

AtriCure, Inc.  
Form 10-K  
April 02, 2007  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-K**

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

For the fiscal year ended December 31, 2006

**.. 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)

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**DELAWARE**  
(State or other jurisdiction of

incorporation or organization)

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

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

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

Identification Number)

**45069**  
(Zip Code)

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

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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)

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

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

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

Indicate by check mark 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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act (check one):

Large Accelerated Filer  Accelerated Filer  Non-accelerated Filer

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, 2006, as reported on the Nasdaq Global Market, was \$50.3 million.

As of March 16, 2007, there were 12,301,590 shares of Common Stock, \$.001 par value, outstanding.

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**DOCUMENTS INCORPORATED BY REFERENCE**

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

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**PART I**

*This Form 10-K, including the sections titled Management's Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors, contains forward-looking statements regarding our future performance. All forward-looking information is inherently uncertain and actual results may differ materially from assumptions, estimates or expectations reflected or contained in the forward-looking statements as a result of various factors, including those set forth under Risk Factors and elsewhere in this Form 10-K. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this Form 10-K other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words may, continue, estimate, intend, plan, will, believe, project, expect, anticipate and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. With respect to the forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. These forward-looking statements speak only as of the date of this Form 10-K. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise.*

**ITEM 1. BUSINESS**

**Overview**

We develop, manufacture and sell innovative surgical devices designed to create precise lesions, or scars, in cardiac and soft tissues. Medical journals have described the adoption by leading cardiothoracic surgeons of our Isolator bipolar ablation clamps as a treatment alternative during open-heart surgical procedures to create lesions in cardiac, or heart, 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 have described our Isolator clamps as a promising treatment alternative for patients who may be candidates for sole-therapy minimally invasive 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 clamps, raising capital, obtaining product clearances, conducting product testing and evaluations, and recruiting personnel. After limited sales of our Isolator clamps in 2002, in January 2003 we commenced the general commercial release of these clamps. Revenues reached \$38.2 million for 2006, were \$31.0 million for 2005 and \$19.2 million for 2004. We anticipate that substantially all of our revenue for the foreseeable future will relate to products we currently sell or are in the process of developing, which surgeons use for the treatment of AF.

Our primary product line is our AtriCure Isolator bipolar ablation system, which accounted for 98% of our 2006 revenue. Our Isolator system consists of a compact power generator known as an ablation sensing unit, or ASU, multiple configurations of our Isolator clamps and our multifunctional bipolar Pen. We sell two configurations of our Isolator clamps, one designed for ablation during open-body, or open, procedures and one designed for ablation during minimally invasive procedures, which are performed on patients who are not undergoing a separate open procedure. Our Isolator clamps and our Pen are each powered by the same ASU. We also sell various configurations of enabling devices, including the Lumitip dissection tool. Additionally, we distribute cryoablation devices that use extreme cold to ablate tissue.

We currently sell our Isolator system to customers in the United States primarily 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. Additionally, we sell our products to other international distributors, primarily in Asia, South America, Central America, Canada and the Middle East. Our

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business is primarily transacted in U.S. dollars, with the exception of transactions with our European subsidiary, which are transacted in Euros. Our sales outside of the United States represented 11% of our 2006 revenue.

Cardiothoracic surgeons have adopted our Isolator system to treat AF in over 35,000 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. Our Isolator system is currently being used in 90% of the 50 highest volume heart centers in the United States. We do not believe that our Isolator clamps are currently being used for their Food and Drug Administration, or FDA, cleared indications, and, accordingly, substantially all of our revenue is currently generated through the non-FDA-approved, or off-label, use of our Isolator clamps 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. 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.

AF is a condition that doctors often find difficult to treat, and historically there has been no widely accepted 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 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 who are consultants to us, describe how cardiothoracic surgeons have used our Isolator clamps 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 Isolator clamps 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.

Our Isolator clamps have been cleared by the FDA for the ablation, or destruction, and coagulation of soft tissues during general and thoracic surgical procedures, but our Isolator clamps have not been approved in the United States for the ablation of cardiac tissue or the treatment of AF. We have received FDA clearance for our Pen for cardiac tissue ablation and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. As such, we may promote our Pen to doctors and provide education and training on the use of this device for its cleared indications. However, other than the FDA-cleared indications for our Pen and our dissection tools, we do not believe that any of our products are currently being used for their FDA-cleared indications and, accordingly, substantially all of our revenue is currently generated through the off-label use of the products comprising our Isolator system for 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 clinical trials on the safety and effectiveness of our Isolator system for the treatment of AF, and if these trials are successful, we intend to seek FDA approval as early as 2009 for the

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use of the products comprising our Isolator system to treat AF, which we view as our market opportunity. If the FDA were to require us to have AF approval for the products comprising our Isolator system in order for us to continue selling these products, not only would we no longer receive revenue 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 assure you 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 Isolator system.

Although the use of our Isolator system to treat AF remains investigational and we are still seeking FDA approval in connection with the use of our Isolator system for the treatment of AF, preliminary clinical studies conducted by doctors at leading medical centers provide support for our Isolator clamps' 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 preliminary 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 clamps were free of AF at six-month follow-up. This success rate was achieved when our Isolator clamps were used during open-heart surgical procedures and also when used as a sole-therapy minimally invasive approach. We believe the overall demand for our Isolator system will increase, including demand for our Isolator system for use in minimally invasive procedures, which we believe will ultimately represent our largest growth opportunity. We are seeking to confirm these results in the ongoing clinical trials we are conducting with the FDA's authorization.

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

## **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 times 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, coronary artery disease, cardiomyopathy 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. According to the National Center for Health Statistics, AF also accounts for an estimated 3.2 million office visits and more than 470,000 hospitalizations annually in the United States. According to *Medtech Insight*, AF accounts for more than \$6 billion in healthcare costs each year in the United States. According to *The Journal of the American Medical Association*, the number of patients with AF in the United States will continue to increase.

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

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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. 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 Isolator clamps for the ablation of cardiac tissue or the treatment of AF, we and others acting on our behalf may not promote our Isolator clamps for these uses, make any claim that they are safe and effective for these uses or train doctors to use them for these uses outside of the clinical trial setting. However, these restrictions do not prevent doctors from choosing to use our Isolator clamps for the treatment of AF or prevent us from engaging in sales and marketing efforts that focus only on the general attributes of our Isolator clamps and their FDA-cleared uses and not on the ablation of cardiac tissue or the treatment of AF. Although we educate and train doctors as to the general skills involved in the proper use of our Isolator clamps, it is our policy not to educate or train them to use our Isolator clamps for the ablation of cardiac tissue or the surgical treatment of AF. However, we provide information to physicians in response to their requests, and also consider requests and often support physician training by providing educational grants to be used for university and physician training programs, which content is developed independently of AtriCure. The FDA has cleared our Pen for the surgical ablation of cardiac tissue and temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. As such, we may promote our Pen to doctors and provide education and training for its FDA-cleared indications.

### **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 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. Current AF treatment alternatives to the use of our Isolator system and other surgical ablation systems generally consist of the following:

*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.

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### **The AtriCure Solution**

We believe that traditional surgical and catheter-based ablation devices are not able to safely, rapidly and reliably create 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 Isolator clamps enable cardiothoracic 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 Isolator clamps' high market penetration and rapid adoption. Some leading cardiothoracic surgeons have also commenced use of our Isolator clamps as a sole-therapy minimally invasive treatment for AF. Our Pen is complementary to our Isolator clamps, and we believe there is a growing trend to utilizing our Pen in conjunction with our Isolator clamps in both open-heart and sole-therapy minimally invasive procedures.

Our clinical studies for the use of our Isolator system to treat AF are ongoing. Leading cardiothoracic surgeons who are consultants to us have published the results of initial clinical studies that were conducted at prominent medical centers, such as the Cleveland Clinic, Washington University, Medical City of Dallas and the University of Cincinnati. The results of these studies were promising in terms of the efficacy, ease of use and safety of our Isolator clamps.

**Efficacy.** We believe that AF treatment devices 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. The initial studies described above found that between 80% and 95% of the study participants treated for AF using our Isolator clamps were free of AF at a six-month follow-up. We are conducting longer term FDA-approved clinical trials for both open-heart and sole-therapy minimally invasive procedures in order to confirm these initial promising results.

**Ease of Use.** In these studies, cardiothoracic surgeons reported that our Isolator clamps are 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, or full-thickness. Our Isolator clamps' unique jaws firmly clamp and compress the targeted tissue being ablated, allowing surgeons to rapidly create transmural lesions. Cardiothoracic surgeons report that they have generally treated AF in only 20 minutes when using our Isolator clamps during an open-heart procedure, or in approximately two to three hours when using our Isolator clamps to treat AF as a sole-therapy minimally invasive procedure.

**Safety.** Although serious complications, including death, may arise from any type of cardiac surgery, these initial studies concluded that our Isolator clamps appear to be a safe treatment alternative for the surgical treatment of AF during open-heart procedures. Cardiothoracic surgeons participating in these studies concluded that our Isolator clamps may potentially reduce damage to adjacent anatomical structures due to their 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 bipolar ablation system consists of our ASU, a compact power generator that uses our proprietary software and delivers bipolar radio-frequency energy, multiple configurations of our Isolator bipolar ablation clamps, and our multifunctional bipolar Pen. We sell two configurations of our Isolator clamps, one designed for ablation during open procedures and one designed for ablation during minimally invasive procedures, which are performed on patients who are not undergoing a separate open procedure. Our Isolator clamps and our Pen are each powered by the same ASU. We generally lend our ASU to doctors and hospitals that purchase our Isolator clamps. All of our Isolator clamps are disposable and have jaws that close in a parallel



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fashion. The parallel closure compresses the tissues and evacuates the blood and fluid from the energy pathway in order to make the ablation more effective.

During the third quarter of 2006, we released Isolator clamps that are specifically designed for open surgical procedures. These Isolator clamps feature an ergonomic design that improves the surgeon's access to key anatomical structures and simplifies the ablation procedure. During the first quarter of 2007, we introduced our new Isolator Synergy ablation clamps, which are our next generation of our Isolator clamps designed for open procedures. The Isolator Synergy clamps are designed to provide more reliable full thickness lesions in thicker and more diseased tissues.

We sell endoscopic Isolator bipolar ablation clamps that are specifically designed for use in minimally invasive procedures. These endoscopic Isolator clamps can be used with our unique glide-path transfer guide and are designed to simplify minimally invasive procedures, making it more adaptable to a broader number of surgeons and allowing surgeons the ability to perform a completely thorascopic (through small incisions in the chest) procedure. We released these endoscopic Isolator clamps in the first quarter of 2006 and anticipate releasing our next generation endoscopic Isolator Synergy version of these clamps in the second half of 2007 that are designed for minimally invasive procedures.

We also sell a pen-shaped ablation device known as the multifunctional bipolar Pen, which has been cleared by the FDA for the surgical ablation of cardiac tissue and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. This disposable handpiece is powered by the same ASU that powers our Isolator clamps and is compatible with standard external pacing, sensing/recording and stimulating systems. Because of its broad range of capabilities, surgeons are using this device during both open and sole-therapy minimally invasive procedures, sometimes in combination with our Isolator clamps. The Pen enables surgeons to evaluate cardiac arrhythmias and ablate cardiac tissue with the same device and when used with a switching system, enables surgeons to toggle back and forth between stimulation and ablation. We released the Pen in the third quarter of 2005.

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 minimally invasive shaft with an articulating index finger-shaped tip that illuminates. The illuminated tip allows 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.

The Glidepath tape is a Class I general surgical instrument guide available in various configurations for use with our Isolator clamps and Lumitip dissector. The Glidepath tape was included as an accessory device to our Isolator clamps and Lumitip dissector in their corresponding cleared 510(K) submissions.

Additionally, we are developing the Cosgrove-Gillinov Left Atrial Appendage Occlusion Clip, which is designed to exclude the left atrial appendage, the small appendage that is attached to the left atrium, during open-heart surgical procedures and which may also be used to provide an option for high risk patients as a stand-alone left atrial appendage exclusion procedure following catheter ablation or pacemaker implantation. 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, we expect to file with the FDA a 510(k) notification for the Clip to obtain an indication that includes left atrial appendage exclusion. Additionally, we anticipate initial implants in humans outside of the United States during 2007.

We also distribute an ablation device that uses cryotherapy, or extreme cold, to ablate tissues. Some surgeons use this device in conjunction with our Isolator clamps to create lesions around heart valves as part of AF treatment.

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

During elective open-heart surgical procedures, such as bypass or valve surgery, cardiothoracic surgeons use our Isolator clamps to treat patients with a pre-existing history of AF. Surgeons report that ablation using our Isolator clamps generally adds approximately 20 minutes to an open-heart surgical procedure. Surgeons use our Isolator clamps to create sets of lesions 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 continuous. Patients who have been diagnosed with AF for a longer duration and have more continuous AF generally receive more ablations than patients who have been diagnosed with AF for a shorter duration or who have intermittent AF. Surgeons using our Isolator clamps 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 tissue surrounding the pulmonary veins to create an electrical barrier between the pulmonary veins and the atrium, or upper chamber of the heart. In patients with intermittent AF, those lesions are often the extent of the treatment required to treat their AF. Cardiothoracic surgeons report that using our Isolator clamps 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 Isolator 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 and that the pulmonary veins have been electrically isolated.

*Additional Lesions.* For those patients who have been diagnosed with AF for a longer period and/or 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 and/or our Pen 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.

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

For those patients with AF that do not require a concomitant open-heart surgical procedure, surgeons have used our endoscopic Isolator clamps in conjunction with our other enabling devices for minimally invasive procedures. These procedures have generally been performed through minimally invasive incisions without the need to place patients on a heart-lung bypass machine. Surgeons report that the procedure takes approximately two to three hours and that the typical hospital stay is approximately five days.

## **Business Strategy**

Our mission is to expand the treatment options for those patients who suffer from AF through the continued development of our products. 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, such as the Cleveland Clinic, Washington University, the Medical City of Dallas, the University of Cincinnati, the University of Oklahoma, the Medical College of Virginia, and the University Community Hospital of Tampa. These key opinion leaders have worked with us as consultants to evaluate and develop our products. Additionally, several key opinion leaders at these prestigious institutions have published peer-review data that describes the use of our Isolator clamps 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 approximately 20 peer-review publications that describe our Isolator clamps' ability to create transmural lesions or as an AF treatment alternative. We believe that these publications, and the presentations given by key opinion leaders, have contributed to the adoption of our Isolator 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

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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 Isolator system 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 System.*** 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.

Our consultants have received grant monies from leading institutions to support certain research activities and they have published the results of an initial series of studies relating to the use of our minimally invasive products. As results of these 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 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 patients an improved treatment alternative. We believe that these research activities and anticipated publications will create an increased demand for our minimally invasive products.

Additionally, we are developing a more comprehensive ablation treatment alternative for patients with more continuous or permanent forms of AF. We are aware of an initial pilot study demonstrating the feasibility of performing a minimally invasive, expanded ablation procedure using our products. This pioneering minimally invasive work will also be evaluated in our FDA regulated Restore IIB clinical trial. We believe that this expanded minimally invasive ablation procedure will potentially offer an improved treatment alternative for those patients with more continuous or permanent forms of AF, as well as patients who have failed catheter ablation procedures, resulting in an increased market for our products. As such, we are rapidly developing new products to enhance the expanded ablation procedure and working with the FDA to further investigate our products.

***New Product Innovation.*** During March 2007, we released our new Isolator Synergy ablation clamps designed for open surgical procedures, and initial human procedures have been successfully completed. We anticipate releasing our minimally invasive, endoscopic version of the Isolator Synergy clamps designed for minimally invasive procedures during the second half of 2007. We believe that the Isolator Synergy clamps offer an important technology advancement and will further enhance our position as the industry innovator and technology leader. The Isolator Synergy clamps also incorporate the design of our new more ergonomic Isolator clamps recently released during the third quarter of 2006.

The unique ablation technology used in our Isolator Synergy clamps provides more reliable full thickness lesions in thicker and more diseased tissues. We believe that physicians will view the capability of the Isolator Synergy clamps to more reliably create transmural lesions in thicker and more diseased tissues as an important competitive advantage. Another important potential advantage of the Isolator Synergy clamps is that we believe they create a more effective ablation line by enhancing the geometry of the lesion. Conventional bipolar ablation clamps form lesions that are shaped like an hour glass, widest on the surfaces of the tissue and thinnest in the center of the tissue. Unlike clamps, unidirectional ablation systems can create ablation lesions shaped like a V, widest closest to the ablation element and thinnest furthest away from the ablation element. Our Isolator Synergy clamps create a uniform, full thickness lesion shaped like a column, which we believe will result in more durable ablation lines than the lines created by more conventional ablation technology. This is a potentially important advancement because it has been established that electrical impulses can propagate across narrow lesions, even if transmural is achieved, due to the reconnection of conduction across the ablation line.

