our Isolator<sup>®</sup> system and other products within the medical community;

liability risks for doctors and hospitals associated with the off-label use of our Isolator<sup>®</sup> system and the use of new technologies or procedures;

findings or perceptions relating to the safety or effectiveness of our products for the safety or effectiveness of the surgical treatment of AF;

medical device reports to the FDA and foreign regulatory authorities, which are required in the event our products cause or contribute to a death or serious injury, or malfunction in a way that if it were to recur would likely cause or contribute to a death or serious injury;

publicity concerning our products, competing products or the surgical treatment of AF;

the cost of our Isolator<sup>®</sup> system and other products;

the availability of alternative treatments or procedures that may be, or may be perceived as, more effective, safer, faster, easier to use or less costly than our products; and

policies of healthcare payors with respect to coverage and reimbursement.

Since we believe that doctors are using our Isolator<sup>®</sup> system only for the surgical treatment of AF, if doctors do not use our Isolator<sup>®</sup> system and other products to treat AF, we would lose substantially all of our revenues.

**Use of our Isolator<sup>®</sup> system as a sole-therapy minimally invasive treatment for AF, which is not currently a well-established market, represents our major growth opportunity. If this market does not further develop or our Isolator<sup>®</sup> system is not widely adopted for use in this market, it may adversely impact our ability to grow our revenues.**

We believe that sole-therapy minimally invasive surgical treatment for AF, which is not currently a well-established market, will ultimately represent the largest segment of the market for the surgical treatment of AF. If this market fails to further develop, or if our Isolator<sup>®</sup> system is not widely adopted for use in this market, it may adversely impact our ability to grow our revenues. In order to further establish the sole-therapy minimally invasive AF treatment market, doctors treating patients with AF who would not otherwise require an open-heart surgical procedure must change their current practice of referring patients to cardiologists and electrophysiologists and instead refer these patients to cardiothoracic surgeons for surgical AF treatment. Doctors may decide not to change their referral patterns for a variety of reasons including, for example, negative publicity relating to our ongoing clinical studies, including publicity focusing on the doctors and institutions carrying out such clinical studies, that limited clinical data is available relating to the safety and effectiveness of our Isolator<sup>®</sup> system, that clinical testing of our Isolator<sup>®</sup>

system is in an early stage, that doctors who refer their patients to cardiothoracic surgeons may risk losing their patients and that doctors may prefer to treat patients using drugs or catheter-based ablation. If doctors do not refer their patients to cardiothoracic surgeons for surgical AF treatment, we will not be able to further establish a market for the use of our Isolator<sup>®</sup> system for the sole-therapy minimally invasive treatment of AF, and our future growth and revenues will suffer.

---

**Table of Contents**

**The failure to educate or train a sufficient number of doctors in the use of our Isolator® system and related products could reduce the market acceptance of our products and reduce our revenues.**

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 Isolator® system and related products. While we educate and train doctors as to the skills involved in the proper use of our Isolator® system, it is not our policy to educate or train them to use our Isolator® system for the surgical treatment of AF unless and until we obtain FDA approval. Currently, doctors learn to use our Isolator® system for the treatment of AF through independent training programs provided by hospitals and universities and through independent peer-to-peer training among doctors. We provide research and educational grants to institutions, some of which are used to fund programs to teach the procedures involved in the surgical treatment of AF, including the use of our Isolator® system for such treatment. However, while we make doctors generally aware of these programs, these institutions determine the faculty and the content of the programs. We also rely on doctors to independently inform their colleagues about these programs. 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 for adequate training in the use of our Isolator® system.

**Unless we obtain FDA approval, we will not be able to promote our Isolator® system to treat AF and our ability to maintain and grow our business could be harmed.**

Generally, a medical device company must first obtain either FDA clearance through the submission to the FDA of a 510(k) notification or FDA approval through the submission of a pre-market approval application, or PMA, before a company may market a medical device in the United States. Certain modifications to a previously marketed device, including a proposed new use or new indication for the device, also require the submission to the FDA of either a 510(k) or PMA before such device with the modifications may be marketed. The process of obtaining these clearances and approvals can be lengthy and expensive. The PMA process is more costly, lengthy and uncertain than the 510(k) process and requires that the device be found to be safe and effective and must be supported by extensive data, including data from preclinical studies and human clinical trials. Though less likely, a 510(k) application may require human clinical trials as well. Because we cannot assure you that any new products, or any product enhancements, that we develop will be subject to the shorter 510(k) clearance process, significant delays in the introduction of any new products or product enhancement may occur.

We have not received FDA clearance or approval to promote our Isolator® system or other products for the treatment of AF and until July of 2007, we were unable to promote our Isolator® system for the ablation of cardiac tissue. Although our Isolator® system and Pen have cardiac tissue ablation clearance, we still need to obtain separate approvals from the FDA for use of our products in the treatment of AF as part of an open-heart procedure and as a sole-therapy minimally invasive procedure through the submission of separate PMAs to the FDA. 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 Isolator® system or other 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 Isolator® system or other products will be granted or that current or future clearances or approvals of our system 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 we are able to complete the clinical trials required to support future submissions to the FDA, and unless the data generated by such trials supports the use of our Isolator® system and other products for the treatment of AF as safe and effective, 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 Isolator® system and other products for the treatment of AF, we will need to demonstrate in clinical trials that our products are safe and effective for such use. In order to

---

**Table of Contents**

conduct clinical trials, it is necessary to receive an investigational device exemption, or IDE, from the FDA. While we have obtained the required IDE from the FDA for the conduct of clinical trials for the use of our Isolator<sup>®</sup> system as a treatment for AF during open-heart surgical procedures in support of our ABLATE trial, the FDA or institutional review boards, or IRBs, that also oversee the trials for the purpose of protecting the study subjects can halt clinical trials at any time for safety reasons or because we or any of our clinical investigators do not follow the FDA's requirements for conducting clinical trials. In addition, the FDA may modify its requirements with respect to various aspects of our clinical study, in which case our ongoing clinical trial may not be achievable. Moreover, future clinical trials of our Isolator<sup>®</sup> system to treat AF as a sole-therapy minimally invasive procedure will likely proceed in phases beginning with a further feasibility trial. The FDA has granted us an IDE to conduct a feasibility and efficacy study relating to the use of our Isolator<sup>®</sup> clamps for the sole-therapy minimally invasive treatment of AF, but there is no guarantee that the FDA will grant us approval to conduct broader clinical trials. If we are unable to receive approval to conduct broader clinical trials or the trials are halted by the FDA or others, we would not be able to promote our Isolator<sup>®</sup> system for use in the treatment of AF in the United States.

Since 2004, we have been conducting the RESTORE-SR trial, a clinical trial to support the submission of our PMA seeking FDA approval to use our Isolator<sup>®</sup> system for the treatment of AF during elective open-heart procedures and enrollment in the trial was slower than expected. As of March 15, 2007, we had enrolled 39 treatment arm patients and only 5 control arm patients required for this multicenter, 226-patient clinical trial (113 patients in each arm). During 2007, we discontinued enrolling new patients in the trial, and the trial is currently during its final close-out stages. The results from this trial were used in support of the cardiac clearance we obtained from the FDA in July 2007 for our Isolator<sup>®</sup> system. During 2007, we worked with the FDA to redesign the RESTORE-SR trial and filed a new IDE and began enrollment into our redesigned open-heart trial for the treatment of patients with permanent AF, ABLATE. As with the current RESTORE-SR trial, we cannot assure you that our ABLATE clinical trial will be completed in a timely manner or successfully or that the results obtained will be acceptable to the FDA.

As of May 31, 2006, we completed enrollment in our RESTORE-SR II study, a clinical study to evaluate the feasibility of using our Isolator<sup>®</sup> clamps as a sole-therapy minimally invasive treatment for AF. This study enrolled 25 patients at 5 leading US centers. During 2007, we worked with our investigators to write a clinical report to the FDA and utilized this clinical data in support of adding a new arm to the study, RESTORE-SR IIB. In RESTORE-SR IIB, we intend to study patients experiencing persistent and permanent AF using our Isolator Synergy<sup>™</sup> system. We anticipate beginning patient enrollment during the later part of 2008. We can not assure you that this study will be completed in a timely manner or successfully or that the results obtained will be acceptable to the FDA.

In 2006, the FDA conducted an inspection of one of the lead investigators of our Restore-SR II clinical study and identified a number of adverse observations concerning his compliance with good clinical practice requirements. The FDA has found no deficiencies at the conclusion of a subsequent related inspection of AtriCure. However, we cannot assure you that the FDA's inspections will not effect subsequent FDA review of the data from that study or that other issues with the FDA will arise in the future as a result of this inspection.