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We believe that the ablation column, created by the Isolator Synergy clamps, will produce more durable ablation lines resulting in improved long-term patient outcomes. For these reasons, we believe the Isolator Synergy clamps will further distinguish us as an innovator and market leader.

Additionally, we are developing a minimally invasive, expanded lesion-set ablation device and integrated mapping system, which we expect will facilitate minimally invasive procedures. Our new expanded lesion-set ablation device will enable surgeons to more easily create additional ablation lines through a minimally invasive procedure. Our new customized integrated mapping system will enable physicians to more effectively confirm that the ablation lines being created are forming lines of transmural or conduction block. We expect to launch these new products during the fourth quarter of 2007.

Additionally, we plan to submit our 510(k) notification in support of our Cosgrove-Gillinov Left Atrial Appendage Occlusion Clip during the second quarter of 2007 and anticipate performing our initial implants in humans outside of the United States during 2007.

The Clip is designed to exclude the left atrial appendage. Literature suggests that the majority of blood clots that form in AF patients can be found in the left atrial appendage. Because in some cases blood clots can lead to stroke, some physicians believe that excluding the left atrial appendage should be integrated into procedures intended to treat AF, when feasible. In terms of initial pre-clinical experience and publications describing the use of our Clip, there have been four manuscripts authored by physicians from the Cleveland Clinic and published in *The Journal of Thoracic and Cardiovascular Surgery and Stroke* highlighting the pre-clinical use of our Clip to successfully exclude the left atrial appendage. We believe that the occlusion of the left atrial appendage will become a growing trend in procedures intended to treat AF. As such, we anticipate that our Clip represents a large opportunity for us. The Clip is technology that we licensed from the Cleveland Clinic and the Cleveland Clinic will be paid royalties on sales generated from this product.

### **Clinical Trials**

We are currently working with the FDA and leading cardiothoracic surgeons to design a new clinical trial for patients with permanent AF undergoing concomitant open-heart surgical ablation procedures. We anticipate being able to use our experience gained from the 44 patients currently enrolled in our on-going FDA-approved clinical trial, RESTORE-SR, to reduce the overall sample size necessary in the new clinical trial. We also anticipate that the data from our RESTORE SR clinical trial will help us to more accurately establish the efficacy and safety endpoints for this new study.

As of February 28, 2007, we have enrolled approximately 19% of the patients required for the RESTORE-SR multicenter, 226-patient clinical trial, and the preliminary efficacy and safety results are similar to those in the published peer review literature for similar patient populations receiving ablation treatments. We anticipate faster enrollment in the new clinical trial based on a simpler study design and removal of previously required tests such as diagnostic imaging for pulmonary vein stenosis assessment. There is no guarantee that the new trial design will be approved by the FDA or that it will enroll patients quickly or demonstrate success. It is likely that we will close the RESTORE SR trial if we are successful in obtaining approval for the new trial design. We expect to file the new investigational device exemption, or IDE, for this clinical trial in the third quarter of 2007 and start enrollment in the second half of the year. If this clinical trial is successful, we anticipate filing a premarket approval application, or PMA, no sooner than the second half of 2009, which if approved by the FDA would allow us to market our Isolator clamps for the treatment of AF during open-heart procedures.

We are also conducting the final phase of our FDA approved RESTORE-SR II clinical study to evaluate the feasibility of using our Isolator clamps in a sole-therapy minimally invasive procedure for the treatment of AF.

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This feasibility study has completed enrollment and treatment of the necessary 25 patients at 5 leading centers in the United States. Based on the success and initial results of the 25 patients treated, we plan to file an extension to our IDE for a new arm to this study, RESTORE-SR IIB, to expand our feasibility trial in order to treat an additional 25 patients with our new endoscopic Isolator Synergy ablation clamps and our Pen. We plan to file the extension with the FDA during the second quarter of 2007 and we anticipate starting the enrollment of the additional patients in the second half of 2007. Additionally during 2008, we plan to request that the FDA permit us to conduct a pivotal clinical trial designed to demonstrate the safety and efficacy of our Isolator clamps in a sole-therapy minimally invasive procedure for the treatment of AF.

Each clinical study that we intend to complete will require a separate IDE or an amendment to an existing IDE. There is a 30-day time period for the FDA to act on an IDE or an amendment to an IDE and the FDA typically requests additional information prior to granting approval for a study to proceed. We generally expect that it will take several months after we file an IDE or an IDE amendment to obtain FDA approval to proceed with a study.

We understand that Randall Wolf, M.D., a consultant who has conducted clinical studies on the use of our Isolator clamps to treat AF and published articles relating to such studies, received a warning letter from the FDA, dated September 28, 2006, regarding certain objectionable conditions observed during the FDA inspection conducted at his clinical site from April 19, 2006 to May 22, 2006. Dr. Wolf was one of the lead investigators in our RESTORE-SRII trial regarding the feasibility of using our Isolator system in sole-therapy minimally invasive procedures, and also conducted his own independent study utilizing our Isolator system. Following the inspection of Dr. Wolf, in June of this year, 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. The FDA informed us that it was inspecting us for cause, based on articles that had appeared in The Wall Street Journal during December 2005 and February 2006 that related to, among other things, Dr. Wolf's relationship to us. At the close of these 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.

## **Regulatory Clearances**

### *United States*

In August 2001, the FDA granted us 510(k) clearance to market our Isolator clamps for the ablation and coagulation of soft tissues during general, ear, nose and throat, thoracic, gynecologic and urologic surgical procedures. We have not received FDA clearance or approval to promote our Isolator clamps for the ablation of cardiac tissue or for the use of our Isolator clamps in the treatment of AF. In December 2004, we submitted a 510(k) notification to obtain clearance for use of our Isolator clamps for the ablation of cardiac tissue, which we had previously sought in 2002 and 2003. In June 2005, the FDA denied that 510(k) clearance, finding that our Isolator clamps were not substantially equivalent to the already cleared predicate devices relied on in our 510(k) notice. This means that we would be required to obtain a PMA prior to the promotion of our Isolator clamps for the ablation of cardiac tissue. In October 2006, we appealed the FDA's decision. We were notified in December 2006 that the FDA reversed its decision that our Isolator clamps were not substantially equivalent to the already-cleared predicate devices. We are currently gathering data from our two clinical trials and our preclinical studies to complete our previously filed 510(k) to obtain clearance for our Isolator clamps for the ablation of cardiac tissue. We plan to file the data with the FDA during the first half of 2007.

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 Pen for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias.

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In October 2005, the FDA granted us 510(k) clearance to market our 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.

We anticipate filing a 510(k) notification in 2007 for the Cosgrove-Gillinov Left Atrial Appendage Occlusion Clip for an indication that includes left atrial appendage exclusion. We anticipate initial implants in humans outside of the United States during 2007.

### *International*

We received our original CE Mark approval for our Isolator bipolar ablation clamps 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 and received approval to market our Isolator clamps for the treatment of cardiac arrhythmias, including atrial fibrillation. We have also received certifications to market and sell our Isolator clamps in several other foreign markets, including Canada, Japan, China, Brazil, Colombia, Israel, Venezuela, Chili, Lebanon and Argentina.

We received our original CE Mark approval 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 approval for our Pen in July 2005, which allows us to market and sell our Pen throughout the European Union. We have also received approvals to market and sell our Pen in 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. It is our policy not to market or promote our Isolator clamps for the treatment of AF or the ablation of cardiac tissue. Our sales personnel visit cardiothoracic surgeons, electrophysiologists and other doctors to discuss the general attributes of our Isolator system, and they also promote our Pen for the surgical ablation of cardiac tissue and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias 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 general aspects of our Isolator system and 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, educate 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 in the treatment of AF. We also provide educational grants to several leading medical centers. These institutions have used these grants to sponsor independent activities to evaluate the effectiveness of our Isolator system and our 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 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.

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We have formed a healthcare compliance committee in support of our ongoing efforts to improve compliance 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. We have modified our training and educational programs to include training on federal and state requirements for marketing medical devices, and we have revised and maintain continuous oversight of our grant application and funding procedures and requirements.

Our sales team in the United States is led by two vice presidents of sales and four area sales directors. As of December 31, 2006, our sales force in the United States had a total of approximately 52 employees, including 23 full-time regional sales representatives and three independent manufacturers representatives. 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. During 2006, sales outside of the United States accounted for approximately 11% of our total revenue. We have a network of distributors outside of the United States who currently market and sell our products in Asia, Europe, Canada, the Middle East, Central America and South America. We continue to expand our presence in markets outside of the United States, including our entry into China, Japan, Canada, Brazil, Kuwait, Colombia, and Argentina and planned sales to Mexico in 2007. See Risk Factors Risks Relating To Our Business We sell the AtriCure Isolator bipolar ablation system outside of the United States and are subject to various risks relating to international operations, which could harm our international revenue and profitability.

We have one reporting segment. For information regarding revenue 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 sales 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., Boston Scientific Corp., Medical CV and CryoCath Technologies Inc. As of December 31, 2006, no company had received FDA approval or clearance to market an ablation system for use as a treatment for AF. However, our competitors have FDA clearance to market their non-bipolar clamp products that ablate cardiac tissue and we market our multifunctional bipolar Pen that is also cleared to ablate cardiac tissue. We and our competitors provide products that have been adopted by doctors for the off-label treatment of AF.

We and many of our competitors have developed surgical ablation devices that have been used to treat AF during open-heart surgical procedures. We and 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. Each of these companies is also currently working with its core technology to develop devices that can be used as a sole-therapy minimally invasive AF treatment.

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Some of our competitors offer catheter-based treatments, including but not limited to Biosense Webster, Inc., EP Technologies, St. Jude Medical, Inc., and Cardima, 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 the same group of patients that we believe would most benefit from minimally invasive AF treatments. Some of these catheter-based treatments already have FDA clearance or approval for cardiac use, including the treatment of certain arrhythmias, although none has 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 system will not be introduced. We also believe that our Isolator 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.

Competitors may develop technologies and products that are safer, more effective, easier to use or less expensive than our Isolator system. To compete effectively, we have to demonstrate that our Isolator system is 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 these competitors. Competitive pressures may result in price reductions and reduced margins for our products over time. Technological advances developed by one or more of our competitors may render our Isolator 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 hospital 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 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. There are several cardiothoracic 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 open-heart DRG. Reimbursement for sole-therapy minimally invasive AF treatment is a different cardiothoracic DRG. 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



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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. For open-heart concomitant ablation procedures, the AMA recommends use of the miscellaneous CPT code.

These new CPT codes better describe how physicians are surgically approaching sole-therapy ablation procedures. They better reflect the surgical approach, the extent of the ablation treatment and work required to perform the procedure. The new CPT choices are expected to reimburse physicians less than the one-size fits all CPT code of 2006 for sole-therapy procedures.

When ablation is performed with an open-heart concomitant procedure, per AMA guidelines, surgeons are now 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. However, reimbursement is determined solely by the payor. Based on this change, we expect that the reimbursement for open-heart concomitant procedures will be less when compared to the preceding year and this could negatively impact the demand for our products.

Currently, we believe that the AF treatment reimbursement rates are adequate for hospitals to cover the use of our Isolator system. In 2006, we estimate that the national Medicare average hospital payment rate for an open-heart procedure, whether or not the AF treatment is included, was approximately \$27,800 to \$38,800, 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 \$27,800 in 2006. 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 clamps have received FDA clearance for the ablation and coagulation of soft tissues during certain non-cardiac-related surgical procedures. However, because the FDA does not regulate the practice of medicine, doctors may use our Isolator clamps in circumstances where they deem it medically appropriate, even though the FDA has not approved or cleared our clamps 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.

### **Acquisition of Enable Medical Corporation**

Contemporaneously with the closing of the initial public offering of our common stock on August 10, 2005, we acquired Enable Medical Corporation, the manufacturer of our disposable Isolator clamps, which are an essential component of our Isolator 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

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Enable assets unrelated to our Isolator 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 product and provided contract design, research and development and manufacturing services to us and other medical device companies.

### **Government Regulation**

Each of the products comprising our Isolator bipolar ablation system is 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 our Isolator clamps in the United States under a 510(k) clearance for the ablation and coagulation of soft tissues during general, ear, nose and throat, thoracic, gynecologic and urologic surgical procedures. Currently, our Isolator clamps may not be marketed for ablation of cardiac tissue or for the treatment of AF without obtaining additional clearances and approvals from the FDA. Our multifunctional bipolar 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 under a 510(k) clearance for the ablation of cardiac tissue during cardiac surgery.

The FDA requires that premarket approval, or PMA, be obtained for a device before it can be marketed for the treatment of AF. A PMA will require clinical data supporting the safe and effective use of the device in the treatment of AF. In December 2003, we received an investigational device exemption, or IDE, from the FDA to conduct clinical trials of our Isolator clamps in a prospective, multi-center trial, known as the RESTORE-SR trial, to evaluate the safety and efficacy of our Isolator clamps for the treatment of AF during open-heart surgery. In addition, in July 2005, we received FDA approval to conduct a clinical study, RESTORE-SR II, to demonstrate the feasibility of using our Isolator clamps for the sole-therapy minimally invasive treatment of AF that also includes removal of a portion of the heart called the left atrial appendage. This feasibility study will likely be followed by a larger scale pivotal trial. We cannot assure you that we will successfully complete RESTORE-SR or RESTORE-SR II, receive approval for any additional clinical trials or submit and obtain approval for any of the products comprising our Isolator system for use in treating AF.

The Lumitip 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 dissector in the United States under a 510(k) clearance for use in the dissection of soft tissues during general, ear, nose and throat, thoracic, urological and gynecological surgical procedures. We anticipate filing a 510(k) application in the second quarter of 2007 for the Cosgrove-Gillinov Left Atrial Appendage Occlusion Clip for an indication that includes left atrial appendage exclusion. We are not currently seeking any further approvals or clearances from the FDA relating to these devices.

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;

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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 associated with 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.

The FDA has previously classified our Isolator clamps as a Class II device and has granted us 510(k) clearance to market these Isolator clamps for the ablation and coagulation of soft tissues during certain surgical procedures. The FDA denied 510(k) clearance of the Isolator clamps for the ablation of cardiac tissue because the FDA determined that our Isolator clamps are not substantially equivalent to an already-cleared device. The FDA has taken a position that no radio-frequency surgical clamps are general cardiac tools because radio-frequency surgical clamps are specifically designed and intended for use in surgical ablation to treat AF. As such, no radio-frequency surgical clamps from any medical device company, including ours, have been cleared for cardiac ablation to date. This means that we would be required to obtain a PMA prior to any promotion of our Isolator clamps for the ablation of cardiac tissue. In October 2006, we appealed the FDA's decision. We were notified in December 2006 that the FDA reversed its decision that our Isolator clamps were not substantially equivalent to the already-cleared predicate devices. We are currently gathering data from our two clinical trials and our preclinical studies to complete our previously filed 510(k) notification to obtain clearance for use of our Isolator clamps for the ablation of cardiac tissue. We plan to file the data with the FDA during the first half of 2007. Notwithstanding the FDA's decision, in order to market our Isolator clamps 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 one year or more. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously-cleared device or use, the device is automatically placed into Class III, requiring the submission of a PMA. Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, in connection with safety and effectiveness, approval of a PMA. The FDA requires every manufacturer to make the determination regarding a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. We have made modifications to elements of our Isolator system, 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

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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. 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 generally required to support a PMA and are sometimes required for 510(k) clearance. In the United States, clinical trials for a significant risk device require the prior submission of an application for an IDE to the FDA for approval. An IDE 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 for a specific number of patients. 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 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.

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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 off-label 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 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 governing the approval and marketing of a product. 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 promotion of products for uncleared, unapproved or off-label use or indication;

clearance or approval of product modifications that could significantly effect safety or efficacy or that would constitute a major change in intended use;

medical device reporting, or MDR, regulations, which require that manufacturers comply with reporting requirements of the FDA and report if their device may have caused or contributed to an adverse event, 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

notices of correction or removal and recall regulations.

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MDR regulations require that we report to the FDA any incident in which our product may have caused or contributed to an adverse event, a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. During 2006 and through March 15, 2007, we notified the FDA of fourteen reports of complications during procedures utilizing our products. Of these MDRs, six relate to our Isolator clamps and eight relate to the Lumitip dissector. There have also been other incidents, including patient deaths that have occurred during open-heart and sole-therapy minimally invasive procedures using our Isolator system that we have not, and believe were not required to be, reported to the FDA, because we determined that these incidents were not related to the use of our Isolator system.

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 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 indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service, for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General of the U.S. Department of Health and 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 imposes civil liability on any person or entity who submits, or causes the submission of a false or fraudulent claim to the United States Government. Damages under the Federal False





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Claims Act 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 Federal False Claims Act against pharmaceutical 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 claims to federal and state healthcare entitlement programs such as Medicaid, resulting in the payment of claims by Medicaid for the off-label use of the drug which was not a use of the drug otherwise covered by Medicaid. Such manufacturers have entered into settlements with the federal government under which they paid amounts and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions.

The federal authorities, and state equivalents, may likewise seek to enforce the False Claims Act against medical device manufacturers. 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 regulatory matters.

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.

***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 with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout

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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 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, 2006, we had issued United States patents that will expire between 2015 and 2022.

As of December 31, 2006, we had the following portfolio of 74 issued patents or patent applications covering our proprietary technologies and products:

24 issued United States patents;

23 United States non-provisional patent applications;

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3 United States provisional patent applications;

6 issued foreign patents;

10 pending foreign patent applications that are in various national stages of prosecution; and

8 pending foreign applications filed pursuant to the Patent Cooperation Treaty, or PCT, not at the national stage.

**Manufacturing**

We manufacture the majority of the components that comprise the AtriCure Isolator bipolar ablation system. However, some of the components of our Isolator system, including our ASU, come from outside suppliers. We inspect, assemble, test and package our products in West Chester, Ohio and our products are sterilized by outside sterilization facilities.

Purchased components for our Isolator system are generally available from more than one supplier, with the exception of our ASU. Our ASU is a critical component of our Isolator system, and there are relatively few alternative sources of supply available. We do not carry a significant inventory of this component and obtaining a replacement supplier for the ASU, if required, may not be accomplished quickly or at all and could involve significant additional costs. With the exception of Stellartech Research Corporation, the supplier of our ASU, our suppliers have no contractual obligations to supply us with, and we are not contractually obligated to purchase from them, any of our supplies.

In June 2005, we entered into a manufacturing agreement with Stellartech whereby we, among other things, are required to purchase at least 75% of our ASU requirements from Stellartech until November 2007. We may, however, extinguish our obligation to purchase 75% of our ASU requirements from Stellartech by paying to Stellartech either a certain percentage of the gross margin Stellartech would have received if it had manufactured the ASUs or a specified dollar amount. This agreement has an initial three-year term and renews for successive one-year periods, unless terminated. This agreement may be terminated by Stellartech for any reason upon six months' notice to us. We may terminate the agreement in the event the development agreement is terminated prior to expiration or after we have fulfilled the purchase requirements under the agreement. Under the terms of this agreement, we have certain indemnification obligations, including with respect to claims relating to intellectual property infringement, design defects and manufacturing defects. Any supply interruption or failure to obtain our ASU would limit our ability to sell our Isolator system and could have a material adverse effect on our business, financial condition and results of operations.

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 are under no 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 subcontractors. Our failure or the failure of our component 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

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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; 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. At the time of our acquisition of Enable, it advised us that it was in full compliance with ISO 9001:1994, and ISO 13485:2003 and it had undergone two full quality system audits and six surveillance audits by TUV America, Inc. Enable's most recent audit was in December 2004 and it was a full quality system audit. There were no major non-conformance issues and Enable had advised us that it was in substantial compliance with ISO 13485:2003 at the time of the acquisition. Additionally, in December 2004, Stellartech, the manufacturer of our ASU, 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 has 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, controlled drug 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 we increase commercialization efforts. 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 will 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 revenue and optimizing procedural results. 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 clamps include the third quarter 2006 release of a new Isolator clamp for open procedures, which incorporates many of the design enhancements of the endoscopic Isolator bipolar ablation clamps for minimally invasive procedures released in the fourth quarter of 2005. Product extensions and improvements of our multifunctional bipolar Pen include development of ancillary products such as the ablation switchbox that was released in the third quarter of 2006. The ablation switchbox allows the Pen to act as a multifunctional device serving as an ablation, stimulation and sensing tool. Our control module, released in the first quarter of 2007, further improved user efficiency of the Pen. Our product lines have also been advanced through software improvements, cost savings and support for increased production capacity.

During the first quarter of 2007, we released our new Isolator Synergy ablation clamps designed for ablation during open procedures and we plan to release the minimally-invasive version of our Isolator

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Synergy clamps in the second half of 2007. The Isolator Synergy products result in more effective ablations by enhancing the geometry of the lesions, creating a more uniform, full thickness ablation line.

Enabling devices, such as our Lunitip dissector, are becoming an increasingly larger portion of our development portfolio. In the first quarter 2007, we plan to release a dissection tool and a transfer guide, each of which is designed to simplify open procedures as the minimally invasive dissection system has done for minimally invasive procedures. Additionally, we continue to develop the Cosgrove-Gillinov Left Atrial Appendage Occlusion Clip, a device for the exclusion of the left atrial appendage.

In June 2005, we entered into a 19-month development agreement with Stellartech whereby Stellartech agreed to develop enhancements to the current ASU technology and granted us a license to use Stellartech's technology in the field of cardiac arrhythmia treatment. This agreement expired by its terms in December 2006. We agreed to pay Stellartech on an hourly basis, based on the types of services being performed. In addition, materials and components, out-of-pocket expenses and outside services were billed at cost plus a specified percentage. The agreement provided for certain indemnification obligations to Stellartech relating to its performance of services under the agreement, except for Stellartech's breach, fraud, negligence or misconduct and infringement relating to intellectual property owned by Stellartech, for each of which it indemnifies us.

In July 2005, we entered into a development and license agreement with UST Inc., whereby UST agreed to design and develop a high intensity focused ultrasound, or HIFU, system to create certain types of lesions and granted us an exclusive, worldwide license to related technology. We believe that HIFU may be a valuable alternative source of energy for making certain kinds of lesions. We agreed to pay UST an initial development fee of \$375,000 and an additional development fee of \$966,000, payable in fourteen monthly installments. In November 2006, in accordance with the terms of the agreement, we provided notice to UST to terminate the development services that it had been performing under the agreement. We are required to pay UST royalties of 4% of the net sales of the HIFU system, up to a maximum amount of \$15 million in royalties during the royalty term. In addition, we are required to make certain license and maintenance payments to UST for the sublicenses granted to us under the terms of this agreement. We may terminate this agreement at any time by giving notice to UST. UST may terminate this agreement if we fail to timely commercialize the HIFU system or if we fail to timely pursue FDA approval or clearance of the HIFU system. The agreement contains certain indemnification obligations in the event of a breach of the agreement. In order to commercialize this HIFU system, we may be required to license additional intellectual property from third parties. We cannot assure you that we will be able to license this technology on commercially reasonable terms, if it all.

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. Under the terms of the agreement, we may be required to spend up to \$2.7 million in the first eighteen months, \$4.3 million in the subsequent twelve months and \$5.4 million in the final twelve months. The agreement terminates in December 2008. However, we and The Cleveland Clinic may terminate the agreement at any time by giving 30 days' prior written notice.

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 Clip. Under this arrangement, we granted approximately 33,000 options 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

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commercialized products using the licensed technology. We have completed a series of pre-clinical studies which will support a 510(k) submission to the FDA in the second quarter of 2007 for a product using the licensed technology coupled with engineering advancement and manufacturing systems development by AtriCure.

### **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 in 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 for a term of one to three years. The agreements may generally be terminated by us or by the consultant upon 30 to 60 days notice. We own the rights to any inventions or ideas made or conceived by our consultants during performance of the consulting services.

Fees paid to consultants during 2006 ranged from \$500 to \$47,500 for the year. Beginning in the fourth quarter of 2005, we entered into new agreements with most of our consultants that replaced their existing agreements. These new agreements provided 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 are 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 will provide 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 will be paid \$12,000 per month. The term of the agreement is one year; provided, however, that if there is a change of control event, the agreement will terminate automatically upon consummation of the change of control event. Additionally, the agreement contains 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 revenue 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 revenue. 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 an 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 on 2006 sales of the Lumitip dissector were \$0.2 million.

### **Employees**

As of December 31, 2006, we had 176 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.

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### **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 clamps, which are an essential part of our Isolator 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 substantially all of our future revenue from sales of our AtriCure Isolator bipolar ablation system. If our Isolator system fails to gain or loses market acceptance for the treatment of AF, we may not generate sufficient revenue to continue our operations.**

Currently, our primary product line is our AtriCure Isolator bipolar ablation system, which we commercially introduced beginning in 2002 in the United States and in 2003 outside of the United States. We expect that sales of our Isolator system will account for substantially all of our revenue for the foreseeable future and that our future revenue will depend on the increasing acceptance by the medical community of our Isolator system 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 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 system. Our Isolator system and the procedures involved with the treatment of AF using our system is relatively new. We cannot assure you that doctors will continue to use our Isolator system or that demand for the surgical treatment of AF will not decline or will not increase as quickly as we expect.

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

our inability to promote our Isolator bipolar ablation clamps for use on cardiac tissue or for the use of any of our products for the treatment of AF until we obtain additional FDA approvals or clearances;



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our inability to train doctors in the use of our Isolator clamps for the ablation of cardiac tissue or for the use of any of our products for the treatment of AF until we obtain additional FDA approvals or clearances;

our inability to sustain acceptance of our Isolator system within the medical community;

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

findings or perceptions relating to the safety or effectiveness of our Isolator system or 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 malfunction or cause or contribute to a death, serious injury or other adverse event;

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

the cost of our Isolator system;

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 Isolator system; and

policies of healthcare payors with respect to coverage and reimbursement.

Since we do not believe that doctors are using our Isolator system for any purpose other than the surgical treatment of AF, if doctors do not use our Isolator system to treat AF, we would lose substantially all of our revenue.

**Use of our Isolator 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 system is not widely adopted for use in this market, it may adversely impact our ability to grow our revenue.**

We believe that sole-therapy minimally invasive 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 system is not widely adopted for use in this market, it may adversely impact our ability to grow our revenue. 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 clamps, that clinical testing of our Isolator system is in the feasibility 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 system for the sole-therapy minimally invasive treatment of AF, and our future growth and revenue will suffer.

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

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

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. 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 ablation of cardiac tissue, with the exception of our multifunctional bipolar Pen, or the

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surgical treatment of AF unless and until we obtain additional FDA approvals or clearances. 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 additional FDA approvals or clearances, we will not be able to promote our Isolator system to treat AF or, with the exception of our Pen, to ablate cardiac tissue 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 for the ablation of cardiac tissue or for the use of our Isolator system in the treatment of AF, with the exception of our Pen, which the FDA has cleared for the ablation of cardiac tissue and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. In December 2004, we submitted a 510(k) notification to obtain clearance for use of our Isolator clamps for the ablation of cardiac tissue, which had previously been sought by us and denied in 2002 and 2003. In June 2005, the FDA denied 510(k) clearance, finding that these Isolator clamps were not substantially equivalent to the already cleared predicate devices relied on in our 510(k) notice. However, we appealed this decision and after a supervisory review meeting with the FDA on October 23, 2006, the FDA's Office of Device Evaluation reversed its decision on December 4, 2006. As a result, we are currently working with the FDA to provide data from our two US clinical trials and preclinical studies to complete our previously filed 510(k) for our Isolator clamps and gain cardiac tissue ablation clearance. We cannot assure you that the FDA will accept this data and clear our Isolator clamps for this indication, but we intend to file this information with the FDA during the first half of 2007. Whether or not the FDA provides clearance for the use of our Isolator clamps to ablate cardiac tissue, we will need to obtain separate approvals from the FDA for use of our Isolator system 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 Isolator clamps for the ablation of cardiac tissue or, with respect to all of our products, for the treatment of AF, we and others acting on our behalf may not promote our Isolator system 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 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.

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**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 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 for the treatment of AF, we will need to demonstrate in clinical trials that our system is safe and effective for such use. In order to 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 clamps as a treatment for AF during open-heart surgical procedures, 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 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 study relating to the use of our Isolator 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 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 clamps for the treatment of AF during elective open-heart procedures and enrollment in the trial has been 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). We are currently working with the FDA to redesign the RESTORE-SR trial and hope to file a new IDE and start enrollment into the redesigned trial in the summer of 2007. As with the current RESTORE-SR trial, we cannot assure you that this new clinical trial will be approved by the FDA or 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 clamps as a sole-therapy minimally invasive treatment for AF. This study enrolled 25 patients at 5 leading US centers. We are currently working with our investigators to write a final clinical report to the FDA and hope to use this clinical data in support of adding a new arm to this study, RESTORE-SR IIB. In RESTORE-SR IIB, we intend to study patients experiencing persistent and permanent AF using an expanded lesion set and new technologies. We cannot assure you that this study will be approved by the FDA or 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 system 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 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 system 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 system. If we do not secure required FDA approval to promote our Isolator 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 system against any alternative treatments without conducting comparative clinical studies, which would be expensive and time

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

If the available data on the use of our Isolator 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 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 have 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 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 system. We also believe that this publicity has had and may continue to have a negative impact on clinical studies involving our Isolator 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 system in the treatment of AF, which is considered an off-label use of our system because the sole indication for which our system has received FDA clearance or approval is the ablation and coagulation of soft tissues during certain non-cardiac-related surgical procedures, except that our Pen has been 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 system, for off-label uses. This means that we may not make claims about the safety or effectiveness of our Isolator system for the ablation of cardiac tissue, except with respect our Pen, or the treatment of AF and may not proactively discuss or provide information on the use of our system for the treatment of AF, except in certain limited scientific and other settings.

Due to these legal constraints, our sales and marketing efforts focus only on the general technical attributes and benefits of our Isolator system and not on the use of our system for AF treatment or other cardiac uses, with the exception of our Pen which we may promote for the ablation of cardiac tissue. At the same time, we provide certain support for the use of our Isolator system in the treatment of AF that we believe is non-promotional and therefore permitted. In particular, since our Isolator system is only being used by doctors for the treatment of AF, we train our sales force on the use of our system by 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 system 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

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training and instructional tools. In addition, medically trained clinical application specialists attend surgical procedures to discuss the general attributes of our Isolator system and respond to unsolicited requests for information on the use of our system 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 Isolator system. 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 Isolator system in the treatment of AF. We also continue to make improvements in our Isolator system which could be viewed as supporting the ablation of cardiac tissue and 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 system for a non-FDA-approved use in violation of the law. We also face the risk that the FDA or other regulatory 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 clamps, which information we subsequently removed. There is also a possibility that we could be enjoined from making sales of our Isolator system for any non-FDA-approved use, which effectively would bar all sales of our system 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 system was 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 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.

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**Our current inability to educate or train doctors in the use of our Isolator system 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 Isolator system, but it is our policy not to educate or train doctors to use our system for the ablation of cardiac tissue, except with respect to our Pen, or for the surgical treatment of AF. Hospitals and universities offer independent educational programs for the treatment of AF utilizing our Isolator system, 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 system have any specific training in the use of our system. We cannot assure you that doctors utilizing our Isolator system are using it 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 system. Not requiring training on the use of our Isolator system may expose us to greater risk of product liability for injuries occurring during procedures utilizing our system. If demand for our Isolator system grows, the increased number of procedures performed using our system may potentially lead to more injuries and an increased risk of product liability. In addition, the off-label use of our Isolator system by the 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 system, 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 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 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 system, are not safe, could harm our business, including in the following ways:

our Isolator system 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 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 system for the ablation of soft tissue;

the FDA or foreign regulatory authorities may refuse, delay or revoke clearances, approvals or clinical trials of our Isolator system for the ablation of cardiac tissue or 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.

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

The medical device industry, including the market for the treatment of AF, is highly competitive, subject to rapid technological change and significantly affected by new product introductions and promotional activities of other participants. We cannot assure you that our Isolator system will compete effectively against drugs, catheter-based ablation, implantable devices such as pacemakers or defibrillators, other ablation

systems or other



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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., Boston Scientific Corporation, 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 or FDA approval for the use of their products to ablate cardiac tissue during open-heart surgery. 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 of our Isolator system. Furthermore, demand for our Isolator system 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 system. 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 issue 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 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.

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

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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 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, 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 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 system may infringe. There could also be existing patents of which we are unaware that one or more components of our Isolator system may inadvertently infringe. As the number of competitors in the market for the treatment of AF grows, 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 system 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.