Clinical trials and regulatory approval of our Isolator<sup>®</sup> system and other products for the treatment of AF can take a number of years to accomplish and require the expenditure of substantial financial, managerial and other resources, and we may never obtain regulatory approval for the use of our Isolator<sup>®</sup> system to treat AF in either an open-heart procedure or a sole-therapy minimally invasive procedure. The FDA may not grant approval to use our Isolator<sup>®</sup> system or other products for the treatment of AF in all types of patients that experience AF, if any, or could limit the type of AF that could be treated using our products. If we do not secure required FDA approval to promote our Isolator<sup>®</sup> system for either or both types of procedures, our business, results of operations and prospects would be negatively affected as a result.

Further, we cannot make comparative claims regarding the use of our Isolator<sup>®</sup> system against any alternative treatments without conducting comparative clinical studies, which would be expensive and time

---

## **Table of Contents**

consuming. We do not have any current plans to conduct such comparative clinical studies to evaluate our Isolator<sup>®</sup> system against any alternative method of treatment.

If the available data on the use of our Isolator<sup>®</sup> system from clinical trials and marketing experience does not establish the safety or effectiveness of our system, our clinical trials may be halted, our system may be withdrawn from the market and we may be prohibited from further distribution and sale of our system.

If the results obtained from our clinical trials, any other clinical studies, or clinical or commercial experience indicate that our Isolator<sup>®</sup> system is not safe or effective, or not as safe or effective as other treatment options, the FDA may not approve our system for the treatment of AF, adoption of the use of our system 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 published in December 2005 and February 2006 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, and concerns that certain of our consultants who are involved with clinical studies of and the publication of articles concerning our products failed to adequately disclose their financial relationships with us. Because these articles relate to the validity of important clinical data on the use of our Isolator<sup>®</sup> system and involve a prominent surgeon and two of the pioneering institutions which have been proponents and investigators of our system, some current and potential customers have been and may continue to be reluctant to purchase our products. We also believe that this publicity has had and may continue to have a negative impact on clinical studies involving our Isolator<sup>®</sup> system. We cannot assure you that this publicity or similar unfavorable publicity will not adversely impact future clinical studies involving our products or adversely impact our current or future submissions to the FDA. We believe that this publicity has had and may continue to have a negative impact on our business, results of operations, financial condition and stock price. We also believe that future unfavorable publicity could cause other adverse effects, including a further 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 Isolator<sup>®</sup> system and other products in the treatment of AF, which is considered an off-label use of our system because the indication for which our system has received FDA clearance is the ablation of cardiac tissue in July of 2007 and prior to that time, our system was cleared for the coagulation of soft tissues during certain non-cardiac-related surgical procedures, except that our multifunctional pen was cleared for the ablation of cardiac tissue and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. Under the Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products, including our Isolator<sup>®</sup> system, for off-label uses. This means that prior to July 2007, we could not make claims about the safety or effectiveness of our Isolator<sup>®</sup> system for the ablation of cardiac tissue, and after July 2007, we can 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.

Due to these constraints, our sales and marketing efforts focus only on the general technical attributes and benefits of our Isolator<sup>®</sup> system and products and not on the use of our products for AF treatment. At the same time, we provide certain support for the use of our Isolator<sup>®</sup> system and our multifunctional pen in the treatment of AF that we believe is non-promotional and therefore permitted. In particular, since our Isolator<sup>®</sup> system is only being used by doctors for the treatment of AF, we train our sales force on the use of our system by

---

**Table of Contents**

cardiothoracic surgeons to treat AF, and off-label sales are included in our sales force compensation structure. Sales personnel call on cardiothoracic surgeons, electrophysiologists, and other doctors to discuss the general attributes of our Isolator<sup>®</sup> system and other products and respond in a non-promotional manner to unsolicited requests for information from doctors on the use of our system in the treatment of AF by providing copies of and citations to peer-reviewed journal articles and/or other training and instructional tools. In addition, medically trained clinical application specialists attend surgical procedures to discuss the general attributes of our Isolator<sup>®</sup> system and products and respond to unsolicited requests for information on the use of our products for the treatment of AF. We have entered into consulting agreements with prominent cardiothoracic surgeons and electrophysiologists who assist us with, among other things, product development and clinical development. In addition, we provide financial support in the form of research and educational grants to several leading institutions in the cardiac field, which they may use to conduct physician training programs, including programs relating to the surgical treatment of AF using our products. We also provide some guidance to physicians and medical institutions regarding what physicians are available and qualified for training other physicians on the use of our products in the treatment of AF. We also continue to make improvements in our Isolator<sup>®</sup> system and other products which could be viewed as supporting the treatment of AF.

There is a material risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of these activities constitute the promotion of our Isolator<sup>®</sup> system and other 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.

Government investigations concerning the promotion of off-label uses and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and would likely be required to change substantially our sales, promotion, grant and educational activities. For example, in November 2004, we received a letter from the FDA relating to certain cardiac-related information on our website in connection with our Isolator<sup>®</sup> clamps, which information we subsequently removed. There is also a possibility that we could be enjoined from making sales of our Isolator<sup>®</sup> system and other products for any non-FDA-approved use, which effectively would bar all sales of our products until we receive FDA clearances or approval, if ever. In addition, 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.

**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' business.**

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 Isolator<sup>®</sup> system and other products were used. Although our manufacturing processes and those of our suppliers are required to comply with the FDA's quality system regulations, or QSR, covering the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products, 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 liability

---

## **Table of Contents**

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 volunteers, injury to our reputation and loss of revenue. Any of these events could negatively affect our earnings and financial condition.

### **Our current inability to educate or train doctors in the use of our Isolator<sup>®</sup> system and other products for the treatment of AF, due to legal prohibitions on off-label promotion of medical devices, could result in injuries to patients or other adverse events that lead to litigation against us, which could be costly to our business.**

Our sales team educates doctors in the technology and general application of our products, but it is our policy not to educate or train doctors to use our system for the surgical treatment of AF. Hospitals and universities offer independent educational programs for the treatment of AF utilizing our Isolator<sup>®</sup> system and other products, and there is independent doctor-to-doctor training to use our system for the treatment of AF. We do not require that doctors who use our Isolator<sup>®</sup> system have any specific training in the use of our system. We cannot assure you that doctors utilizing our products are using them correctly. Because we rely on training by hospitals and universities and doctor-to-doctor training, we do not control the quality of the training received by the doctors who use our Isolator<sup>®</sup> system and other products. Not requiring training on the use of our products may expose us to greater risk of product liability for injuries occurring during procedures utilizing our system. If demand for our Isolator<sup>®</sup> system and other products grows, the increased number of procedures performed using our products may potentially lead to more injuries and an increased risk of product liability. In addition, the off-label use of our Isolator<sup>®</sup> system and other products by doctors may expose us to greater risks relating to product liability claims.

### **Serious complications arising out of surgical procedures for the treatment of AF, including surgical AF treatments involving our Isolator<sup>®</sup> system and other products could harm our business in a variety of important ways.**

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 Isolator<sup>®</sup> system was used. The rate of serious complications associated with surgical AF treatments in general, or surgical AF treatments involving the use of our Isolator<sup>®</sup> system in particular, may be greater than the rate of serious complications associated with alternative therapies for the treatment of AF or AF itself.

Adverse outcomes, or the perception that surgical AF treatments, including treatments involving the use of our Isolator<sup>®</sup> system, are not safe, could harm our business, including in the following ways:

our Isolator<sup>®</sup> system or other products may fail to gain or may lose market acceptance;

the market for the sole-therapy minimally invasive treatment of AF may fail to further develop;

the medical community may fail to further adopt our Isolator<sup>®</sup> system for the sole-therapy minimally invasive treatment of AF;

the FDA or foreign regulatory authorities may revoke the clearances or approvals they have granted for the use of our Isolator<sup>®</sup> system for the ablation of cardiac tissue;

the FDA or foreign regulatory authorities may refuse, delay or revoke clearances, approvals or clinical trials of our Isolator<sup>®</sup> system for the treatment of AF; and

the FDA or other domestic or foreign regulatory or enforcement authorities may be more likely than otherwise to pursue an action against us for promoting our products for off-label uses.

The significance of each of these identified risks is discussed elsewhere under the caption Risks Relating to Our Business.



---

**Table of Contents**

**Competition from existing and new products and procedures may decrease our market share and cause our revenues 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 other participants. We cannot assure you that the our Isolator<sup>®</sup> system and other products will compete effectively against drugs, catheter-based ablation, implantable devices such as pacemakers or defibrillators, other ablation systems or other surgical AF treatments, which may be more well-established among doctors and hospitals. Many companies are promoting devices for the treatment of AF, and we anticipate that new or existing competitors may develop competing products, procedures 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. Our primary competitors include Medtronic, Inc., St. Jude Medical Inc., Medical CV and CryoCath Technologies Inc. These companies may enjoy competitive advantages, including:

broader product offerings;

established and more comprehensive distribution networks;

less expensive products and procedures that take less time to perform;

greater resources, including financial resources and more extensive experience in product development, manufacturing, regulatory clearance and approval, promotion, distribution and selling and patent litigation; and

established relationships with hospitals, healthcare providers and payors.