**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 by doctors for an off-label indication may cause certain doctors or hospitals to decide not to use our system 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

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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 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 \$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, 2006, we had an accumulated deficit of \$56.1 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. 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 revenue sufficiently to offset these higher expenses. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' deficit and we may never become profitable.

### **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 \$21 million at December 31, 2006 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 revenue generated by sales of our products;

the costs associated with expanding and growing our business;

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.



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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 revenue 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, 2006, we had a total of 176 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 must manufacture commercial quantities of our Isolator system's 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 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 revenue 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 system. For example, we rely on one vendor to manufacture our ASU, and we have not been able to identify any alternate supplier to manufacture our ASU if it 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 Isolator system. We also distribute a cryothermy, or extreme cold, ablation device that doctors have used to make specialized lesions in the heart for the treatment of AF in addition to the lesions made by our Isolator system, and our inability to offer this device to potential users of our system could negatively affect sales of our system.

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 system;

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.

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Identifying and qualifying additional or replacement suppliers for any of the components used in our Isolator system, 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.

**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.**

At the time we acquired Enable, we recorded an asset called goodwill for the amount we paid for Enable, including liabilities assumed, in excess of the fair value of the assets we acquired. As of December 31, 2006, we have recorded \$3.8 million of goodwill in connection with the acquisition of Enable. 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 the assets acquired from Enable as of September 30, 2006. 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 revenue or estimated 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 the products or components supplied to us by third parties. Managing our inventory levels is important to our cash position and results of operations. As we expand, managing our inventory levels becomes more difficult. 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 revenue. An inability to forecast future revenue or estimated life cycles of products may result in inventory-related charges that would negatively affect our gross margins and results of operations.

**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 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 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

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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;

product advertising, sales and promotion;

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

product corrective actions, removals and recalls; and

import and export.

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

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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.



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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. During 2006 and through March 15, 2007, we have submitted a total of fourteen medical device reports to the FDA involving our products. There have also been other incidents, including patient deaths, that have occurred during open-heart and sole-therapy minimally invasive procedures using our products that we have not, and believe were not required to be, reported to the FDA because we determined that these incidents were not related to the use of our products. 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 product in the market.

**Modifications to our Isolator system may require new clearances or approvals or require us to cease promoting or recall the modified products until such clearance or approvals are obtained.**

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 in the first instance, but the FDA may review any medical device company's decision. We have previously made modifications to our Isolator system but do not believe such modifications require us to submit an additional 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;

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

state laws that prohibit the practice of medicine by non-doctors and by doctors not licensed in a particular state, and fee-splitting arrangements between doctors and non-doctors, as well as state law equivalents to the Anti-Kickback Statute and the Stark Law, which may not be limited to government-reimbursed items;

Federal and State healthcare fraud and abuse laws or laws protecting the privacy of patient medical information, including the Health Insurance Portability and Accountability Act, or HIPAA;

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

similar and other regulations outside the United States.

Certain federal and state laws regarding Medicare, Medicaid and physician self-referrals are broad and we may be required to change one or more of our practices to be in compliance with these laws. Healthcare fraud and abuse regulations are complex and even minor, inadvertent irregularities in submissions can potentially give rise to claims that a statute has been violated. Any violations of these laws could result in a material adverse effect on our business, financial condition and results of operations. For example, if we were found to be in violation of the federal False Claims Act, we would likely face significant fines and penalties and would likely be required to change substantially our sales, promotion, grant and educational activities. There is also a possibility that we could face an injunction that would prohibit in whole or in part our current business activities, and, as a result of enforcement actions against us or our senior officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations.

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 from governmental or other third-party payors, it could affect the adoption or use of our system and may cause our revenue 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

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system. 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. The new 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 recommends use of the miscellaneous CPT code. We expect that the reimbursement for open-heart concomitant procedures will be less when compared to the preceding year and this could negatively impact the demand for our products.

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 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 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 system.**

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 system 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 system. 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 system. Alternatively, government or private payors may deem the treatment of AF utilizing our Isolator 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.

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**We have limited long-term clinical data regarding the safety and efficacy of our Isolator system. 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 Isolator system is adopted by the medical community.**

Our success depends upon the increasing acceptance of our Isolator 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 of sole-therapy minimally invasive procedures in which our Isolator system was used. Important factors upon which the efficacy of our Isolator 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 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 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 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 system for the treatment of AF, our system 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 treatment of AF during open-heart surgical procedures and as a sole-therapy minimally invasive treatment.

If the results obtained from our RESTORE-SR trial or any other clinical studies or clinical or commercial experience indicate that our Isolator system is 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 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.

Even if we believe the data collected from clinical studies or clinical experience indicates positive results, each doctor's actual experience with our Isolator system may vary. Clinical studies conducted with our Isolator clamps 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 rates of adoption of our Isolator system.

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

During the twelve months ended December 31, 2006, 11% of our total revenue was attributable to sales in markets outside of the United States. We currently depend on third-party distributors to sell our Isolator system outside of the United States, and if these distributors underperform, we may be unable to increase or maintain our level of international revenue. Over the long term, we intend 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 Isolator system. Distributors may not commit the necessary resources to promote and sell our Isolator system 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 international revenue growth.

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

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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 system outside of the United States;

international terrorism and anti-American sentiment;

fluctuations in exchange rates for future sales denominated in foreign currency; 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 system outside of the United States may decrease and we may fail to achieve or maintain significant sales outside of the United States.**

Our revenue generated from sales outside of the United States is also dependent upon the availability of coverage and reimbursement within prevailing foreign healthcare payment systems. In general, foreign healthcare payors do not provide reimbursement for sole-therapy minimally invasive procedures utilizing ablation devices such as our Isolator 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 system, and these efforts are expected to continue. To the extent that use of an ablation device such as our Isolator system has 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 system 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.**

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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.

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**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 effect 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 carriers should deny coverage, 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 Isolator 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.

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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 system 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 on direct sales employees and manufacturer's representatives to sell our Isolator system 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 and tool development, market development and clinical development. If any of these doctors end their relationship with us, our business would 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.

### **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 system;

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;





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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;

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.

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 revenue and earnings, have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. These market prices generally are not sustainable and are highly volatile. In the past, companies that experience volatility in the market price of their securities have often faced securities class action litigation. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management's attention and resources and harm our ability to grow our business.

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

We had approximately 12.3 million shares of common stock outstanding as of March 16, 2007. 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 approximately 6.0 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 that may be favorable to you.**

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

As of December 31, 2006, our executive officers, directors and principal stockholders, and entities affiliated with them, beneficially owned in the aggregate approximately 45% of our common stock. This significant

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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 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 dictate 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.

**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.**

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

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

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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.

**ITEM 2. PROPERTIES**

We maintain our headquarters in West Chester, Ohio in a facility of approximately 12,200 square feet, which contains both office and warehouse space. We currently pay monthly rent of approximately \$11,000 and the lease for this facility expires in May 2009. In addition, we have four separate leases for a total of approximately 26,000 square feet of office, production and warehouse space in West Chester, Ohio, with an aggregate monthly rent of approximately \$17,000 and three of the leases for these facilities expire in 2010 and the other is 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*

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, and our motion to dismiss this suit is currently pending.

*Life Support Technology LST B.V.*

Multiple proceedings exist between Life Support Technology LST B.V., a former distributor of our products in Europe, and us. In January 2006, LST filed an action against us in Den Bosch, Netherlands and in March 2006 we brought an action in Ohio against LST.

On January 11, 2006, Udink & De Jong, our Netherlands counsel, received a copy of a summons to be served on us in the United States. The summons was prepared on behalf of LST. We and LST were party to a distribution agreement, dated January 1, 2004. The summons alleges that we and LST reached an agreement, which would succeed the January 1, 2004 agreement, pursuant to which LST agreed to continue distributing our products in certain European countries. The summons also alleges that, in addition to the value for LST of a continued distributorship, the agreement would have provided approximately \$330,000 to LST and its principal, J.L.M. Marinus. We believe that we did not reach such an agreement with LST and that the original distribution agreement with LST was terminated as of December 31, 2005. We have vigorously defended this action in the Netherlands. Among other things, our Netherlands counsel moved for dismissal based on lack of jurisdiction or, in the alternative, for suspension of the Netherlands proceedings pending determination of the Ohio proceedings.

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described below. By decision dated February 14, 2007, the Netherlands District Court dismissed LST's action, holding that the Court lacks jurisdiction. This decision can be appealed up to May 14, 2007, within three months after the decision. To date, LST has given no indication that it intends to appeal the decision.

Pursuant to the January 1, 2004 distribution agreement with LST, certain of LST's obligations survive termination of the agreement. Such obligations include, among other things, the timely payment for equipment purchased and the return of all information materials (such as marketing literature and sales and promotional materials) supplied by us to LST. LST has not complied with certain of these obligations. Therefore, in March 2006 we filed a complaint in Ohio State Court (Butler County, Ohio Court of Common Pleas) against LST claiming that LST has not complied with these obligations and we are seeking damages which, due to Ohio pleading limitations, are alleged to be more than \$25,000 but which, in fact, we believe are in an amount in excess of \$185,000. In this Ohio proceeding, LST has asserted, in the form of counterclaims against us, similar claims to which it has asserted in the Netherlands proceeding. We recently filed a motion for summary judgment seeking to dismiss LST's counterclaims. Discovery in the Ohio action has been substantially completed and the trial is set for April 30, 2007.

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 March 15, 2007.

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
David J. Drachman	48	<i>President, Chief Executive Officer and Director</i>
Julie A. Piton	35	<i>Vice President, Finance and Administration and Chief Financial Officer</i>
Elsa Chi Abruzzo	39	<i>Vice President, Regulatory and Clinical Affairs</i>
James L. Lucky	45	<i>Vice President, Quality Assurance and Healthcare Compliance</i>
Frederick Preiss	56	<i>Vice President, Operations</i>
Salvatore Privitera	40	<i>Vice President, Product Development</i>
Maureen A. Shaffer	42	<i>Vice President, Marketing</i>

*David J. Drachman* has served as President, Chief Executive Officer and a 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.

*Julie A. Piton*, CPA has served as our Vice President of 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 Master's in Business Administration from the University of Wisconsin.

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*Elsa Chi Abruzzo* has served as our Vice President, Regulatory and Clinical Affairs since February 2004. From 2002 to 2004, Ms. Abruzzo served as Senior Director, Regulatory and Clinical Affairs of Percutaneous Valve Technologies, Inc., a medical device manufacturer. From 1997 to 2002, Ms. Abruzzo served as Director of Regulatory Affairs and Manager of Regulatory Affairs of CryoLife, Inc., a publicly-held developer of implantable medical devices. Prior thereto, Ms. Abruzzo held a number of increasingly responsible positions in manufacturing, engineering, quality assurance, clinical research and regulatory affairs at various medical device companies, including Baxter International, Inc., Cordis Corporation and Cordis Endovascular (a subsidiary of Johnson & Johnson). Ms. Abruzzo received her B.S. from the University of Miami and is a Regulatory Affairs Certified Professional.

*James L. Lucky* has 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 M.B.A. 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, Product Development since October 2003, and previously served 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 15 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 20 issued and filed U.S. patents. Mr. Privitera received his B.S. from the University of Buffalo and his M.B.A. from Xavier University.

*Maureen A. Shaffer* has served as our Vice President, Marketing since October 2006 and previously was our Director of Marketing since 2004. From 1999 to 2002, Ms. Shaffer served as the Director of Marketing at Converge Medical, a developer of cardiovascular medical devices. Prior to 1999, Ms. Shaffer held a variety of marketing and business development positions with medical device companies, including United States Surgical, Heartport, Fiberoptic Sensors and Cordis Corporation. Ms. Shaffer received her B.S. in Biomedical Engineering from Duke University. Ms. Shaffer filed for personal bankruptcy in September 2005.



**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**

We closed our initial public offering on August 10, 2005. 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 since the date of our initial public offering through December 31, 2006.

	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
	Price Range	
	High	Low
<b>2005</b>		
Third Quarter (from August 10, 2005)	\$ 15.45	\$ 12.03
Fourth Quarter	\$ 14.32	\$ 10.50

As of March 16, 2007, the closing price of our common stock on the Nasdaq Global Market was \$10.96 per share, and the number of stockholders of record was 86.

**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.

As of December 31, 2006, we had \$19.5 million in cash, cash equivalents and short-term investments. Of the \$43.2 million in net proceeds from the initial public offering of our common stock, through December 31, 2006, we have spent \$6.4 million of these proceeds toward the acquisition of Enable Medical Corporation, \$3.6 million to acquire property and equipment and \$13.7 million was primarily spent to fund our business operations.

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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**

In connection with the establishment of a credit facility with Lighthouse Capital Partners V, L.P. on March 8, 2005, we granted Lighthouse a warrant to purchase 55,208 shares of our common stock, or shares into which such series of stock is converted, at a price of \$11.29 per share. The warrant expired unexercised on August 10, 2006.

Warrants to purchase an aggregate of 195,160 shares of common stock at an exercise price of \$5.43 per share were automatically exercised on August 10, 2006. The automatic exercise was effected as a net issue exercise in accordance with the terms of the warrants, pursuant to which the warrant holders were not required to make a cash payment to exercise their warrants. The exercise price was instead deducted from the number of shares of common stock that the warrant holders received based on the fair market value of the common stock as determined in accordance with the terms of the warrants.

**Equity Compensation Plans**

The following table summarizes information about our equity compensation plans as of December 31, 2006.

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	1,906,928	\$ 6.79	1,321,551
Equity compensation plans not approved by security holders	0	0	0
<b>Total</b>	<b>1,906,928</b>	<b>\$ 6.79</b>	<b>1,321,551</b>

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

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**Performance Graph**

The following graph compares the cumulative total stockholder return on our common stock with the cumulative total return of the Nasdaq Market, U.S. Index ( Nasdaq U.S. Index ) 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, 2006.

\* The graph assumes that \$100 was invested on August 5, 2005 in our common stock, the Nasdaq U.S. Index and the Nasdaq Medical Equipment Index, and that all dividends were 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. This graph was prepared by Valuation Research Corporation.

**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, 2006, 2005, and 2004, and the balance sheet data as of December 31, 2006 and 2005 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, 2003 and 2002, and the balance sheet data as of December 31, 2004, 2003 and 2002 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,				
	2006	2005	2004	2003	2002
(in thousands, except per share data)					
<b>Operating Results:</b>					
Revenues	\$ 38,243	\$ 30,957	\$ 19,157	\$ 9,792	\$ 1,766
Cost of revenues	7,626	8,057	5,202	2,612	681
Gross profit	30,617	22,900	13,955	7,180	1,085
Gross margin	80.1%	74.0%	72.8%	73.3%	61.4%
Operating expenses	45,386	33,750	19,608	10,537	6,747
Preferred stock interest expense		2,332	3,905	3,905	2,563
Net loss	(13,717)	(12,683)	(9,452)	(7,108)	(9,031)
Basic and diluted net loss per share	\$ (1.13)	\$ (2.10)	\$ (5.17)	\$ (3.97)	\$ (5.08)
Weighted average shares outstanding	12,137	6,025	1,828	1,792	1,777
<b>Financial Position:</b>					
Cash, cash equivalents and short-term investments	\$ 19,488	\$ 33,802	\$ 5,175	\$ 10,399	\$ 15,434
Working capital	23,031	35,903	6,590	11,985	15,836
Total assets	39,128	50,040	12,731	14,759	17,586
Long-term obligations	693	1,084			
Redeemable preferred stock			36,756	32,805	2
Accumulated deficit	(56,055)	(42,337)	(29,633)	(20,135)	(9,047)
Stockholders' equity (deficit)	30,694	43,183	(27,331)	(18,937)	17,020

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**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 develop, manufacture and sell innovative surgical devices designed to create precise lesions, or scars, in cardiac and soft tissues. Our primary product line is our AtriCure Isolator bipolar ablation system, which accounted for a total of 98% of our revenues for the fiscal year ended December 31, 2006, 97% of our revenues for the fiscal year ended December 31, 2005 and 99% of our revenues for the fiscal year ended December 31, 2004. Our Isolator system consists of our ASU, a compact power generator that uses our proprietary software and delivers bipolar radio-frequency energy, multiple configurations of our Isolator bipolar ablation clamps and our multifunctional bipolar Pen. We sell two configurations of our Isolator clamps, one designed for ablation during open-body, or open, procedures and one designed for ablation during minimally invasive procedures, which are performed on patients who are not undergoing a separate open procedure. Our Isolator clamps and our Pen are each powered by the same ASU. 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 fluid from the energy pathway in order to make the ablation more effective.

Medical journals have described the adoption by leading cardiothoracic surgeons of our Isolator clamps 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. Cardiothoracic surgeons have used our Isolator system to treat AF in over 35,000 patients since January 2003. Based on this adoption of our products, we believe that our Isolator clamps are currently the market leader in the surgical treatment of AF during open-heart surgical procedures. Additionally, leading cardiothoracic surgeons have described our Isolator clamps as a promising treatment alternative for patients who may be candidates for sole-therapy minimally invasive procedures.

During the third quarter of 2006, we released our Isolator clamps that are designed for ablation during open procedures, which feature an ergonomic design that improves the surgeon's access to key anatomical structures and simplifies the ablation procedure. During the first quarter of 2007, we introduced the new Isolator Synergy ablation clamps for ablation during open procedures, which is the next generation of our Isolator clamps for open procedures.

We sell a pen-shaped ablation device known as the multifunctional bipolar Pen, which has been cleared by the FDA for the surgical ablation of cardiac tissue and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. This disposable handpiece is powered by the same ASU that powers our Isolator clamps and is compatible with standard external pacing, sensing/recording and stimulating systems. Because of its broad range of capabilities, surgeons are using this device during both open-heart and sole-therapy minimally invasive procedures in combination with our Isolator clamps. The Pen enables surgeons to evaluate cardiac arrhythmias and ablate cardiac tissue with the same device and allows surgeons to toggle back and forth between stimulation and ablation. We released the Pen for sale in the third quarter of 2005.

Additionally, we are developing the Cosgrove-Gillinov Left Atrial Appendage Occlusion Clip, which is designed to exclude the left atrial appendage, the small appendage that is attached to the left atrium, during open-

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heart surgical procedures and which may also be used to provide an option for high risk patients as a stand-alone left atrial appendage exclusion procedure following catheter ablation or pacemaker implantation. 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, we expect to file with the FDA a 510(k) notification for the Clip for an indication that includes left atrial appendage exclusion. Additionally, we anticipate initial implants in humans outside of the United States during 2007.

In September 2006, we expanded our CE Mark indications and received approval to market our Isolator clamps for the treatment of cardiac arrhythmias, including atrial fibrillation. Our Isolator clamps are the only bipolar radiofrequency clamps that are approved for this indication in the European Union. The expanded European Union indication provides physicians the reassurance that clinical data supporting the AF treatment claims were reviewed and accepted by European regulatory authorities.

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 clamps, raising capital, obtaining product clearances, conducting product testing and evaluations, and recruiting personnel. After limited sales of our Isolator clamps in 2002, we commenced the general commercial release of our clamps designed for open procedures in January 2003.

We currently sell our Isolator system to customers in the United States primarily through our direct sales force. Our European subsidiary, based in the Netherlands, markets and sells our products throughout Europe, primarily through distributors. Additionally, we sell our products to other international distributors, primarily in Asia, Europe, Central America, South America, Canada and the Middle East. Our business is primarily transacted in U.S. dollars, with the exception of transactions with our European subsidiary, which are transacted in Euros. Our sales outside of the United States constituted 10.9%, 8.7% and 7.4% of our total revenue for 2006, 2005 and 2004, respectively. We expect international sales to be relatively constant as a percentage of sales for the foreseeable future.

Our future growth will depend on the increasing acceptance by the medical community of our Isolator system as a standard treatment alternative for the surgical treatment of AF. Acceptance of our Isolator system is dependent upon, among other factors, awareness and education of the medical community about the surgical treatment of AF, in general, and the safety and effectiveness of our Isolator system, in particular.

Our Isolator clamps have been cleared by the FDA for the ablation and coagulation of soft tissues during general and thoracic surgical procedures, but they have not been cleared or approved in the United States for the ablation of cardiac tissue. We have received FDA clearance for our Pen for cardiac tissue ablation and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. As such, we may promote our Pen to doctors and provide education and training on its use for those approved indications. However, other than the FDA-cleared indications for our Pen and our dissection tools, we do not believe that any of our products are currently being used for their FDA-cleared indications and, accordingly, substantially all of our revenue is currently generated through the off-label use of our Isolator system for the treatment of AF.

None of our products have been approved by the FDA for the treatment of AF. While the FDA does not prevent doctors from using products off-label, we cannot legally market a product for an off-label use. Because our Isolator system is currently our only significant product line, the sustainability of our current operations, as well as our future viability, is dependent upon the continuation of sales of our Isolator system. We believe that sole-therapy minimally invasive treatment for AF represents the largest growth opportunity for us. If this market fails to develop, or our Isolator system is not widely adopted for use in this market, we may not achieve greater revenue or become profitable. In order to establish the minimally invasive sole-therapy AF treatment market, the current referral practices of physicians must change.

We are in the process of conducting clinical trials and if these trials are successful, we intend to seek FDA approval as early as 2009 for the use of our Isolator system to treat AF, which we view as our market

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opportunity. If the FDA were to require us to have AF approval for the products comprising our Isolator system in order for us to continue selling these products, not only would we no longer receive revenue 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 assure you that we can obtain these FDA approvals, 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 Isolator system.

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 trials. We are conducting the FDA-approved RESTORE-SR clinical trial relating to the use of our Isolator clamps for procedures to treat AF during open-heart surgery. A total of 44 patients have been enrolled in the clinical trial as of March 15, 2007, 19% of the patients required for this multi-center, 226-patient clinical trial. We are also conducting the FDA-approved RESTORE-SR II clinical study to evaluate the feasibility of using our Isolator clamps as a minimally invasive sole-therapy treatment for AF. This feasibility study has completed enrollment and treatment of the necessary 25 patients at 5 leading US centers as of May 31, 2006. Selling, general and administrative expenses consist principally of costs associated with our sales, marketing and administrative functions, accounting and legal fees and unrestricted educational grants to medical institutions.

**Results of Operations****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 total revenue:

	Year Ended December 31,			
	2006	% of Revenue (dollars in thousands)	2005	% of Revenue
	Amount		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 income (expense):				
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 a 26% increase in the total number of disposable units sold domestically and internationally. This volume increase in disposable units sold contributed \$8.3 million to the increase in revenues and an increase in non-disposable units sold contributed \$0.6 million to the increase in revenues. Though our domestic and international revenues were both favorably impacted by increases in the





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average selling prices of our disposable units, 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. The decline in our worldwide average selling prices partially offset the overall revenue increase by \$1.6 million.

**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 Isolator clamps. The decrease in our average cost per unit contributed \$1.4 million to the decrease in cost of revenues and was partially offset by an increase in the total number of units sold. 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 activities. Our product development activities included projects to extend and improve our Isolator bipolar ablation system, develop our new Isolator Synergy ablation clamps and the Cosgrove-Gillinov Left Atrial Appendage Occlusion Clip, 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. Research and development costs are expected to increase in 2007 in absolute dollars as a result of costs associated with the continued expansion of product development initiatives and clinical trials and are expected to decrease as a percentage of revenues.

**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 revenue, selling, general and administrative expenses increased from 79.6% in 2005 to 86.7% in 2006. Selling, general and administrative costs are expected to increase in 2007 in absolute dollars as a result of increased costs associated with sales and marketing efforts and are expected to decrease as a percentage of revenues.

**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 cash, cash equivalents and investments resulting from the proceeds of our August 2005 initial public offering.

**Table of Contents****Years Ended December 31, 2005 compared to December 31, 2004**

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,		2004	
	2005	% of	2004	% of
	Amount	Revenue	Amount	Revenue
	(dollars in thousands)			
Revenues	\$ 30,957	100.0%	\$ 19,157	100.0%
Cost of revenues	8,057	26.0%	5,202	27.2%
Gross profit	22,900	74.0%	13,955	72.8%
Operating expenses:				
Research and development expenses	9,109	29.4%	4,422	23.1%
Selling, general and administrative expenses	24,641	79.6%	15,186	79.3%
Total operating expenses	33,750	109.0%	19,608	102.4%
Loss from operations	(10,850)	-35.0%	(5,653)	-29.5%
Other (expense) income:				
Preferred stock interest expense	(2,332)	-7.5%	(3,905)	-20.4%
Interest income, net	414	1.3%	106	0.6%
Grant income	85	0.3%		0.0%
Net loss	\$ (12,683)	-41.0%	\$ (9,452)	-49.3%

**Revenues.** Total revenues increased \$11.8 million or 61.6%, from \$19.2 million in 2004 to \$31.0 million in 2005. The increase was primarily attributable to a 65% increase in the number of disposable units sold. This volume increase in disposable units sold contributed \$11.5 million to the increase in revenues and an increase in non-disposable units sold contributed \$0.2 million to the increase in revenues. Though our domestic and international revenues were both favorably impacted by increases in the average selling prices of our disposable units, the increased number of generally lower-priced international units sold as a percentage of total units sold resulted in a modest increase in our worldwide average selling prices year over year, contributing \$0.1 million to the overall revenue increase.

**Cost of revenues.** Cost of revenues increased \$2.9 million, from \$5.2 million in 2004 to \$8.1 million in 2005. This increase resulted primarily from an increase in the total units sold, additional depreciation associated with generators and cryo-units that are loaned at no cost to hospitals, a \$0.2 million increase in our obsolescence reserve, and a \$0.3 million write-off related to production equipment for discontinued products. These increases in cost of revenues were partially offset by our lower average cost per unit as a result of our third quarter acquisition of Enable Medical Corporation. As a percentage of revenues, cost of revenues decreased from 27.2% in 2004 to 26.0% in 2005.

**Research and development expenses.** Research and development expenses increased \$4.7 million, from \$4.4 million in 2004 to \$9.1 million in 2005. The increase was primarily attributable to the addition of 25 full-time research and development personnel, including 13 former Enable employees, the expansion of our research and development activities to increase our product offerings and the expansion of our clinical trial activities. Our product development activities included projects to extend and improve our Isolator system, develop our endoscopic Isolator bipolar ablation clamps, create new enabling devices such as new dissection, guidance and ablation tools, and research new technologies. As a percentage of revenues, research and development expenses increased from 23.1% in 2004 to 29.4% in 2005 due to increased spending on new product initiatives, expanded clinical trials and the addition of personnel.

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**Selling, general and administrative expenses.** Selling, general and administrative expenses increased \$9.5 million, from \$15.2 million in 2004 to \$24.6 million in 2005. The increase was primarily attributable to an increase in headcount-related charges of \$6.7 million, an increase in unrestricted grants and training expenditures of \$1.0 million, and an increase in general corporate expenditures of \$1.7 million. The increase in headcount-related charges is primarily attributable to the acquisition of Enable and the addition of sales personnel. As a percentage of revenues, selling, general and administrative expenses increased from 79.3% 2004 to 79.6% in 2005.

**Preferred stock interest expense.** Preferred stock interest expense decreased \$1.6 million, from \$3.9 million in 2004 to \$2.3 million in 2005. The decrease was attributable to the conversion of all shares of preferred stock into common stock upon the closing of our initial public offering in August 2005.

**Net interest income.** Net interest income increased \$0.3 million, from \$0.1 million in 2004 to \$0.4 million in 2005, due to an increase in cash, cash equivalents and investments resulting from the proceeds of our August 2005 initial public offering. The increase was partially offset by the interest expense incurred as a result of our long-term debt.

## **Liquidity and Capital Resources**

Prior to our initial public offering, we financed our operations primarily through private sales of preferred stock, with aggregate net proceeds of \$21.3 million of cash, excluding the conversion of \$4.7 million of promissory notes.

In August 2005, we completed an initial public offering in which we received net proceeds, after deducting underwriting discounts, commissions and expenses, of \$43.2 million from our sale and issuance of an aggregate of 4,150,000 shares of common stock, including 150,000 shares sold by us as part of the underwriters' over-allotment option. Offering expenses were \$3.1 million.

As of December 31, 2006, we had cash, cash equivalents and short-term investments of \$19.5 million and short-term and long-term debt of \$1.0 million, resulting in a net cash position of \$18.5 million. We had working capital of \$23.0 million and an accumulated deficit of \$56.1 million as of December 31, 2006.

**Cash flows used in operating activities.** Net cash used in operating activities was \$12.5 million in 2006, \$7.6 million in 2005 and \$3.8 million in 2004. 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, \$1.2 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 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. Net cash used in operations in 2004 was primarily attributable to a net loss of \$9.5 million and increases in accounts receivable and inventory balances of \$1.9 million and \$0.4 million, respectively, as we increased our revenue, partially offset by adjustments for non-cash charges related to stock-based compensation of \$1.0 million, depreciation of \$1.0 million, preferred stock interest of \$3.9 million and increases in payables and accrued liabilities of \$2.4 million due to our increase in operating expenses.

**Cash flows provided by and used in investing activities.** Net cash provided by investing activities was \$0.1 million in 2006 and cash flows used in investing activities were \$14.7 million in 2005 and \$1.5 million in

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2004. For each of these periods, cash used in investing activities reflected purchases of property and equipment of \$1.7 million, \$2.0 million and \$1.5 million for 2006, 2005 and 2004, respectively, the net purchases and maturities of \$1.8 million of investments and, in 2005, the purchase of \$6.4 million of short-term investments, and the acquisition of Enable for a net purchase price of \$6.4 million.

**Cash flows used in and provided by financing activities.** Net cash used in financing activities was \$0.3 million in 2006, net cash provided by financing activities was \$44.6 million in 2005 and cash flow provided by financing activities was \$0.1 million in 2004. Cash flows used in financing activities during 2006 reflected payments made on our debt and capital lease obligations of \$0.4 million. Cash flows provided by financing activities during 2005 were primarily attributable to the net proceeds from the issuance of common stock related to our initial public offering of \$43.2 million and borrowings under our credit facility of \$1.5 million discussed below, which were partially offset by payments made on our debt and capital lease obligations.

**Credit facility.** We entered into a \$5.0 million credit facility on March 8, 2005 with Lighthouse Capital Partners V, L.P. for working capital requirements. Outstanding borrowings under the facility bear interest at the prime rate plus 1.75%. Our ability to draw down funds under this facility terminated upon our initial public offering. Under the terms of the facility, we are required to pay any monthly installments of interest only through August 2005 and monthly installments of principal and interest thereafter, in addition to a fee due at maturity on September 1, 2009 equal to 15% of the aggregate amount borrowed under the credit facility, with prepayment in whole allowed at any time without penalty. As of December 31, 2006, there was \$1.0 million in borrowings outstanding under this facility.

In connection with establishing this facility, we granted Lighthouse a warrant to purchase 55,208 shares of our common stock, or shares into which such series of stock is converted, at a price of \$11.29 per share. The warrant expired unexercised on August 10, 2006. In addition, we granted Lighthouse a first perfected lien on all our tangible and intangible assets, including accounts receivable, inventory, equipment, furniture and fixtures, but excluding intellectual property.

**Uses of liquidity and capital resources.** Our future capital requirements depend on a number of factors, including possible acquisitions and joint ventures, the rate of market acceptance of our current and future products, the resources we devote to developing and supporting our products, future expenses to expand and support our sales and marketing efforts, costs relating to changes in regulatory policies or laws that affect our operations and costs of filing, prosecuting, defending and enforcing our intellectual property rights. We expect to increase capital expenditures consistent with our anticipated growth in research and development, manufacturing, infrastructure and personnel. In addition, we acquired Enable contemporaneously with the closing of our initial public offering for a purchase price of \$6.4 million, net of \$0.6 million cash acquired.

We believe that our current cash and cash equivalents, along with the cash we expect to generate from operations, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. If these sources of cash are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. Additional financing may not be available at all, or in amounts or terms acceptable to us. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned research and development and selling and marketing efforts.

**Table of Contents****Contractual Obligations and Commitments**

The following sets forth our approximate aggregate obligations at December 31, 2006 for future payments under contracts and other contingent commitments:

Contractual Obligations	Total	Payments Due by December 31,			
		2007	2008	2009	2010*
Long-term debt and capital leases <sup>(1)</sup>	\$ 1,430,741	\$ 464,310	\$ 450,416	\$ 516,015	\$
Operating leases <sup>(2)</sup>	1,107,293	478,365	333,121	254,110	41,697
Royalty obligations <sup>(3)</sup>	600,000	200,000	200,000	200,000	
Purchase obligations <sup>(4)</sup>	400,000	400,000			
<b>Total contractual obligations</b>	<b>\$ 3,538,034</b>	<b>\$ 1,542,675</b>	<b>\$ 983,537</b>	<b>\$ 970,125</b>	<b>\$ 41,697</b>

\* There are no contractual obligations after year 2010.