Some competitors have FDA clearance for the use of their products to ablate cardiac tissue. Some of our competitors are currently conducting clinical trials for the use of their products in the treatment of AF, which if successful, may impact the future sales and demand for Isolator<sup>™</sup> system and other products could be diminished by equivalent or superior products and technologies being offered by competitors, including products utilizing bipolar technology which could prove to be more effective, faster, safer or less costly than our Isolator<sup>®</sup> clamps. The introduction of new products, procedures or clinical solutions by competitors 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 entered into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, investigators and advisors, such agreements 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.

## **Table of Contents**

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

**The medical device industry is characterized by patent litigation 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. The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights.**

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. Any of these events could negatively affect our earnings and financial condition.

Our competitors or others may assert that our Isolator<sup>®</sup> system or the methods employed in the use of our system infringes on United States or foreign patents held by them. This risk is exacerbated by the fact that there are numerous issued and pending patents relating to surgical ablation, the surgical treatment of AF and other surgical devices. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our Isolator<sup>®</sup> system or other products may infringe. There could also be existing patents of which we are unaware that one or more of our products may inadvertently infringe. As the number of competitors in the market for the treatment of AF increases, the possibility of inadvertent patent infringement by us or a patent infringement claim against us increases.

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 Isolator<sup>®</sup> system or other 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.

**We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.**

Many of our employees were previously employed at other medical device companies. Although there are no claims currently pending against us, we may be subject to future claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research or sales personnel or their work product could hamper or prevent our ability to improve our products or sell our existing products, which would harm our business.

---

**Table of Contents**

**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 Isolator® system or other 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 Isolator® system or other products due to the cost or unavailability of insurance coverage.

**We have a limited history of operations and a history of net losses available to common stockholders and we may never become profitable.**

We have a limited operating history and have incurred net losses each year since our inception, including net losses available to common stockholders of \$11.3 million in 2007, \$13.7 million in 2006, \$12.7 million in 2005, \$9.5 million in 2004 and \$7.1 million in 2003. As of December 31, 2007, we had an accumulated deficit of \$67.3 million.

Our net losses available to common stockholders have resulted principally from costs and expenses relating to sales and promotional efforts, research and development, seeking regulatory clearances and approvals, and general operating expenses. We expect to continue to make substantial expenditures and to incur additional operating losses in the future as we expand our manufacturing, marketing and product development activities, and further develop and commercialize our products, including completing clinical trials and seeking regulatory clearances and approvals for our Isolator® system and other products. If sales of our Isolator® system 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 revenues 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.

**Our federal tax net operating loss carryforwards will be limited or lost, resulting in greater income tax expense 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 the Internal Revenue Code of 1986 that will limit the availability of our net operating loss carryforwards to offset any future taxable income, which may increase our future income tax expense. Our inability to use these net operating loss carryforwards to reduce taxable income is based on an ownership change of more than 50 percentage points under rules contained in the United States Internal Revenue Code. We had federal income tax net operating loss carryforwards of approximately \$39 million at December 31, 2007 that, if not utilized to reduce our taxable income, will begin to expire in 2021.

**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 short-term investments, will be sufficient to meet our projected capital requirements for at least the next 12 months. Our capital requirements will depend on many factors, including:

the revenues generated by sales of our products;

the costs associated with expanding and growing our business;

---

**Table of Contents**

the rate of progress and cost of our research and development activities;

the costs of obtaining and maintaining FDA and other regulatory clearances and approvals of, and intellectual property protection for, our products and products in development;

the effects of competing technological and market developments; and

the number and timing of acquisitions and other strategic transactions.

As a result of these factors, we may need to raise additional funds, and 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 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.

**If we are unable to manage the anticipated growth of our business, our future revenues and operating results may be adversely affected and our growth could be limited.**

The growth that we may experience in the future may require us to rapidly expand our personnel and manufacturing operations. As of December 31, 2007, we had approximately 200 employees. Rapid expansion in personnel could result in unanticipated costs and disruptions to our operations. Organizational growth could strain our existing managerial, operational, financial and other resources. We may need to expand our current, or implement new, financial and operating systems, which could be costly and time-consuming. For us to maintain and expand our business successfully, we or a third party must manufacture commercial quantities of our Isolator<sup>®</sup> system's and components, as well as components for other existing and future products, in compliance with regulatory requirements, including the FDA's Quality System Regulation, or QSR, at an acceptable cost and on a timely basis. Our anticipated growth may strain our or a third party's ability to manufacture an increasingly large variety and supply of our products. Manufacturing facilities often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. If we cannot scale and manage our business or our manufacturing operations appropriately, maintain control over expenses or otherwise adapt to future growth, our growth may be impaired and our future revenues and operating results will suffer.

**We depend upon single and limited source third-party suppliers, 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 Isolator<sup>®</sup> system and other products. For example, we rely on one vendor to manufacture our ASU and ASB, and we have not been able to identify any alternate supplier to manufacture our ASU or ASB if our current supplier becomes unable to do so. 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.

Our reliance on these 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 Isolator<sup>®</sup> system or other

products;

---

## **Table of Contents**

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, 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 or materials, 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.

**We recently acquired and transferred to our facilities the manufacturing of the Frigitronics® CCS-200 product line for cardiac cryoablation. Our inability to efficiently and effectively manufacture this product line could negatively affect the sale of these products and other products we sell, as well as result in the potential impairment of goodwill and intangible assets.**

In August 2007, we purchased the Frigitronics® CCS-200 product line for cardiac cryoablation for \$3.7 million. We initially recorded \$2.9 million in goodwill and \$0.3 million in amortizable intangible assets. Prior to the acquisition, we had distributed this product line, which uses cryotherapy, or extreme cold, to make specialized ablations during concomitant open-heart procedures for the treatment of AF. In December 2007, we transferred the manufacturing for the product line, which includes a generator and a line of reusable probes, to our manufacturing facilities in West Chester, Ohio. If we are unable to effectively or efficiently manufacture the acquired product line, or if we experience quality issues as we manufacture the product line, it could negatively affect our revenues and operating results for this product line, as well as our other products, as these products are often used during open-heart procedures when our Isolator® system is used. Further, if our sales and operating results specific to these products are negatively affected, we may be required to record an impairment of the required goodwill and intangible assets, which would further negatively affect our results of operations.

**If the value of our goodwill becomes impaired, it could materially reduce the value of our assets and reduce our net income for the year in which the write-off occurs.**

As of December 31, 2007, we had \$6.8 million in goodwill recorded, which represents the excess purchase price we paid for the purchase of Enable and the Frigitronics® product line in excess of the fair value of the net assets we acquired. We recorded \$3.9 million in goodwill related to our acquisition of Enable and \$2.9 million related to our acquisition of the Frigitronics® product line. The Financial Accounting Standards Board's (FASB) Statement of Financial Accounting Standards (SFAS) No. 142, Goodwill and Other Intangible Assets, requires that goodwill be tested at least annually (absent any impairment indicators). The testing includes comparing the fair value of each reporting unit with its carrying value. Fair value is determined using discounted cash flows, market multiples and market capitalization. Impairment adjustments, if any, are required to be recognized as operating expenses. We may have future impairment adjustments to our recorded goodwill. We performed an impairment test of our goodwill as of September 30, 2007 and concluded no impairment existed. Any finding that the value of our goodwill has been impaired would require us to write-off the impaired portion, which could materially reduce the value of our assets and reduce our net income for the year in which the write-off occurs.

**An inability to forecast future revenues 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 determine to maintain excess inventory of our products or component parts. Managing our inventory levels is important to our cash position and results of operations. As

---

**Table of Contents**

we expand, managing our inventory levels becomes more difficult, particularly as we expand into new product areas and bring product enhancements to market. An excessive amount of inventory reduces our cash available for operations and may result in excess or obsolete materials. Inadequate inventory levels may make it difficult for us to meet customer product demand, resulting in decreased revenues. An inability to forecast future revenues or estimated life cycles of products may result in inventory-related charges that would negatively affect our gross margins and results of operations.

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

Our manufacturing facility and the manufacturing facility of any of our third-party component manufacturers, critical suppliers or third-party sterilization facility are required to comply with the FDA's quality systems regulations, 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<sup>®</sup> system and other products that we sell. The FDA may enforce its QSR, among other ways, through periodic unannounced inspections. If our manufacturing facility or the manufacturing facility of any of our third-party component manufacturers, critical suppliers or third-party sterilization facility, fails a QSR inspection, our and their operations could be disrupted, and manufacturing interrupted. Failure to take adequate and timely corrective action in response to an adverse QSR inspection could force a shutdown of our manufacturing operations or a recall of our products. Adverse QSR inspections could delay FDA approval of our Isolator<sup>®</sup> system and could have an adverse effect on our production, sales and profitability. We and any of our third party vendors may also encounter other problems during manufacturing including failure to follow specific protocols and procedures, equipment malfunction and environmental factors, any of which could delay or impede our ability to meet demand. The manufacture of our product also subjects us to risks that could harm our business, including problems relating to the sterilization of our products or facilities and errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products. Any interruption or delay in the manufacturer 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;

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;

premarket clearance or approval;

record keeping and document retention procedures;

37

**Table of Contents**

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.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

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

repair, replacement, refunds, recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

refusing or delaying our pending 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.

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. From January 1, 2007 through February 29, 2008, we have submitted a total of fourteen medical device reports to the FDA involving our products, including two 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 surgical 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 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 Isolator<sup>®</sup> system and other products may require new clearances or approvals or require us to cease promoting or to recall the modified products until such clearance or approvals are obtained.**

## Edgar Filing: AtriCure, Inc. - Form 10-K/A

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 previously made modifications to our Isolator<sup>®</sup> system and other products but do not believe such modifications require us to submit an additional

## **Table of Contents**

510(k) clearance. The FDA may not agree with our decisions regarding whether new clearances or approvals are required. 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;

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;

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

---

**Table of Contents**

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.

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

**If doctors or hospitals were to receive inadequate levels of reimbursement for surgical AF treatments using our Isolator® system and other products from governmental or other third-party payors, it could affect the adoption or use of our products and may cause our revenues to decline.**

Widespread adoption or use of our Isolator® system by the medical community is unlikely to occur if doctors and hospitals do not receive sufficient reimbursement from payors for surgical treatment of AF using our products. Currently, hospitals do not receive any additional reimbursement from the fee-for-service Medicare program, which is administered by the Centers for Medicare and Medicaid Services, or CMS, for the cost of AF treatment, or for the cost of our Isolator® system, as part of an open-heart procedure. However, doctors performing AF treatment during an open-heart surgical procedure are eligible to receive separate reimbursement for performing these AF treatments. Sole-therapy minimally invasive AF treatment does qualify for reimbursement from the fee-for-service Medicare program allowing both doctors and hospitals to receive reimbursement for this type of AF treatment. In addition, the Medicare program has already adopted specific hospital inpatient treatment codes describing AF treatment by ablation in sole-therapy minimally invasive procedures such as that provided through the use of our Isolator® system.

On January 1, 2007, several new CPT codes for sole-therapy surgical ablation procedures were published by the American Medical Association (AMA) in the CPT coding book for 2007. The "one-size fits all" maze CPT code was deleted effective December 31, 2006. In its place, surgeons now have the choice of five different CPT codes for sole-therapy ablation procedures. These limited CPT choices are expected to reimburse physicians less than the "one-size fits all" CPT code of 2006 for sole-therapy procedures. For open-heart concomitant ablation procedures, the AMA recommended use of the miscellaneous CPT code. Although we do not believe that this change in CPT coding for 2007 had a material affect on our open-heart product revenues, we do believe that it negatively affected reimbursement for open-heart concomitant procedures and consequently demand for our products. Effective January 1, 2008, three new CPT codes were created for physician reimbursement for ablation during open-heart concomitant procedures.

---

## **Table of Contents**

Many private payors look to CMS as a guideline in setting their reimbursement policies and amounts. If CMS or other agencies decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payors. Additionally, some private payors do not follow the Medicare guidelines and those payors may reimburse only a portion of the cost of AF treatment or not at all. Furthermore, for some governmental payors, such as the Medicaid program, reimbursement differs from state to state, and some state Medicaid programs may not reimburse for our procedure in an adequate amount, if at all.

We are unable to predict all changes to the coverage or reimbursement methodologies that will be employed by private or governmental third-party payors. We cannot be certain that under prospective payment systems and applicable fee schedules, such as those used by CMS and by many private healthcare payors, the cost of the procedures utilizing our Isolator<sup>®</sup> system will be adequately reimbursed or that it will receive reimbursement consistent with historical levels or at all. Any denial of private or governmental third-party payor coverage or inadequate reimbursement for procedures performed using our Isolator<sup>®</sup> system could harm our business and reduce our revenue.

### **Adverse changes in payors policies toward coverage and reimbursement for surgical AF treatment would harm our ability to promote and sell our Isolator<sup>®</sup> 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 Isolator<sup>®</sup> system and other 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 Isolator<sup>®</sup> system and other products. Alternatively, government or private payors may deem the treatment of AF utilizing our Isolator<sup>®</sup> system 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 Isolator<sup>®</sup> system and other 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.**

Our success depends upon the increasing acceptance of our Isolator<sup>®</sup> system by the medical community as safe and effective in the treatment of AF. Serious complications, including death, have been encountered in connection with the surgical treatment of AF, including in connection with a limited number procedures in which our Isolator<sup>®</sup> system and other products were used. Important factors upon which the efficacy of our Isolator<sup>®</sup> system will be measured include long-term data on the number of patients that continue to experience AF following treatment with our system and the number of patients that have serious complications resulting from AF treatment using our system. Our clinical trials may produce limited data regarding the efficacy of our Isolator<sup>®</sup> system 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 or to the FDA, because it may not be scientifically meaningful and may not demonstrate that our Isolator<sup>®</sup> system is an attractive procedure when compared against data from alternative procedures and products. In addition, the long-term effects of ablation system procedures are not known.

The results of short-term clinical experience of our Isolator<sup>®</sup> system do not necessarily predict long-term clinical benefit. If the long-term clinical trial results are not as positive as the short-term results or the long-term results do not otherwise meet doctors expectations, the FDA may not approve our Isolator<sup>®</sup> system or other

---

## **Table of Contents**

products for the treatment of AF, our products may not become widely adopted, and doctors may recommend alternative treatments for their patients. Another significant factor is acute safety data on complications that occur during the surgical treatment of AF.

If the results obtained from our clinical studies or clinical or commercial experience indicate that our Isolator<sup>®</sup> system and other products are not safe or effective, or not as safe or effective as other treatment options or than current short-term data would suggest, the FDA may not approve our Isolator<sup>®</sup> system or other 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.

Even if we believe the data collected from clinical studies or clinical experience indicates positive results, each doctor's actual experience with our Isolator<sup>®</sup> system may vary. Clinical studies conducted with our Isolator<sup>®</sup> system have involved procedures performed by doctors who are technically proficient. Consequently, both short- and long-term results reported in these studies may be significantly more favorable than typical results of practicing doctors, which could negatively impact the rate of adoption of our Isolator<sup>®</sup> system and other products.

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

During the twelve months ended December 31, 2007, 14% of our total revenues were attributable to sales in markets outside of the United States. This increased from 11% of our revenues for 2006. We primarily depend on third-party distributors to sell our Isolator<sup>®</sup> system and other products outside of the United States, and if these distributors underperform, we may be unable to increase or maintain our level of international revenues. During 2007, we began to build a direct sales force to market to customers in Germany and Austria. Over the long term, we intend to continue to grow our business outside of the United States, and to do so we will need to attract additional distributors or hire direct sales personnel to expand the territories in which we sell our products. Distributors may not commit the necessary resources to promote and sell our products to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, we may not realize expected long-term growth in international revenues.

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 or our distributors' failure 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, our ability to conduct our international operations could be limited and the 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:

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;

potentially adverse tax consequences, tariffs and other trade barriers;

the need to hire additional personnel to promote our Isolator<sup>®</sup> system outside of the United States;

international terrorism and anti-American sentiment;

---

**Table of Contents**

fluctuations in exchange rates for future sales denominated in foreign currency, which represent a majority of our sales outside of the United States; and

difficulty in obtaining and enforcing intellectual property rights.

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

**If coverage and adequate levels of reimbursement from governmental and third-party payors outside of the United States are not attained and maintained, sales of our Isolator<sup>®</sup> system and other products outside of the United States may decrease and we may fail to achieve or maintain significant sales outside of the United States.**

Our revenues generated from sales outside of the United States are also dependent upon the availability of coverage and reimbursement within prevailing foreign healthcare payment systems. In general, foreign healthcare payors do not provide reimbursement for sole-therapy minimally invasive procedures utilizing ablation devices such as our Isolator<sup>®</sup> system. In addition, healthcare cost containment efforts similar to those we face in the United States are prevalent in many of the other countries in which we sell our Isolator<sup>®</sup> system, and these efforts are expected to continue. To the extent that use of an ablation device such as our Isolator<sup>®</sup> clamps have historically received reimbursement under a foreign healthcare payment system, if any, such reimbursement has typically been significantly less than the reimbursement provided in the United States. If coverage and adequate levels of reimbursement from governmental and third-party payors outside of the United States are not attained and maintained, sales of our Isolator<sup>®</sup> system and other products outside of the United States may decrease and we may fail to achieve or maintain significant sales outside of the United States.

**If we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or to successfully integrate them in a cost-effective and non-disruptive manner.**

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and technologies. Accordingly, we may in the future pursue the acquisition of, or joint ventures relating to, complementary businesses, products or technologies instead of developing them ourselves. We do not know if we will be able to successfully complete any acquisitions or joint ventures, or future acquisitions or joint ventures, or whether we will be able to successfully integrate any acquired business, product or technology or retain any key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we are unable to integrate any acquired businesses, products or technologies effectively, our business will suffer. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses.