- (1) Long-term debt represents principal repayment and a 15% fee due at maturity, which are required under the terms of our credit facility with Lighthouse Capital Partners V, L.P. In addition to principal and fees, we pay interest at the prime rate plus 1.75%. Capital leases consist of principal and interest payments required for our manufacturing machinery and equipment.
- (2) Represents lease commitments under various operating leases.
- (3) Represents minimum payments required under the terms of a royalty agreement between us and Randall K. Wolf, M.D.
- (4) Represents estimated minimum payments to Stellartech for the purchase of our ASUs. We are required to purchase at least 75% of our ASUs from Stellartech through November 2007. Our estimated payments are based on anticipated demand.

**Off-Balance-Sheet Arrangements**

As of December 31, 2006, we did not have any off-balance-sheet arrangements.

**Inflation**

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

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses, and disclosures of contingent assets and liabilities at the date of the financial statements. On a periodic basis, we evaluate our estimates, including those related to accounts receivable, inventories and stock based compensation. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates under different assumptions or conditions.

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

**Stock-Based Compensation.** On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004),

Share-Based Payment, ( SFAS 123(R) ), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including employee stock options and employee stock purchases related to an employee stock purchase plan, based on estimated fair values. Stock-based compensation expense recognized under SFAS 123(R) for the year

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ended December 31, 2006 was \$1,258,124 on a before and after tax basis, which consisted of stock-based compensation expense related to employee stock options. For the years ended December 31, 2005 and 2004, we incurred charges for stock compensation for employees for options issued with exercise prices below market value. We recorded charges of approximately \$259,000 and \$327,000, which represent the portion pertaining to the years ended December 31, 2005 and 2004, respectively, based on the options vesting requirements. See Note 15 to the Notes to Condensed Consolidated Financial Statements for additional information.

We estimate the fair value of options on the date of grant using the Black-Scholes option-pricing model. Our determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. Due to our limited trading history, we used the implied volatility of a group of comparable companies. The weighted-average estimated fair value of options granted during the years ended December 31, 2006, 2005 and 2004 was \$3.92, \$6.22 and \$6.22, respectively, using the Black-Scholes model with the following assumptions:

	2006		2005		2004	
Risk free interest rate	4.44	5.14%	3.75	3.99%	2.89	3.25%
Expected life of option (years)	6.0		4.0 6.0		4.0	
Expected volatility of stock	38.06	46.00%	0.00	57.00%	0.00%	
Weighted-average volatility	38.92%		43.48%		0.00%	
Dividend yield	0.00%		0.00%		0.00%	

The risk-free interest rate assumption is based upon the U.S. treasury yield curve at the time of grant for the expected option life. Due to our limited operating history, the expected lives are estimated based on other companies in the industry.

If factors change and we employ different assumptions in the application of SFAS 123(R) in future periods, the compensation expense that we record under SFAS 123(R) may differ significantly from what we have recorded in the current period.

**Revenue Recognition.** Revenue is generated primarily from the sale of our Isolator bipolar ablation system. Pursuant to our standard terms of sale, revenue is recognized when title to the goods and risk of loss transfer to customers and there are no remaining obligations that will affect the customer's final acceptance of the sale. Generally, our standard terms of sale define the transfer of title and risk of loss to occur upon shipment to the respective customer. We maintain no post-shipment obligations to the recipients of the products. No installation, calibration or testing of this equipment is performed by us subsequent to shipment to the customer in order to render it operational. Product revenue includes shipping revenue of approximately \$241,000, \$141,000, and \$87,000 in 2006, 2005, and 2004, respectively. Cost of freight is included in cost of revenues. We sell our products through a direct and indirect sales force and through AtriCure Europe, B.V., our wholly-owned subsidiary incorporated in the Netherlands. Terms of sale are consistent for both end-users and distributors, with terms generally not exceeding 120 days. Customers and distributors generally have no right of return.

We comply with SEC Staff Accounting Bulletin No. 101, Recognition in Financial Statements, or SAB 101, as amended by SAB 104. SAB 101 sets forth guidelines on the timing of revenue recognition based upon factors such as passage of title, installation, payment terms and ability to return products. We recognize revenue when all of the following criteria are met: persuasive evidence that an arrangement exists; delivery of the products or services has occurred; the selling price is fixed or determinable; and collectibility is reasonable assured.

**Allowance for Uncollectible Accounts Receivable.** We periodically and systematically evaluate the collectibility of accounts receivable and determine the appropriate reserve for doubtful accounts. In determining the amount of the reserve, we consider historical credit losses, the past due status of the receivables, and other customer-specific information, and any other relevant factors or considerations.

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***Inventory Valuation.*** Inventories are stated at the lower of cost or market using the first-in, first-out, or FIFO, cost method and consist of raw materials, work in process and finished goods. Reserves are estimated for excess, slow-moving and obsolete inventory, as well as inventory with a carrying value in excess of its net realizable value. Write-offs are recorded when the product is destroyed. We review inventory on hand at least quarterly and record provisions for excess and obsolete inventory based on several factors including current assessment of future product demand, anticipated release of new products into the market, historical experience and product expiration. Our industry is characterized by rapid product development and frequent new product introductions. Uncertain timing of product approvals, variability in product launch strategies, product recalls and variation in product utilization all impact the estimates related to excess and obsolete inventory.

***Impairment of Long-Lived Assets.*** We, using our best estimates based on reasonable and supportable assumptions and projections, review for impairment our property and equipment and definite-lived intangible assets in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 144, Accounting for the Impairment or Disposable of Long-Lived Assets. In 2005, we recorded a charge of \$0.3 million for the impairment of certain obsolete tooling equipment. We did not recognize any impairment of long-lived assets in 2006 and 2004.

***Deferred Tax Asset Valuation Allowance.*** Our estimate for the valuation allowance for deferred tax assets requires us to make significant estimates and judgments about our future operating results. Our ability to realize the deferred tax assets depends on our future taxable income as well as limitations on their utilization. A deferred tax asset is reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized prior to its expiration. The projections of our operating results on which the establishment of a valuation allowance is based involve significant estimates regarding future demand for our products, competitive conditions, product development efforts, approvals of regulatory agencies, and product cost. If actual results differ from these projections, or if our expectations of future results change, it may be necessary to adjust the valuation allowance.

### **Recent Accounting Pronouncements**

In November 2004, the FASB issued SFAS No. 151, Inventory Costs. This Statement amends the guidance in Accounting Research Bulletin No. 43, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight handling costs and wasted material (spoilage). We implemented SFAS No. 151 on January 1, 2006 and it did not have a material impact on our financial position or results of operations.

In February 2006, the FASB issued SFAS No. 155, Accounting for Certain Hybrid Financial Instruments-an amendment of FASB Statements No. 133 and 140 ( SFAS 155 ). SFAS 155 amends SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities and SFAS 140 Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities. The provisions of SFAS 155 are effective for financial instruments acquired, issued, or subject to a remeasurement event occurring after the beginning of an entity's first fiscal year that begins after September 15, 2006. The adoption of SFAS No. 155 in 2007 is not expected to have a material impact on our financial statements.

In July 2006, the FASB issued FASB Interpretation No. 48 ( FIN 48 ), Accounting for Uncertainty in Income Taxes, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, FIN 48 provides criteria for subsequently recognizing, derecognizing and measuring changes in uncertain tax positions and requires expanded disclosure with respect to the uncertainty of income taxes. The accounting provisions of FIN 48 will be effective for us beginning January 1, 2007 with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. The adoption of FIN 48 is not expected to have a material impact on our financial statements.

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In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements ( SFAS 157 ), which establishes a framework for measuring fair value and expands disclosures about fair value measurements. The provisions of SFAS 157 will be effective for us beginning January 1, 2008. We are in the process of determining the effect, if any, the adoption of SFAS 157 will have on our financial statements.

In September 2006, the SEC issued SAB No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Current Year Misstatements. SAB No. 108 requires analysis of misstatements using both an income statement (rollover) approach and a balance sheet (iron curtain) approach in assessing materiality and provides for a one-time cumulative effect transition adjustment. The provisions of SAB 108 were effective for our 2006 financial statements, and the adoption of this standard did not have an impact on our financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities-including an amendment of FASB Statement No. 115, which permits entities to measure many financial instruments and certain other items at fair value. The provisions of SFAS 159 will be effective for us beginning January 1, 2008. We are in the process of determining the effect, if any, the adoption of SFAS 159 will have on our financial statements.

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

We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions. We are exposed to various market risks, which are potential losses arising from adverse changes in market rates and prices, such as foreign exchange fluctuations and interest rates.

For the year ended December 31, 2006, products sold by AtriCure Europe B.V. accounted for 4.8% of our revenues. Since such revenues were denominated in Euros, we have exposure to exchange rate fluctuations between the Euro and the U.S. dollar. To date, the effect of the foreign exchange rate fluctuations on our financial results has not been material. For the years ended December 31, 2005 and 2004, none of our revenues were denominated in currencies other than U.S. dollars.

For revenues denominated in Euros, if there is an increase in the rate at which Euros are exchanged for U.S. dollars, it will require more Euros to equal a specified amount of U.S. dollars than before the rate increase. In such cases and if we price our products in Euros, we will receive less in U.S. dollars than we did before the rate increase went into effect. If we price our products in U.S. dollars and competitors price their products in Euros, an increase in the relative strength of the U.S. dollar could result in our price not being competitive in a market where business is transacted in the Euro.

Although 95.2% of our 2006 revenues were denominated in U.S. dollars, future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products outside the United States.

We invest our excess cash primarily in U.S. government securities, corporate bonds and commercial paper. Accordingly, we believe that, while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.



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**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA  
ATRICURE, INC.**

**INDEX TO FINANCIAL STATEMENTS**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

AtriCure, Inc.:

We have audited the accompanying consolidated balance sheets of AtriCure, Inc. and subsidiary (the Company) as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2006. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 1 to the consolidated financial statements, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123(R), Share Based Payment, on January 1, 2006.

/s/ Deloitte & Touche LLP

Cincinnati, Ohio

April 2, 2007

**Table of Contents****ATRICURE, INC.****CONSOLIDATED BALANCE SHEETS****DECEMBER 31, 2006 and 2005**

	<b>2006</b>	<b>2005</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,890,383	\$ 27,432,948
Short-term investments	4,598,032	6,369,234
Accounts receivable, less allowance for doubtful accounts of \$343,127 and \$261,707, respectively	6,562,342	4,865,065
Inventories, net	3,389,400	2,135,143
Other current assets	1,247,738	845,330
Total current assets	30,687,895	41,647,720
Property and equipment, net	3,643,069	3,359,549
Intangible assets, net	772,778	986,778
Goodwill	3,840,837	3,840,837
Other assets	183,486	205,531
Total assets	\$ 39,128,065	\$ 50,040,415
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,929,983	\$ 1,243,365
Accrued liabilities	5,335,441	4,131,633
Current maturities of long-term debt and capital leases	391,460	369,835
Total current liabilities	7,656,884	5,744,833
Long-term debt and capital leases	692,544	1,084,005
Other liabilities	84,375	28,125
Total liabilities	8,433,803	6,856,963
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, \$0.001 par value, 90,000,000 shares authorized and 12,188,600 and 12,086,482 issued and outstanding, respectively	12,189	12,086
Additional paid-in capital	86,646,064	86,107,520
Unearned compensation		(599,591)
Accumulated other comprehensive income	90,673	826
Accumulated deficit	(56,054,664)	(42,337,389)
Total stockholders' equity	30,694,262	43,183,452
Total liabilities and stockholders' equity	\$ 39,128,065	\$ 50,040,415

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See accompanying notes to consolidated financial statements.

**Table of Contents****ATRICURE, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****YEARS ENDED DECEMBER 31, 2006, 2005, and 2004**

	<b>2006</b>	<b>2005</b>	<b>2004</b>
Revenues	\$ 38,243,243	\$ 30,956,987	\$ 19,157,032
Cost of revenues (a)	7,626,362	8,056,680	5,201,562
Gross profit	30,616,881	22,900,307	13,955,470
Operating expenses:			
Research and development expenses (a)	12,215,617	9,108,600	4,422,014
Selling, general and administrative expenses	33,170,328	24,641,421	15,186,081
Total operating expenses	45,385,945	33,750,021	19,608,095
Loss from operations	(14,769,064)	(10,849,714)	(5,652,625)
Other income (expense):			
Preferred stock interest expense		(2,332,254)	(3,905,169)
Interest expense	(208,551)	(110,335)	
Interest income	1,187,708	524,471	105,926
Grant income	72,632	84,868	
Net loss	\$ (13,717,275)	\$ (12,682,964)	\$ (9,451,868)
Basic and diluted loss per share	\$ (1.13)	\$ (2.10)	\$ (5.17)
Weighted average shares outstanding:			
Basic and diluted	12,137,258	6,025,300	1,828,452

(a) Includes the following expenses resulting from transactions with Enable Medical Corporation prior to the acquisition as of August 10, 2005:

Cost of revenues	\$	\$ 4,259,269	\$ 4,941,341
Research and development expenses	\$	\$ 1,201,583	\$ 1,228,659

See accompanying notes to consolidated financial statements.

**Table of Contents****ATRICURE, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)****YEARS ENDED DECEMBER 31, 2006, 2005, and 2004**

	Common Stock		Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Other Comprehensive Income	Total Stockholders Equity (Deficit)	Comprehensive Loss
	Shares	Amount						
Balance December 31, 2003	1,805,842	1,806	1,196,522		(20,135,170)		(18,936,842)	
Issuance of common stock under stock option plans	74,327	74	89,109				89,183	
Intrinsic value of stock options granted			1,308,816	\$ (1,308,816)				
Issuance of stock options for services provided			687,000				687,000	
Amortization of intrinsic value of stock options granted				327,204			327,204	
Accretion of issuance costs preferred stock					(45,971)		(45,971)	
Net loss					(9,451,868)		(9,451,868)	
Comprehensive loss								(9,451,868)
Balance December 31, 2004	1,880,169	1,880	3,281,447	(981,612)	(29,633,009)		(27,331,294)	
Issuance of common stock under stock option plans	44,293	44	42,170				42,214	
Intrinsic value of stock options granted			216,211	(216,211)				
Adjustment to intrinsic value of stock options granted due to cancellations			(338,992)	338,992				
Issuance of stock options for services provided			413,962				413,962	
Amortization of intrinsic value of stock options granted				259,240			259,240	
Accretion of issuance costs preferred stock					(21,416)		(21,416)	
Issuance of warrants			216,083				216,083	
Issuance of common stock from initial public offering, net of issuance costs	4,150,000	4,150	43,172,844				43,176,994	
Conversion of preferred stock to common stock	6,012,020	6,012	39,103,795				39,109,807	
Unrealized gains on investments						826	826	
Net loss					(12,682,964)		(12,682,964)	
Comprehensive loss								(12,682,138)
Balance December 31, 2005	12,086,482	12,086	86,107,520	(599,591)	(42,337,389)	826	43,183,452	
Issuance of common stock under stock option plans and warrants	102,118	103	92,367				92,470	
Non-employee stock option fair market value adjustment			(212,356)				(212,356)	
Reclassification upon adoption of SFAS 123(R)			(599,591)	599,591				
Share-based employee compensation expense			1,258,124				1,258,124	
Unrealized gains on investments						85,887	85,887	
						3,960	3,960	

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Foreign currency translation  
adjustment

Net loss	(13,717,275)	(13,717,275)
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Comprehensive loss				(13,627,428)
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Balance	December 31, 2006	12,188,600	\$ 12,189	\$ 86,646,064	\$	\$ (56,054,664)	\$ 90,673	\$ 30,694,262
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See accompanying notes to consolidated financial statements.

**Table of Contents****ATRICURE, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****YEARS ENDED DECEMBER 31, 2006, 2005, and 2004**

	2006	2005	2004
<b>Cash flows from operating activities:</b>			
Net loss	\$ (13,717,275)	\$ (12,682,964)	\$ (9,451,868)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation	1,622,378	1,434,323	962,355
Amortization of intangible assets	214,000	83,222	
Amortization of deferred financing costs	48,925	36,693	
(Gain) loss on disposal of equipment	(20,000)	303,008	16,561
Provision for losses in accounts receivable	81,420	204,928	28,902
Share-based compensation expense	1,045,768	673,199	1,014,204
Preferred stock interest		2,332,254	3,905,169
<b>Changes in assets and liabilities (net of assets acquired and liabilities assumed in business combinations):</b>			
Accounts receivable	(1,778,699)	(112,496)	(1,921,697)
Inventories	(1,254,259)	(193,559)	(448,413)
Other current assets	(402,408)	(709,880)	97,482
Accounts payable	554,952	27,911	454,730
Accrued liabilities	1,060,690	577,467	1,959,957
Other non-current assets and other non-current liabilities	78,778	409,985	(417,453)
<b>Net cash used in operating activities</b>	<b>(12,465,730)</b>	<b>(7,615,909)</b>	<b>(3,800,071)</b>
<b>Cash flows from investing activities:</b>			
Purchases of property & equipment	(1,680,520)	(1,951,733)	(1,513,273)
Proceeds from sale of property & equipment	20,000		
Purchases of available-for-sale securities	(6,289,837)	(6,368,408)	
Maturities of available-for-sale securities	8,065,000		
Cash paid for acquisition, net of cash acquired		(6,420,681)	
<b>Net cash provided by (used in) investing activities</b>	<b>114,643</b>	<b>(14,740,822)</b>	<b>(1,513,273)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from long-term debt borrowings		1,500,000	
Payments on long-term debt and capital leases	(369,835)	(104,706)	
Proceeds from stock offering, net of related fees		43,176,994	
Proceeds from stock option exercises and warrants	92,470	42,214	89,183
<b>Net cash (used in) provided by financing activities</b>	<b>(277,365)</b>	<b>44,614,502</b>	<b>89,183</b>
Effect of exchange rate changes on cash	85,887		
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(12,542,565)</b>	<b>22,257,771</b>	<b>(5,224,161)</b>
Cash and cash equivalents beginning of period	27,432,948	5,175,177	10,399,338
<b>Cash and cash equivalents end of period</b>	<b>\$ 14,890,383</b>	<b>\$ 27,432,948</b>	<b>\$ 5,175,177</b>
<b>Supplemental cash flow information:</b>			
Cash paid for income taxes	\$ 51,534	\$ 311,000	\$



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Cash paid for interest	\$ 159,626	\$ 47,949	\$
Non-cash investing and financing activities:			
Warrants issued in connection with line of credit	\$	\$ 216,083	\$
Preferred stock conversion	\$	\$ 39,109,808	\$
Purchases of property & equipment in current liabilities	\$ 274,784	\$ 74,485	\$

See accompanying notes to consolidated financial statements.

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**ATRICURE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

***Nature of the Business*** AtriCure, Inc. (the Company) was incorporated in the State of Delaware on October 31, 2000, as a spin-off of Enable Medical Corporation, to focus on the surgical treatment of atrial fibrillation. Atrial fibrillation (AF) is a rapid, irregular quivering of the upper chambers of the heart. The Company sells its medical devices to hospitals and medical clinics both in the United States and internationally. International sales were approximately \$4.2 million, \$2.7 million, and \$1.4 million in 2006, 2005, and 2004, respectively.

***Principles of Consolidation*** The consolidated financial statements include the accounts of the Company and AtriCure Europe B.V., the Company's wholly owned subsidiary incorporated in the Netherlands. Intercompany accounts and transactions are eliminated.

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

***Short-Term Investments*** The Company places its investments primarily in U.S. Government securities, corporate notes, and commercial paper. The Company classifies all investments as available-for-sale. Such investments are recorded at fair value, with unrealized gains and losses recorded as a separate component of stockholders' equity. The Company recognizes gains and losses when these securities are sold using the specific identification method.

***Revenue Recognition*** Revenues are generated primarily from the sale of the Company's disposable surgical products. Pursuant to the Company's standard terms of sales, revenue is recognized when title to the goods and risk of loss transfers to customers and there are no remaining obligations that will affect the customer's final acceptance of the sale. Generally, the Company's standard terms of sale define the transfer of title and risk of loss to occur upon shipment to the respective customer. The Company maintains no post-shipment obligations to the recipients of the products. No installation, calibration or testing of this equipment is performed by the Company subsequent to shipment to the customer in order to render it operational. Product revenue includes shipping revenue of approximately \$241,000, \$141,000, and \$87,000 in 2006, 2005, and 2004, respectively. Cost of freight is included in cost of goods sold. The Company sells its products through a direct and indirect sales force and through AtriCure Europe B.V. Terms of sale are consistent for both end-users and distributors, with terms generally not exceeding 120 days. Customers generally have no right of return.

The Company complies with the Securities and Exchange Commission (SEC) Staff Accounting Bulletin No. 101, Recognition in Financial Statements (SAB 101), as amended by SAB 104. SAB 101 sets forth guidelines on the timing of revenue recognition based upon factors such as passage of title, installation, payment terms and ability to return products. The Company recognizes revenue when all of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectibility is reasonably assured.

***Allowance for Doubtful Accounts*** The Company periodically and systematically evaluates the collectibility of accounts receivable and determines the appropriate reserve for doubtful accounts. In determining the amount of the reserve, the Company considers historical credit losses, the past due status of the receivables, other customer-specific information, and any other relevant factors or considerations.

***Inventories*** Inventories are stated at the lower of cost or market using the first-in, first-out (FIFO) cost method and consist of raw materials, work in process, and finished goods. Reserves are estimated for excess, slow moving and obsolete inventory as well as inventory with a carrying value in excess of its net realizable

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**ATRICURE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

value. Write-offs are recorded when a product is destroyed. The Company reviews inventory on hand at least quarterly and records provisions for excess and obsolete inventory based on several factors including current assessment of future product demand, anticipated release of new products into the market, historical experience and product expiration.

**Property and Equipment** Property and equipment is stated at cost, less accumulated depreciation. Depreciation is computed on the straight-line method for financial reporting purposes over the estimated useful lives of the assets, which range from the lesser of three to seven years or the remaining lease term for leasehold improvements. Maintenance and repair costs are expensed as incurred.

Included in Property and equipment are generators and cryo-units that are loaned at no cost to medical providers who use the Company's product. These generators and cryo-units are depreciated over three years and such depreciation is included in cost of revenues. The total of such depreciation was approximately \$681,000, \$777,000, and \$543,000, in 2006, 2005, and 2004, respectively.

**Impairment of Long-Lived Assets (Other than Goodwill)** The Company reviews property and equipment and definite-lived intangibles for impairment using its best estimates based on reasonable and supportable assumptions and projections in accordance with Statement of Financial Accounting Standards (SFAS) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. In 2005, the Company recorded a charge of approximately \$266,000 for the impairment of certain obsolete tooling equipment. The Company did not recognize any impairment of property and equipment in 2006 and 2004.

**Goodwill and Intangible Assets** Goodwill is not amortized, but is evaluated at least annually for impairment. Intangible assets with determinable useful lives are amortized on a straight line basis over the estimated periods benefited.

**Grant Income** The Company receives research grants, which are recognized as funds are expended and not as awarded by awarding agencies.

**Income Taxes** Income taxes have been computed using the asset and liability method, under which deferred income taxes are provided for the temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities. Deferred taxes are measured using provisions of currently enacted tax laws. A valuation allowance against deferred tax assets is recorded when it is more likely than not that such assets will not be fully realized. Tax credits are accounted for as a reduction of income taxes in the year in which the credit originates.

The Company's estimate for the valuation allowance for deferred tax assets requires it to make significant estimates and judgments about its future operating results. The Company's ability to realize the deferred tax assets depends on its future taxable income as well as limitations on their utilization. A deferred tax asset is reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized prior to its expiration. The projections of the Company's operating results on which the establishment of a valuation allowance is based involve significant estimates regarding future demand for the Company's products, competitive conditions, product development efforts, approvals of regulatory agencies, and product cost. If actual results differ from these projections, or if the Company's expectations of future results change, it may be necessary to adjust the valuation allowance.

**Earnings (Loss) Per Share** Basic net loss per share is computed by dividing net loss available to common stockholders by the weighted average number of common shares outstanding during the period. Since the

**Table of Contents****ATRICURE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Company has experienced losses for all periods presented, net loss per share excludes the effect of 1,906,928, 1,863,353, and 1,234,322 options and warrants in 2006, 2005, and 2004, respectively, because such options are anti-dilutive. Therefore the number of shares calculated for basic net loss per share is also used for the diluted net loss per share calculation. All share and per share amounts reflect the 1-for-3.8 reverse stock split that was effected on July 27, 2005.

**Other Comprehensive Income** Other Comprehensive income consisted of the following:

	Unrealized Gains on Investments	Foreign Currency Translation Adjustment	Other Comprehensive Income
Balance as of December 31, 2003	\$	\$	\$
Current-period change			
Balance as of December 31, 2004			
Current-period change	826		826
Balance as of December 31, 2005	826		826
Current-period change	3,960	85,887	89,847
Balance as of December 31, 2006	\$ 4,786	\$ 85,887	\$ 90,673

**Research and Development** Research and development costs are expensed as incurred.

**Share-Based Employee Compensation** On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment, ( SFAS 123(R) ), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including employee stock options and employee stock purchases related to an employee stock purchase plan, based on estimated fair values. SFAS 123(R) supersedes the Company's previous accounting under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ( APB 25 ) for periods beginning in fiscal 2006. In March 2005, the SEC issued Staff Accounting Bulletin No. 107 ( SAB 107 ) relating to SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

The Company adopted SFAS 123(R) using the modified prospective transition method. In accordance with the modified prospective transition method, the Company's Consolidated Financial Statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). Stock-based compensation expense recognized under SFAS 123(R) for the year ended December 31, 2006 was \$1,258,124 on a before and after tax basis, which consisted of stock-based compensation expense related to employee stock options. For the years ended December 31, 2005 and 2004, the Company incurred charges for stock compensation for employees for options issued with exercise prices below fair market value of approximately \$259,000 and \$327,000, respectively.

**Table of Contents****ATRICURE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table summarizes the pro forma net loss and loss per share as if the fair value method had been applied for the years ended December 31, 2005 and 2004:

	2005	2004
Net loss	\$ (12,682,964)	\$ (9,451,868)
Add: Share-based employee compensation expense included in net loss, net of related tax effect	259,240	327,204
Deduct: Share-based employee compensation expense if the fair value method had been applied, net of related tax effects	(711,856)	(684,204)
Pro forma net loss if the fair value method had been applied	\$ (13,135,580)	\$ (9,808,868)
Net loss per common share:		
Basic and diluted as reported	\$ (2.10)	\$ (5.17)
Basic and diluted pro forma	\$ (2.18)	\$ (5.36)

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's Consolidated Statement of Operations. Prior to the adoption of SFAS 123(R), the Company accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123).

Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized in the Company's Consolidated Statement of Operations for the year ended December 31, 2006 included compensation expense for share-based payment awards granted prior to, but not yet vested as of December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). As stock-based compensation expense recognized in the Consolidated Statement of Operations for year ended December 31, 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In the Company's pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred. The cumulative effect of the change in accounting for forfeitures under SFAS 123(R) was not material to the consolidated financial statements.

The Company estimates the fair value of options on the date of grant using the Black-Scholes option-pricing model (Black-Scholes model). The Company's determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by the Company's stock price, as well as assumptions regarding a number of highly complex and subjective variables. These variables include but are not limited to the Company's expected stock price volatility over the term of the awards and actual and projected employee stock option exercise behaviors.

On November 10, 2005, the Financial Accounting Standards Board (FASB) issued FASB Staff Position No. FAS 123(R)-3 Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards (the FASB Staff Position). The Company has elected to adopt the alternative transition method provided in the FASB Staff Position for calculating the tax effects of stock-based compensation pursuant to SFAS 123(R). The alternative transition method includes simplified methods to establish the beginning balance of the additional

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**ATRICURE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

paid-in capital pool ( APIC pool ) related to the tax effects of employee stock-based compensation and to determine the subsequent impact on the APIC pool and Consolidated Statements of Cash Flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of SFAS 123(R).

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

**Reclassification** The Company reclassified certain prior period financial statement balances to conform to the current year presentation, including franchise tax expense to selling, general, and administrative expense from income tax expense for 2005 and 2004; accrued fees associated with the Company's credit facility to other long-term liabilities from current liabilities for 2005; and certain reclassifications from changes in assets and liabilities within the operating section to reconcile net loss to net cash used in operating activities of the Consolidated Statements of Cash Flows.

**Fair Value Disclosures** The fair value of the Company's assets and liabilities approximates the carrying values.

**2. RECENT ACCOUNTING PRONOUNCEMENTS**

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*. This Statement amends the guidance in Accounting Research Bulletin No. 43, *Inventory Pricing*, to clarify the accounting for abnormal amounts of idle facility expense, freight handling costs and wasted material (spoilage). The Company implemented SFAS No. 151 on January 1, 2006 and it did not have a material impact on the Company's financial position or results of operations.

In February 2006, the FASB issued SFAS No. 155, *Accounting for Certain Hybrid Financial Instruments—an amendment of FASB Statements No. 133 and 140 ( SFAS 155 )*. SFAS 155 amends SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* and SFAS 140 *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. The provisions of SFAS 155 are effective for financial instruments acquired, issued, or subject to a remeasurement event occurring after the beginning of an entity's first fiscal year that begins after September 15, 2006. The adoption of SFAS No. 155 in 2007 is not expected to have a material impact on the Company's financial statements.

In July 2006, the FASB issued FASB Interpretation No. 48 ( *FIN 48* ), *Accounting for Uncertainty in Income Taxes*, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, FIN 48 provides criteria for subsequently recognizing, derecognizing and measuring changes in uncertain tax positions and requires expanded disclosure with respect to the uncertainty of income taxes. The accounting provisions of FIN 48 will be effective for the Company beginning January 1, 2007 with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. The adoption of FIN 48 is not expected to have a material impact on the Company's financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements ( SFAS 157 )*, which establishes a framework for measuring fair value and expands disclosures about fair value measurements. The provisions of SFAS 157 will be effective for the Company beginning January 1, 2008. The Company is in the process of determining the effect, if any, the adoption of SFAS 157 will have on its financial statements.

**Table of Contents****ATRICURE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In September 2006, the SEC issued SAB No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Current Year Misstatements." SAB No. 108 requires analysis of misstatements using both an income statement (rollover) approach and a balance sheet (iron curtain) approach in assessing materiality and provides for a one-time cumulative effect transition adjustment. The provisions of SAB 108 were effective for the Company's 2006 financial statements, and the adoption of this standard did not have an impact on the Company's financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities-including an amendment of FASB Statement No. 115," which permits entities to measure many financial instruments and certain other items at fair value. The provisions of SFAS 159 will be effective for the Company beginning January 1, 2008. The Company is in the process of determining the effect, if any, the adoption of SFAS 159 will have on its financial statements.

**3. ACQUISITION OF ENABLE MEDICAL CORPORATION**

On August 10, 2005, the Company acquired all of the outstanding shares of Enable Medical Corporation (Enable) for an aggregate purchase price, net of cash acquired, of \$6,420,681. Enable was a related party and the developer and manufacturer of the Company's disposable ablation clamps (see Note 13). The acquisition provided better control over product development and manufacturing, in addition to enhancing the Company's engineering capabilities. The purchase price allocation resulted in goodwill of approximately \$3,841,000, which is not deductible for tax purposes.

In connection with the acquisition, the Company identified and valued Enable's intangible assets, which consist of proprietary manufacturing technology of approximately \$1,070,000 and will be amortized straight-line over five years. The following table presents details of the intangible asset:

	<b>2006</b>	<b>2005</b>
Gross value	\$ 1,070,000	\$ 1,070,000
Accumulated amortization	(297,222)	(83,222)
Net book value	\$ 772,778	\$ 986,778

Amortization expense included in cost of revenues was approximately \$214,000 and \$83,000 in 2006 and 2005, respectively. Estimated annual amortization expense for each of 2007, 2008, and 2009 is \$214,000, and \$131,000 for 2010.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed on August 10, 2005.

Current assets	\$ 2,361,762
Property and equipment	660,612
Goodwill	3,840,837
Intangible assets	1,070,000
Other assets	11,502
Current liabilities	(1,437,361)
Capital lease obligation	(86,671)
Net assets acquired	\$ 6,420,681





**Table of Contents****ATRICURE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table summarizes unaudited pro forma financial information assuming the Enable acquisition had occurred on January 1, 2004. The unaudited pro forma information is based on information currently available and assumptions that the Company believes are reasonable. This unaudited pro forma information does not necessarily represent what would have occurred if the transaction had taken place on the dates presented and should not be taken as representative of future combined results of operations.