**The outcome of litigation in which we have been named as a defendant, including class action shareholder lawsuits, is unpredictable and an adverse decision in any such matter could have a material adverse affect on our financial position and results of operations.**

We, along with certain of our current and former officers, were named defendants in purported securities class action lawsuits filed in the United States District Court for the Southern District of New York. The plaintiffs allege violations of the federal securities laws and seek damages on behalf of purchasers of our common stock during the period from our initial public offering in August 2005 through February 16, 2006. These proceedings have resulted, and are expected to continue to result, in a diversion of management's attention and resources and in significant professional fees. These professional fees have increased, and in the near term may continue to increase our cash needs.

We have certain obligations to indemnify our officers and directors and to advance expenses to such officers and directors. Although we have purchased liability insurance for our directors and officers, if our insurance

---

## **Table of Contents**

carriers should deny coverage for all or a portion of the amount to be paid, or if the indemnification costs exceed the insurance coverage, we may be forced to bear some or all of these indemnification costs directly, which could be substantial and may have an adverse effect on our business, financial condition, results of operations and cash flows. If the cost of our liability insurance increases significantly, or if this insurance becomes unavailable, we may not be able to maintain or increase our levels of insurance coverage for our directors and officers, which could make it difficult to attract or retain qualified directors and officers.

We are not able to estimate the amount of any damages that may arise from these legal proceedings and the internal efforts associated with defending ourselves and current or former officers. If we are unsuccessful in defending ourselves, these lawsuits could adversely affect our business, financial condition, results of operations and cash flows as a result of the damages that we would be required to pay. It is possible that our insurance policies either may not cover potential claims of this type or may not be adequate to indemnify us for all liability that may be imposed. While we believe that the allegations and claims made in these lawsuits are wholly without merit and intend to defend these actions vigorously, we cannot be certain that we will be successful in any or all of these actions.

These claims, as well as any others, may divert financial and management resources that could otherwise be used to benefit our operations. Although we believe that we have meritorious defenses to the claims, no assurances can be given that the results of these matters will be favorable to us. An adverse resolution of any lawsuits could have a material adverse effect on our financial position and results of operations. Concerns with respect to the circumstances surrounding our pending litigations may have created uncertainty regarding our ability to focus on our business operations and remain competitive with other companies in our industry. Because of this uncertainty, we may have difficulty retaining personnel or replacing personnel who leave us.

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

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

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

## **Table of Contents**

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

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

### **Risks Relating To Our Common Stock**

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

Because we operate within the medical device segment of the healthcare industry, our stock price is likely to be volatile. The market price of our common stock may fluctuate substantially due to a variety of factors, including:

doctor and patient acceptance of the surgical treatment of AF using our Isolator<sup>®</sup> system and other products;

adverse regulatory developments with respect to our products, such as recalls, new regulatory requirements, changes in regulatory requirements or guidance and timing of regulatory clearances and approvals for new products;

coverage and reimbursement determinations for our products and the related procedures;

the timing of orders received;

delays or interruptions in manufacturing or shipping of our products;

pricing of our products;

media reports and publications and announcements about products or new innovations that could compete with our products or about the medical device product segment in general;

market conditions or trends related to the medical device and healthcare industries or the market in general;

additions to or departures of our key personnel;

## Edgar Filing: AtriCure, Inc. - Form 10-K/A

disputes, litigation or other developments relating to proprietary rights, including patents, and our ability to obtain patent protection for our technologies;

changes in financial estimates, investors' perceptions or recommendations by securities analysts;

variations in our quarterly financial and operating results;

changes in accounting principles; and

failure to achieve and maintain an effective internal control environment.

---

**Table of Contents**

These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. For example, we believe that negative publicity in the fourth quarter of 2005 and the first quarter of 2006 caused our stock price to decline.

If our quarterly or annual operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. We believe the quarterly and annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

**The future sale of our common stock could dilute your investment and negatively affect our stock price.**

We had approximately 14.1 million shares of common stock outstanding as of February 29, 2008. If our common stockholders sell substantial amounts of our common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock could fall. The holders of up to 3.9 million shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Furthermore, if we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registration rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock. In addition, we may need to raise capital in the future to fund our operations. If we raise funds by issuing equity securities, our stock price may decline and our existing shareholders may experience significant dilution. Furthermore, we may enter into financing transactions at prices that represent a substantial discount to market price. A negative reaction by investors and securities analysts to any sale of our equity securities could result in a decline in the trading price of our common stock.

**If our principal stockholders, executive officers and directors choose to act together, they may be able to control our management and operations, which may prevent us from taking actions which may be favorable to you.**

As of December 31, 2007, our executive officers, directors and principal stockholders, and entities affiliated with them, beneficially owned in the aggregate approximately 40% of our common stock. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling or significant stockholders. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could have a substantial influence over the determination of the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

## **Table of Contents**

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

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

authorizing the issuance without further approval of blank check preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;

prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates;

limiting the ability to remove directors;

limiting the ability of stockholders to call special meetings of stockholders;

prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of stockholders; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

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

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

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

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

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. These requirements may place a strain on our systems and resources. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight will be required. This may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

47

**Table of Contents****ITEM 2. PROPERTIES**

We maintain our headquarters in West Chester, Ohio in a facility of approximately 12,200 square feet, which contains primarily office space. We currently pay monthly rent of approximately \$11,000 and the lease for this facility expires in May 2009. In addition, we have five separate leases for a total of approximately 31,000 square feet of office, production and warehouse space in West Chester, Ohio, with an aggregate monthly rent of approximately \$19,000 and three of the leases for these facilities expire in 2010 and the other two are renewable annually. We believe that our existing facilities are adequate to meet our immediate needs and that suitable additional space will be available in the future on commercially reasonable terms as needed.

**ITEM 3. LEGAL PROCEEDINGS**

We are not party to any material pending or threatened litigation, except as described below:

*Class Action Lawsuit*

We and certain of our current and former officers were named as defendants in a purported securities class action lawsuit filed in the United States District Court for the Southern District of New York (Levine v. AtriCure, Inc., Case No. 06 CV 14324 (United States District Court for the Southern District of New York)). The suit alleges violations of the federal securities laws and seeks damages on behalf of purchasers of our common stock during the period from our Initial Public Offering in August 2005 through February 16, 2006. We believe that the allegations are without merit and intend to vigorously defend against them. Our motion to dismiss the lawsuit for lack of subject matter jurisdiction was denied in September 2007 and a motion for reconsideration of that denial is pending.

We may from time to time become a party to additional legal proceedings.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

**Executive Officers of the Registrant**

Set forth below is the name, age, position and a brief account of the business experience of each of our executive officers as of February 29, 2008.

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
David J. Drachman	49	<i>President, Chief Executive Officer and Director</i>
Julie A. Piton	36	<i>Vice President, Finance and Administration and Chief Financial Officer</i>
James L. Lucky	46	<i>Vice President, Regulatory Affairs and Quality Assurance</i>
Frederick C. Preiss	57	<i>Vice President, Operations</i>
Salvatore Privitera	41	<i>Vice President, Business Development and Research</i>
Jonathon A. Sherman	58	<i>Vice President, Product Development</i>
Stewart W. Strong	41	<i>Vice President, United States Sales</i>

*David J. Drachman* has served as President, Chief Executive Officer and Director since October 2002. From 2000 to 2002, Mr. Drachman served as President of Impulse Dynamics N.V., a development stage medical device company focusing on implantable electrical solutions for the treatment of heart failure, diabetes and eating disorders. From 1997 to 1999, Mr. Drachman served in a variety of positions, including Vice President of Strategic Development at Biosense Webster, Inc., a Johnson & Johnson, Inc. subsidiary that designs and manufactures diagnostic and therapeutic cardiac catheters. In addition, Mr. Drachman has also served in a variety of positions at Ventritex, Inc. and Boston Scientific Corporation. Mr. Drachman received his B.A. from the University of Louisville and holds North American Society of Pacing and Electrophysiology certification in Electrophysiology, Cardiac Pacing and Defibrillation.

---

**Table of Contents**

*Julie A. Piton, CPA* has served as our Vice President, Finance and Administration and Chief Financial Officer since January 2007. From 1999 to 2007, Ms. Piton held various financial executive positions with School Specialty, Inc., a publicly-held supplier, publisher and manufacturer of educational products to the pre K-12 market, including Vice President of Finance and Investor Relations, Corporate Controller, Vice President Finance and divisional Chief Financial Officer. Prior to joining School Specialty, Ms. Piton held various financial management positions with Sensient Technologies and Schneider National and was a Senior Auditor for Deloitte & Touche LLP. Ms. Piton received her B.A. and her Masters in Business Administration from the University of Wisconsin.

*James L. Lucky* has served as our Vice President, Regulatory Affairs and Quality Assurance since February 2008, having previously served as our Vice President, Quality Assurance and Healthcare Compliance since January 2004. From 1997 to 2004, Mr. Lucky served as Vice President of Quality Assurance and Regulatory Affairs for the medical segment of Teleflex, Inc., a publicly-held designer and manufacturer of specialty engineered devices for various industries. Prior to that position, Mr. Lucky held a number of quality assurance positions in the medical device industry, including at Ethicon Endo-Surgery, Inc., Bristol-Myers Squibb Company and Parker Hannifin Corp. Mr. Lucky received his B.S. from Western Michigan University, his M.S. from North Carolina State University and his Masters in Business Administration from Duke University.

*Frederick C. Preiss* has served as our Vice President, Operations since May 2005. From 2002 to 2005, Mr. Preiss served as Vice President of Operations, OEM of Teleflex Medical, a medical device manufacturer and subsidiary of Teleflex, Inc., a publicly-held designer and manufacturer of specialty engineered devices for various industries. From 1998 to 2002, Mr. Preiss served as Vice President of Operations of Regeneration Technologies, a tissue-based biotechnology company. Prior thereto, from 1971 to 1998, Mr. Preiss held a number of responsible positions relating to operations, manufacturing, engineering and purchasing at various companies, including Wright Medical Technology, United States Surgical Corporation and Cyromedics Inc. Mr. Preiss received his B.S. from the University of New Haven.

*Salvatore Privitera* has served as our Vice President, Business Development and Research since May 2007, previously serving as our Vice President, Product Development since October 2003, and in the same capacity from 2000 to 2001. From 2001 to 2003, Mr. Privitera served as Director of Product Development for Ethicon Endo-Surgery, a developer and manufacturer of minimally invasive surgical instruments. Mr. Privitera has 17 years of medical product development experience and has been associated with the release of over 30 medical devices in the fields of cardiac surgery, laparoscopic general surgery, breast biopsy, and sedation. He is a named inventor on over 25 issued and filed U.S. patents. Mr. Privitera received his B.S. from the University of Buffalo and his Masters in Business Administration from Xavier University.

*Jonathon A. Sherman* has served as our Vice President, Product Development since May 2007, previously serving as our Director of Engineering since October 2005. From 1995 through AtriCure's acquisition of Enable Medical Corporation in August 2005, Mr. Sherman served as Vice President, Engineering for Enable. Mr. Sherman has over 30 years of medical product development experience and has been named inventor on 4 issued and filed U.S. patents. Mr. Sherman received his B.S. from the University of Toledo.

*Stewart W. Strong* has served as our Vice President, United States Sales since June 2007, having previously served as Vice President, Eastern United States Sales, Northeast Area Sales Director and Regional Sales Manager since joining AtriCure in October 2003. Mr. Strong has over 10 years of cardiac and general surgery sales experience. Prior to joining AtriCure, Mr. Strong held sales positions with the Heart Valve Division of Medtronic, Inc. and Johnson and Johnson's Ethicon Endo-Surgery division. Mr. Strong received his B.A. from the University of Connecticut.

**Table of Contents****PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Common Stock Market Price**

Our common stock is traded on the Nasdaq Global Market under the symbol "ATRC". The following table sets forth the high and low closing sales price of our common stock for 2007 and 2006.

	Price Range	
	High	Low
<b>2007</b>		
First Quarter	\$ 13.14	\$ 9.14
Second Quarter	\$ 11.67	\$ 8.44
Third Quarter	\$ 10.98	\$ 8.48
Fourth Quarter	\$ 13.59	\$ 10.57
	Price Range	
	High	Low
<b>2006</b>		
First Quarter	\$ 11.80	\$ 6.96
Second Quarter	\$ 9.37	\$ 6.94
Third Quarter	\$ 7.61	\$ 5.44
Fourth Quarter	\$ 10.86	\$ 6.85

As of February 29, 2008, the closing price of our common stock on the Nasdaq Global Market was \$11.90 per share, and the number of stockholders of record was 80.

**Dividend Policy**

Since our incorporation, we have never declared or paid any dividends on our capital stock. Furthermore, pursuant to our credit facility, we are currently subject to restrictions on our ability to pay dividends. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

**Use of Proceeds from the Sale of Registered Securities**

We registered the initial public offering of our common stock, par value \$.001 per share, on a Registration Statement on Form S-1, as amended (Registration No. 333-124197), which was declared effective on August 4, 2005. On August 10, 2005, we consummated an initial public offering of 4.6 million shares of our common stock at \$12.00 per share, which includes the underwriters' exercise of their over-allotment option, on August 9, 2005, to purchase 600,000 shares of our common stock, of which 450,000 shares were sold by selling shareholders and 150,000 shares were sold by us. Gross proceeds from the offering were \$49.8 million. We did not receive any proceeds from the sale of the 450,000 shares of common stock that were sold by selling shareholders. Total expenses from the offering were \$6.6 million, which included underwriting discounts and commissions of \$3.5 million and \$3.1 million in other offering-related expenses. Proceeds to us from the offering after deducting underwriting discounts, commissions and offering expenses were \$43.2 million.

Of the \$43.2 million in net proceeds from the initial public offering of our common stock, through December 31, 2007, we have spent \$6.4 million of these proceeds toward the acquisition of Enable Medical Corporation, \$3.3 million of these proceeds toward the acquisition of the Cooper Frigitrionics® CCS-200 product line, \$6.6 million to acquire property and equipment and \$22.2 million was primarily spent to fund our business operations.

**Table of Contents**

The use of proceeds does not represent a material change from the use of proceeds described in the prospectus relating to the Registration Statement. We have invested the remaining proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of our equity securities or to any other affiliates except for payments made to Epstein, Becker & Green P.C., our corporate counsel, for legal fees and expenses incurred in connection with the offering. Theodore L. Polin, our corporate Secretary, is a shareholder of Epstein, Becker & Green P.C. Other than the exception described above, all offering expenses were paid directly to third parties who were not our directors or officers (or their associates), persons owning ten percent or more of our equity securities or any other affiliate.

**Recent Sales of Unregistered Securities**

On May 30, 2007, we completed a private placement of 1,789,649 shares of common stock with gross proceeds to us of \$16.5 million and net proceeds of \$15.2 million. The shares issued were registered in July 2007 for resale by the investors.

**Equity Compensation Plans**

The following table summarizes information about our equity compensation plans as of December 31, 2007.

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	2,296,035	\$ 8.11	1,174,399
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>2,296,035</b>	<b>\$ 8.11</b>	<b>1,174,399</b>

Equity compensation plans approved by our stockholders include our 2001 Stock Option Plan and our 2005 Equity Incentive Plan.

**Table of Contents**

**Performance Graph**

The following graph compares the cumulative total stockholder return on our common stock with the cumulative total return of the NASDAQ Composite and the NASDAQ Medical Equipment Index for the period beginning on August 5, 2005, our first day of trading after our initial public offering, and ending on December 31, 2007.

\* This graph assumes that \$100.00 was invested on August 5, 2005 in our common stock, the NASDAQ Composite index and the NASDAQ Medical Equipment Index, and that all dividends are reinvested. No dividends have been declared or paid on our common stock. Stock performance shown in the above chart for our common stock is historical and should not be considered indicative of future price performance.

**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA**

The following table reflects selected financial data derived from our consolidated financial statements for each of the last five years. The statement of operations data for the years ended December 31, 2007, 2006 and 2005, and the balance sheet data as of December 31, 2007 and 2006 are derived from our audited financial statements included in this Form 10-K and include the operations of Enable Medical Corporation since its acquisition on August 10, 2005. The statement of operations data for the years ended December 31, 2004 and 2003, and the balance sheet data as of December 31, 2005, 2004 and 2003 are derived from our audited financial statements not included in this Form 10-K. Historical results are not necessarily indicative of future results. The selected financial data set forth below should be read in conjunction with our financial statements, the related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Form 10-K.

	Year ended December 31,				
	2007	2006 <sup>(2)</sup>	2005 <sup>(1)</sup>	2004	2003
(in thousands, except per share data)					
<b>Operating Results:</b>					
Revenues	\$ 48,309	\$ 38,243	\$ 30,957	\$ 19,157	\$ 9,792
Cost of revenues	10,137	7,626	8,057	5,202	2,612
Gross profit	38,172	30,617	22,900	13,955	7,180
Gross margin	79.0%	80.1%	74.0%	72.8%	73.3%
Operating expenses	50,740	45,386	33,750	19,608	10,537
Other income (expense)	1,315	1,052	(1,833)	(3,799)	(3,751)
Net loss	(11,253)	(13,717)	(12,683)	(9,452)	(7,108)
Basic and diluted net loss per share	\$ (0.84)	\$ (1.13)	\$ (2.10)	\$ (5.17)	\$ (3.97)
Weighted average shares outstanding	13,382	12,137	6,025	1,828	1,792
<b>Financial Position:</b>					
Cash, cash equivalents and short-term investments	\$ 20,007	\$ 19,488	\$ 33,802	\$ 5,175	\$ 10,399
Working capital	24,624	23,031	35,903	6,590	11,985
Total assets	46,071	39,128	50,040	12,731	14,759
Long-term debt and capital lease	282	693	1,084		
Redeemable preferred stock				36,756	32,805
Accumulated deficit	(67,308)	(56,055)	(42,337)	(29,633)	(20,135)
Stockholders' equity (deficit)	36,237	30,694	43,183	(27,331)	(18,937)

1. On August 10, 2005 the Company acquired Enable Medical Corporation. For further discussion regarding the acquisition see Business Combinations in Note 3 to our Consolidated Financial Statements.
2. Effective January 1, 2006, the Company adopted SFAS No. 123(R), Share-Based Payment ( SFAS 123R ), which requires the measurement and recognition of compensation cost at fair value for all share-based payments. The Company adopted SFAS 123R using the modified prospective transition method and, as a result, did not retroactively adjust results from prior periods. For further discussion regarding SFAS 123R see the section entitled Stock-Based Employee Compensation in Note 1 to our Consolidated Financial Statements.

---

**Table of Contents**

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

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

**Overview**

We are a medical device company and a leader in developing, manufacturing and selling innovative cardiac ablation products designed to create precise lesions, or scars, in cardiac, or heart, tissue. Our primary product line, which accounts for a majority of our revenues, is our AtriCure Isolator<sup>®</sup> bipolar ablation system. Our Isolator<sup>®</sup> system consists primarily of a compact power generator known as an ablation and sensing unit, or ASU, a switchbox unit, or ASB, which allows physicians to toggle between multiple products and multiple configurations of our Isolator<sup>®</sup> clamps, including our recently introduced Isolator Synergy<sup>™</sup> clamps. We sell two configurations of our clamps, one designed for ablation during open-heart, or open, procedures and one designed for ablation during sole-therapy minimally invasive procedures. We also sell a multifunctional bipolar Pen which is often used by physicians in combination with our Isolator<sup>®</sup> system to ablate cardiac tissue and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. Additionally, we sell various configurations of enabling devices, such as our Lumitip<sup>™</sup> dissection tool. In August of 2007, we acquired a cardiac cryoablation product line, which uses extreme cold to ablate tissue. Prior to our acquisition of the product line, we sold the product line as a distributor.

We commenced a full commercial release of our primary product line, the Isolator<sup>®</sup> system for use during open heart procedures in 2003, and have brought new products to market over time. During 2005, we commercialized the Isolator<sup>®</sup> system for use during minimally invasive sole-therapy procedures. Our revenues have grown from \$9.8 million in 2003 to \$48.3 million in 2007. In August 2005, we raised net proceeds of \$43.2 million through an initial public offering. Since then, we have invested heavily in expanding our product development organizations and activities and building our sales and marketing organizations and activities. Our operating expenses have increased from \$10.5 million in 2003 to \$50.7 million in 2008.

Medical journals have described the adoption by leading cardiac surgeons of our Isolator<sup>®</sup> bipolar ablation clamp system as a treatment alternative during open-heart surgical procedures to create lesions in cardiac tissue to block the abnormal electrical impulses that cause atrial fibrillation, or AF, a rapid, irregular quivering of the upper chambers of the heart. Additionally, leading cardiac surgeons, treatment guidelines as published by the Heart Rhythm Society and publications in medical journals have described our Isolator<sup>®</sup> system as a standard treatment alternative for patients who may be candidates for sole-therapy minimally invasive procedures designed to treat patients with AF.

In the United States, we primarily sell our products through our direct sales force. AtriCure Europe BV, our wholly-owned European subsidiary incorporated and based in the Netherlands, sells our products throughout Europe, primarily through distributors, with the exception of Germany and Austria, where we began to sell directly through our sales force during 2007. 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 primarily transacted in Euros. Our sales outside of the United States represented 14% of our 2007 revenues.

In July 2007 the FDA cleared our Isolator<sup>®</sup> system for the ablation, or destruction, of cardiac tissue. Prior to July 2007, our Isolator<sup>®</sup> system had been cleared in the United States for the ablation of soft tissues during

**Table of Contents**

general and thoracic surgical procedures. Our multifunctional Pen has been cleared by the FDA for cardiac tissue ablation and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. We may only promote our products to doctors and provide education and training on the use of our devices for their cleared indications, which does not include the treatment of AF. While the FDA does not prevent doctors from using products off-label, we cannot market a product for an off-label use.

We are in the process of conducting a clinical trial, known as ABLATE, to evaluate the safety and effectiveness of our Isolator<sup>®</sup> system for the treatment of patients who have permanent AF and are undergoing a concomitant open-heart procedure. If this trial is successful, we intend to seek FDA approval as early as 2010 for the use of Isolator<sup>®</sup> system during open procedures to treat patients with permanent AF. The first patient was treated as part of the ABLATE trial in February 2008.

During 2008 we plan to introduce several new products, including our new Coolrail<sup>™</sup> Linear Ablation Pen system, our disposable cryoablation probe for use during open heart procedures and the AtriCure Left Atrial Appendage Exclusion System, which is designed to exclude the left atrial appendage. The Coolrail<sup>™</sup> Linear Pen, which we plan to introduce during the first half of 2008, will likely be adopted by physicians to perform an expanded lesion set during minimally invasive procedures. We plan to release our new disposable, cryoablation probe during the second half of 2008 and believe it will be adopted by physicians in combination with our other products to create ablations during certain open-heart procedures. Our left atrial appendage exclusion system is currently being utilized and has been safely and effectively implanted in humans as part of a clinical evaluation in Europe. The left atrial appendage exclusion system has not yet been approved for human use by the FDA in the United States. However, we have filed a 510(k) notification with the FDA and if the FDA review is favorable, we expect to have clearance from them for commercial use to permanently exclude the left atrial appendage in the second half of 2008 or 2009. We believe the market for our left atrial appendage exclusion system is large and represents a significant new growth opportunity for us.

In August of 2007, The Centers for Medicare & Medicaid, or CMS, issued the final 2008 Inpatient Prospective System (IPPS) final rule for hospital inpatient reimbursement by Medicare s-Severity Diagnostic Related Groups, or MS-DRGs, effective October 1, 2007. Under the 2008 IPPS, Medicare hospital reimbursement has moved to a severity-adjusted DRG system. Based on our preliminary interpretation of the final rule and experience to date, we do not expect these changes to have a material impact on our business or revenues.

Our costs and expenses consist of cost of revenues, research and development expenses and selling, general and administrative expenses. Cost of revenues consists principally of the cost of purchasing materials and manufacturing our products. Research and development expenses consist principally of expenses incurred with respect to internal and external research and development activities and the conduct of clinical activities and trials. Selling, general and administrative expenses consist principally of costs associated with our sales, marketing and administrative functions, and unrestricted educational grants to medical institutions.

**Table of Contents****Results of Operations****Years Ended December 31, 2007 compared to December 31, 2006**

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

	Year Ended December 31,			
	2007	% of Revenue (dollars in thousands)	2006	% of Revenue
Revenues	\$ 48,309	100.0%	\$ 38,243	100.0%
Cost of revenues	10,137	21.0%	7,626	19.9%
Gross profit	38,172	79.0%	30,617	80.1%
Operating expenses:				
Research and development expenses	10,987	22.7%	12,216	31.9%
Selling, general and administrative expenses	39,753	82.3%	33,170	86.7%
Total operating expenses	50,740	105.0%	45,386	118.7%
Loss from operations	(12,568)	-26.0%	(14,769)	-38.6%
Other income (expense):				
Interest expense	(213)	-0.4%	(209)	-0.5%
Interest income	948	2.0%	1,188	3.1%
Other	580	1.2%	73	0.2%
Other income	1,315	2.7%	1,052	2.8%
Net loss	\$ (11,253)	-23.3%	\$ (13,717)	-35.9%

**Revenues.** Total revenues increased \$10.1 million, or 26.3%, from \$38.2 million in 2006 to \$48.3 million in 2007. The increase was primarily attributable to an increase in unit sales of approximately 36% and a 2.5% increase as a result of currency rate fluctuation. These increases were partially offset by a decrease in worldwide average selling prices, or ASPs, driven by an increased mix of international sales, which generally carry a lower ASP per unit due to the use of distributors to sell into most international markets, and product mix.

**Cost of revenues.** Cost of revenues increased \$2.5 million, from \$7.6 million in 2006 to \$10.1 million in 2007, primarily due to an increase in the total number of units sold. As a percentage of revenues, cost of revenues increased from 19.9% for the year ended December 31, 2006 to 21.0% for the year ended December 31, 2007. The increase in cost of revenues as a percentage of revenues was primarily due to an increased mix of international revenues, which carry a lower ASP than domestic revenues.

**Research and development expenses.** Research and development expenses decreased \$1.2 million, from \$12.2 million in 2006 to \$11.0 million in 2007. The decrease was primarily attributable to a net decrease in our external product development expenses and redeployment during 2007 of several individuals who previously focused on clinical activities to selling activities, a component of selling, general and administrative expenses. As a percentage of revenues, research and development expenses decreased from 31.9% in 2006 to 22.7% in 2007.

**Selling, general and administrative expenses.** Selling, general and administrative expenses increased \$6.6 million, from \$33.2 million in 2006 to \$39.8 million in 2007. The increase was primarily attributable to an increase in headcount-related charges of \$4.8 million, primarily in the sales and marketing functions, an increase in marketing expenditures of \$1.0 million to support an increased presence at several key industry events, a \$0.8 million increase in stock option expense and \$0.3 million related to our settlement of an outstanding legal dispute with a former European distributor. As a percentage of total revenues, selling, general and administrative expenses decreased from 86.7% in 2006 to 82.3% in 2007.



**Table of Contents**

**Net interest income.** Net interest income decreased \$0.3 million, from \$1.0 million in 2006 to \$0.7 million in 2007, due primarily to a decrease in average net cash, cash equivalents and investments outstanding.

**Other.** Other income consists of grant income, foreign currency transaction gain and non-employee option expense. Grant income increased \$0.5 million, from \$0.1 million in 2006 to \$0.6 million in 2007 and consisted of income related to expense sharing under a grant for research and development related activities. Foreign currency transaction gain was \$0.2 million in 2007 in connection with a partial settlement of our intercompany payable balance with our subsidiary. Non-employee option expense of \$0.2 million is related to the fair market value change for fully vested options outstanding for consultants, which are accounted for as free standing derivatives.

**Years Ended December 31, 2006 compared to December 31, 2005**

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

	Year Ended December 31,			
	2006	% of Revenue	2005	% of Revenue
	Amount	(dollars in thousands)	Amount	
Revenues	\$ 38,243	100.0%	\$ 30,957	100.0%
Cost of revenues	7,626	19.9%	8,057	26.0%
Gross profit	30,617	80.1%	22,900	74.0%
Operating expenses:				
Research and development expenses	12,216	31.9%	9,109	29.4%
Selling, general and administrative expenses	33,170	86.7%	24,641	79.6%
Total operating expenses	45,386	118.7%	33,750	109.0%
Loss from operations	(14,769)	-38.6%	(10,850)	-35.0%
Other (expense) income:				
Preferred stock interest expense		0.0%	(2,332)	-7.5%
Interest income, net	979	2.6%	414	1.3%
Grant income	73	0.2%	85	0.3%
Net loss	\$ (13,717)	-35.9%	\$ (12,683)	-41.0%

**Revenues.** Total revenues increased \$7.3 million or 23.5%, from \$31.0 million in 2005 to \$38.2 million in 2006. The increase was primarily attributable to an increase in the total number of disposable units sold, partially offset by a decrease in worldwide ASPs. Though our domestic and international revenues were both favorably impacted by increases in the average selling prices, the increase in lower-priced international units sold as a percentage of total units sold resulted in a decline in our worldwide average selling prices.

**Cost of revenues.** Cost of revenues decreased \$0.4 million, from \$8.1 million in 2005 to \$7.6 million in 2006. The decrease was primarily due to a decrease in our average cost per unit as a result of our third quarter 2005 acquisition of Enable Medical Corporation, the manufacturer of our disposable products. This was partially offset by an increased mix of international sales, which carry a lower ASP. As a percentage of revenues, cost of revenues decreased from 26.0% in 2005 to 19.9% in 2006.

**Research and development expenses.** Research and development expenses increased \$3.1 million, from \$9.1 million in 2005 to \$12.2 million in 2006. The increase was primarily attributable to the hiring of additional full-time research and development personnel, including the former Enable employees, the expansion of our research and development activities to increase our product offerings and the expansion of our clinical trial



---

## **Table of Contents**

activities. Our product development activities included projects to extend and improve our Isolator<sup>®</sup> system, develop our new Isolator Synergy ablation clamps and the AtriCure Left Atrial Appendage Exclusion System, create new enabling devices and ablation tools and research new technologies. As a percentage of revenues, research and development expenses increased from 29.4% in 2005 to 31.9% in 2006 due to increased spending on new product initiatives, expanded clinical trials and the addition of personnel.

**Selling, general and administrative expenses.** Selling, general and administrative expenses increased \$8.6 million, from \$24.6 million in 2005 to \$33.2 million in 2006. The increase was primarily attributable to an increase in headcount-related charges of \$4.9 million, an increase in marketing expenditures of \$0.8 million, increases in unrestricted grants and training expenditures of \$0.3 million and increases in general corporate expenditures of \$2.6 million. The increase in headcount-related charges is primarily attributable to the acquisition of Enable and the expansion of our sales and marketing organizations. As a percentage of total revenues, selling, general and administrative expenses increased from 79.6% in 2005 to 86.7% in 2006.

**Preferred stock interest expense.** Preferred stock interest expense was \$2.3 million in 2005. Shares of preferred stock were converted into common stock upon the closing of our initial public offering in August 2005.

**Net interest income.** Net interest income increased \$0.6 million, from \$0.4 million in 2005 to \$1.0 million in 2006, due to the increase in average cash, cash equivalents and investments outstanding, primarily due to our August 2005 initial public offering.

## **Liquidity and Capital Resources**

On May 30, 2007, we completed a private placement of 1,789,649 shares of common stock, with gross proceeds to us of \$16.5 million. Of the total shares issued, 1,683,060 shares were issued to ten institutional investors at \$9.15 per share and 106,589 shares were issued to an entity affiliated with one of our directors at \$10.32 per share, the closing bid price on May 23, 2007. The shares issued were registered for resale in July 2007. Net proceeds to us from the sale of the shares were \$15.2 million after deducting transaction related expenses. The net proceeds from the offering will be used for working capital and general purposes, including research and development activities and potential acquisitions or other strategic initiatives.

As of December 31, 2007, we had cash, cash equivalents and short-term investments of \$20.0 million and short-term and long-term debt of \$1.1 million, resulting in a net cash position of \$18.9 million. We had working capital of \$24.6 million and an accumulated deficit of \$67.3 million.

**Cash flows used in operating activities.** Net cash used in operating activities was \$8.1 million in 2007, \$12.5 million in 2006, and \$7.6 million in 2005. Net cash used in operating activities in 2007 was primarily attributable to the net loss of \$11.3 million and increases in accounts receivable, inventory and other current assets of \$0.6 million, \$1.4 million and \$0.2 million, respectively, which increased as revenues increased and expansion of our product offering. Those increases were partially offset by adjustments for depreciation and amortization of \$2.3 million, loss on disposal of equipment of \$0.1 million and non-cash charges related to stock-based compensation of \$1.9 million and increases in payables and accrued liabilities of \$0.9 million, due primarily to the growth in the business and expansion of our product offering. Net cash used in operating activities in 2006 was primarily attributable to the net loss of \$13.7 million and increases in accounts receivable, inventory and other current assets of \$1.8 million, \$1.3 million and \$0.4 million, respectively, which increased as revenues increased. Those increases were partially offset by adjustments for depreciation and amortization of \$1.9 million and non-cash charges related to stock-based compensation of \$1.0 million and increases in payables and accrued liabilities of \$1.6 million due to our increase in operating expenses. Net cash used in operations in 2005 was primarily attributable to a net loss of \$12.7 million and increases in inventory and other current assets of \$0.2 million and \$0.7 million, respectively, as we increased our revenue, partially offset by adjustments for non-cash charges related to stock-based compensation of \$0.7 million, depreciation and amortization of \$1.6

**Table of Contents**

million, preferred stock interest of \$2.3 million, loss on disposal of equipment of \$0.3 million, a decrease in other non-current assets of \$0.4 million, and increases in payables and accrued liabilities of \$0.6 million due to our increase in operating expenses.

**Cash flows used in and provided by investing activities.** Net cash used in investing activities was \$8.8 million in 2007 and cash flows provided by investing activities were \$0.1 million in 2006 and cash used in investing activities was \$14.7 million in 2005. For each of these periods, cash used in investing activities reflected purchases of property and equipment of \$3.0 million, \$1.7 million, and \$2.0 million for 2007, 2006, and 2005, respectively, the net purchases and maturities of investments of \$2.4 million, (\$1.8) million, and \$6.4 million for 2007, 2006, and 2005, respectively and, in 2007 and 2005, cash paid for acquisitions, net of cash acquired of \$3.3 million and \$6.4 million, respectively. During 2007, the increase in the purchase of property, plant and equipment was primarily due to the introduction of our ASB in accordance with the launch of our Isolator Synergy<sup>TM</sup> platform. The ASB is new hardware which we generally loan to our customers. During 2007, our cash paid for acquisitions was for the acquisition of the Frigitronics<sup>®</sup> CCS-200 product line and in 2005 cash paid for acquisitions reflects the net purchase price for the acquisition of Enable.