	2005	2004
Revenues	\$ 31,163,628	\$ 19,611,285
Net loss	\$ (11,996,151)	\$ (8,508,737)
Basic and diluted loss per share	\$ (1.99)	\$ (4.65)

**4. INITIAL PUBLIC OFFERING**

On August 10, 2005, the Company consummated an initial public offering of 4,600,000 shares of its common stock at \$12.00 per share, which included the underwriters' exercise of their over-allotment option on August 9, 2005 to purchase 600,000 shares of the Company's common stock, of which 450,000 shares were sold by selling stockholders and 150,000 shares were sold by the Company. The Company did not receive any proceeds from the sale of the 450,000 shares of common stock that were sold by selling stockholders. These share amounts reflect a 1-for-3.8 reverse split of the capital stock that was affected on July 27, 2005. In connection with the offering, all of the 6,012,020 outstanding shares of preferred stock were converted into 6,012,020 shares of common stock. Proceeds to the Company from the offering, after deducting underwriting discounts, commissions and offering expenses, were approximately \$43.2 million. Offering expenses were approximately \$3.1 million.

**5. INVESTMENTS**

Investments consisted of the following:

	Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
<b>December 31, 2006</b>				
U.S. Government securities	\$ 1,787,804	\$ 6,700	\$	\$ 1,794,504
Foreign debt securities	804,441		(723)	803,718
Medium-term notes	1,001,179		(1,059)	1,000,120
Corporate notes	999,822		(132)	999,690
Total	\$ 4,593,246	\$ 6,700	\$ (1,914)	\$ 4,598,032
<b>December 31, 2005</b>				
Commercial paper	\$ 2,428,992	\$ 6,119	\$	\$ 2,435,111
U.S. Government securities	1,998,467		(2,217)	1,996,250
Corporate notes	1,940,949		(3,076)	1,937,873
Total	\$ 6,368,408	\$ 6,119	\$ (5,293)	\$ 6,369,234

The Company has not experienced any significant realized gains or losses on its investments in the periods presented in the statements of operations.



**Table of Contents****ATRICURE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. INVENTORIES**

Inventories consisted of the following at December 31:

	<b>2006</b>	<b>2005</b>
Raw material	\$ 763,862	\$ 387,484
Work in process	1,086,685	708,676
Finished goods	1,633,520	1,297,541
Reserve for obsolescence	(94,667)	(258,558)
<b>Inventories, net</b>	<b>\$ 3,389,400</b>	<b>\$ 2,135,143</b>

**7. PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following at December 31:

	<b>2006</b>	<b>2005</b>
Machinery and equipment	\$ 6,175,950	\$ 4,984,633
Computer and other office equipment	761,127	652,227
Furniture and fixtures	400,469	262,013
Leasehold improvements	220,602	142,190
Equipment under capital lease	82,424	102,429
Construction in progress	510,313	153,083
<b>Total</b>	<b>8,150,885</b>	<b>6,296,575</b>
Less accumulated depreciation	(4,507,816)	(2,937,026)
<b>Property and equipment, net</b>	<b>\$ 3,643,069</b>	<b>\$ 3,359,549</b>

**8. ACCRUED LIABILITIES**

Accrued liabilities consisted of the following at December 31:

	<b>2006</b>	<b>2005</b>
Accrued commissions	\$ 1,415,667	\$ 987,599
Accrued bonus	695,101	600,813
Accrued vacation	430,172	469,049
Other accrued liabilities	2,794,501	2,074,172
<b>Total accrued liabilities</b>	<b>\$ 5,335,441</b>	<b>\$ 4,131,633</b>

**9. FINANCING ARRANGEMENTS**

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Long-term debt and capital leases consisted of the following at December 31:

	<b>2006</b>	<b>2005</b>
Credit facility, interest at 8%, due 2009	\$ 1,045,149	\$ 1,383,232
Capital leases	38,855	70,608
<b>Total debt and capital leases</b>	<b>1,084,004</b>	<b>1,453,840</b>
Less: Current maturities	391,460	369,835
<b>Total long-term debt and capital leases</b>	<b>\$ 692,544</b>	<b>\$ 1,084,005</b>

**Table of Contents****ATRICURE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In March 2005, the Company entered into a credit facility with Lighthouse Capital Partners V, L.P. of up to \$5,000,000, to be drawn down by the earlier of an initial public offering of common stock or September 1, 2005. This credit facility is secured by substantially all of the Company's assets, excluding intellectual property. Under the credit facility, the Company was required to pay monthly installments of interest only through August 2005 and monthly installments of principal and interest thereafter, in addition to a fee due at maturity on September 1, 2009 equal to 15% of the aggregate amount borrowed under the credit facility, with prepayment in whole allowed at any time without penalty. As of December 31, 2006, there was approximately \$1.0 million outstanding under this facility, which bears interest at a fixed rate of 8%. In addition, the facility required the Company to issue to Lighthouse a warrant to purchase 55,208 shares of common stock at an exercise price of \$11.29 per share. In valuing this warrant, the Company relied upon recognized option pricing models. The valuations used closed-form models, such as the Black-Scholes-Merton model and the Bjerksund and Stensland approximation model, as well as the lattice form binomial models. The warrant expired on August 10, 2006.

The Company has capital leases for manufacturing machinery and equipment. As of December 31, 2006, the cost of the assets under lease was \$82,424. These assets are depreciated over the estimated useful life of the asset. Accumulated amortization on the capital leases were \$23,244 and \$8,495 at December 31, 2006 and 2005, respectively.

Maturities of long-term debt and capital leases are as follows:

2007	\$ 393,930
2008	410,426
2009	282,475
Less interest payments for capital leases	(2,827)
<b>Total maturities of long-term debt and capital leases</b>	<b>\$ 1,084,004</b>

**10. COMMITMENTS AND CONTINGENCIES*****Operating Leases***

The Company leases various types of office, manufacturing and warehouse facilities and equipment under noncancelable operating leases that expire at various terms through 2010. Future minimum lease payments under non-cancelable operating leases are as follows:

2007	\$ 478,000
2008	333,000
2009	254,000
2010	42,000

There are no payments scheduled after 2010.

Rent expense was approximately \$502,500, \$205,500, and \$98,600 in 2006, 2005, and 2004, respectively.

***Purchase Obligations***

In June 2005, the Company entered into a 19-month development agreement with Stellartech Research Corporation whereby Stellartech agreed to develop enhancements to the current ASU technology and granted the Company a license to use Stellartech's technology in the field of cardiac arrhythmia treatment. This agreement



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**Table of Contents****ATRICURE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

expired by its terms in December 2006. The Company agreed to pay Stellartech on an hourly basis, based on the types of services being performed. In addition, materials and components, out-of-pocket expenses and outside services will be billed to the Company at cost plus a specified percentage. The Company may terminate this agreement upon 30 days' notice and have no minimum purchase obligations. Under the terms of this agreement, the Company has certain indemnification obligations to Stellartech for its performance of services under the agreement, except for Stellartech's breach, fraud, negligence or misconduct and infringement relating to intellectual property owned by Stellartech, for each of which it indemnifies the Company.

In June 2005, the Company also entered into a manufacturing agreement with Stellartech whereby the Company agreed, among other things, to purchase, and Stellartech agreed to supply, the first 400 Ablation Sensing Units, or ASUs, that the Company requires. As of December 31, 2006, the Company had fulfilled its obligation to purchase the first 400 ASUs from Stellartech and was required to purchase at least 75% of its ASU requirements from Stellartech until November 2007. The Company may, however, extinguish its obligation to purchase 75% of its ASU requirements from Stellartech by paying to Stellartech either a certain percentage of the gross margin Stellartech would have received if it had manufactured the ASUs or a specified dollar amount. This agreement has an initial three-year term and renews for successive one-year periods, unless terminated. This agreement may be terminated by Stellartech for any reason upon six months' notice to the Company. The Company may terminate the agreement in the event the development agreement is terminated prior to expiration or after the Company has fulfilled the purchase requirements under the agreement. Under the terms of this agreement, the Company has certain indemnification obligations, including with respect to claims relating to intellectual property infringement, design defects and manufacturing defects. Any supply interruption or failure to obtain the Company's ASU would limit the Company's ability to sell its Isolatx system and could have a material adverse effect on its business, financial condition and results of operations.

***Royalty Obligation***

In October 2005, the Company entered into a royalty agreement with the inventor of its Lumitip dissector. Under the terms of the agreement, the Company is required to make minimum quarterly payments of \$50,000 for the use of the Lumitip dissector as well as for those inventions, improvements or ideas made or conceived by Dr. Wolf within the field of atrial fibrillation treatment. Royalty payments may exceed the \$50,000 minimum and are based on a percentage of the Company's net sales of the Lumitip dissector. The royalty rate declines over the life of the agreement and was 10.5% and 15.0% in 2006 and the fourth quarter of 2005, respectively, and will be 4.0% in 2007, 2.5% in 2008, and 1.5% in 2009. The royalty agreement terminates on December 31, 2009, and total payments under the agreement shall not exceed \$2,000,000. The Company expensed approximately \$234,000 and \$85,000 under this agreement in 2006 and 2005, respectively.

***Consultant Agreement***

The Company entered into a Consulting Agreement, dated as of January 1, 2007, with Michael D. Hooven, the Company's co-founder and also one of its directors. Under the terms of the agreement, Mr. Hooven will provide consulting services and advice to the Company 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 will be paid \$12,000 per month. The term of the agreement is one year; provided, however, that if there is a change of control event, the agreement will terminate automatically upon consummation of the change of control event.

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**ATRICURE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Grant Rights and Obligations***

On July 18, 2006, the Company entered into an Agreement effective as of June 6, 2005 with The Cleveland Clinic relating to the Company's rights and obligations with respect to the publicly announced grants from the State of Ohio for, among other things, the creation of an Atrial Fibrillation Innovation Center. Pursuant to the terms of the Agreement, the Company is 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, the Company will receive up to a total of approximately \$900,000 for personnel and materials and The Cleveland Clinic will acquire up to approximately \$2,400,000 in capital equipment for the Company's use in support of its performance of the Agreement. Over the period of the agreement, the Company is required to expend up to approximately \$7,700,000 for operating expenses and up to approximately \$4,800,000 for capital expenses in support of the Agreement. The Company believes these amounts represent ordinary course expenditures that it would have otherwise anticipated making.

The terms of the Agreement specify the division of ownership of intellectual property developed in the performance of the Agreement and provide, among other things, that the Company will own all intellectual property it develops alone and certain intellectual property that is jointly developed and it will have the option to license certain intellectual property that is owned by The Cleveland Clinic and developed in the performance of the Agreement. Additionally, the Agreement terminates on December 6, 2008. However, the Company and The Cleveland Clinic may terminate the Agreement at any time by giving 30 days' prior written notice.

***Legal***

***Class Action***

The Company and certain of its 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 the Company's common stock during the period from the Company's Initial Public Offering in August 2005 through February 16, 2006. The Company believes that the allegations are without merit and intends to vigorously defend against them, and the Company's motion to dismiss this suit is currently pending.

***Life Support Technology LST B.V.***

Multiple proceedings exist between Life Support Technology LST B.V., a former distributor of the Company's products in Europe, and the Company. In January 2006, LST filed an action against the Company in Den Bosch, Netherlands and in March 2006 the Company brought an action in Ohio against LST.

On January 11, 2006, Udink & De Jong, the Company's Netherlands counsel, received a copy of a summons to be served on the Company in the United States. The summons was prepared on behalf of LST. The Company and LST were party to a distribution agreement, dated January 1, 2004. The summons alleges that the Company and LST reached an agreement, which would succeed the January 1, 2004 agreement, pursuant to which LST agreed to continue distributing the Company's products in certain European countries. The summons also alleges that, in addition to the value for LST of a continued distributorship, the agreement would have provided approximately \$330,000 to LST and its principal, J.L.M. Marinus. The Company believes that it did not reach such an agreement with LST and that the original distribution agreement with LST was terminated as of December 31, 2005. The Company has vigorously defended this action in the Netherlands. Among other things, the Company's Netherlands counsel moved for dismissal based on lack of jurisdiction or, in the alternative, for



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**Table of Contents****ATRICURE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

suspension of the Netherlands proceedings pending determination of the Ohio proceedings described below. By decision dated February 14, 2007, the Netherlands District Court dismissed LST's action, holding that the Court lacks jurisdiction. This decision can be appealed up to May 14, 2007, within three months after the decision. To date, LST has given no indication that it intends to appeal.

Pursuant to the January 1, 2004 distribution agreement with LST, certain of LST's obligations survive termination of the agreement. Such obligations include, among other things, the timely payment for equipment purchased and the return of all information materials (such as marketing literature and sales and promotional materials) supplied by the Company to LST. LST has not complied with certain of these obligations. Therefore, in March 2006 the Company filed a complaint in Ohio State Court (Butler County, Ohio Court of Common Pleas) against LST claiming that LST has not complied with these obligations and the Company is seeking damages which, due to Ohio pleading limitations, are alleged to be more than \$25,000 but which, in fact, the Company believes are in an amount in excess of \$185,000. In this Ohio proceeding, LST has asserted, in the form of counterclaims against the Company, similar claims to which it has asserted in the Netherlands proceeding. The Company recently filed a motion for summary judgment seeking to dismiss LST's counterclaims. Discovery in the Ohio action has been substantially completed and the trial is set for April 30, 2007.

**11. REDEEMABLE PREFERRED STOCK**

In 2001, the Company issued 2,182,521 shares of Series A Preferred Stock at \$2.39 per share. In exchange for the Series A Preferred Stock, the Company received \$4,025,000 in cash and converted a \$1,150,000 promissory note that was issued in January 2001 and the related accrued interest of \$49,958. The proceeds were reduced by \$131,426 in direct expenses associated with the offering. Amortization of the direct issuance expenses was \$12,058 and \$23,572 in 2005 and 2004, respectively.

In 2002, the Company issued 3,829,499 shares of Series B Preferred Stock at \$5.43 per share. In exchange for the Series B Preferred Stock, the Company received \$17,274,500 in cash and converted a \$3,500,000 note and the related accrued interest of \$35,000. The proceeds were reduced by \$96,704 in direct expenses associated with the offering. Amortization of the direct issuance expenses was \$9,358 and \$22,399 in 2005 and 2004, respectively.

Each share of Series A and B Preferred Stock was convertible by the holders into common stock of the Company at any time after the date of issuance. The number of shares of common stock that would be received upon conversion would have been determined by dividing \$2.39 by the Series A conversion price and \$5.43 by the Series B conversion price (original issue price subject to adjustments as specified in the Company's Certificate of Incorporation) in effect at the time of conversion. In addition, upon conversion, the holder of each share of Series A or B Preferred Stock would have received cash in an amount equal to all dividends declared but unpaid and any and all other amounts owing with respect to the Series A or B Preferred Stock. Upon the closing of the Company's initial public offering, all of the 6,012,020 outstanding shares of preferred stock were converted into 6,012,020 shares of common stock.

The holders of at least two-thirds of the then issued and outstanding shares of Series A or a majority of the then issued and outstanding shares of Series B Preferred Stock may have caused the Company, beginning on June 6, 2007, and on each of the first and second anniversaries thereof, to redeem from the holders of the Series A or B Preferred Stock at a price equal to the original Series A or B Preferred Stock purchase price plus all declared or accrued but unpaid dividends and an amount equal to 15% per annum (by simple interest calculation) of the original Series A or B per share purchase price from the date of May 25, 2001 (Series A) and June 6, 2002 (Series B), through and until the redemption date. The 15% rate was payable only if the Series A or B Preferred

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Stock was redeemed. Since the Series A and B Preferred Stock were converted prior to redemption, no amount was due for the 15% rate. Pursuant to their terms, the Series A and B Preferred Stock converted into shares of common stock on a one-for-one basis upon completion of the initial public offering since the Company received gross proceeds of at least \$35,000,000. The preferred stock was converted to common stock on the initial public offering date and the carrying amount of the preferred stock was reclassified to common stock. There was no gain or loss recognized, and the amounts accrued in prior periods for the 15% return were not reversed. Increases in the cumulative Series A preferred stock, included in the accompanying financial statements, for the 15% rate were \$468,069 and \$783,744 in 2005 and 2004, respectively. Increases in the Series B preferred stock, included in the accompanying financial statements, for the 15% rate were \$1,864,185 and \$3,121,425 in 2005 and 2004, respectively.

**12. INCOME TAXES**

Deferred income tax assets and liabilities are computed annually for differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

Deferred tax assets relate primarily to operating loss carryforwards and research and development credits. The Company recorded a valuation allowance due to the uncertainty of when these assets may be realized. The detail of deferred tax assets and liabilities at December 31 is as follows:

	2006	2005
Deferred tax assets (liabilities)		
Net operating loss carryforward	\$ 11,713,000	\$ 8,323,000
Research and development credit carryforward	2,046,000	1,095,000
Stock compensation	347,000	444,000
Accruals and reserves	267,000	342,000
Intangible assets	(263,000)	(355,000)
Other-net	527,000	32,000
Subtotal	14,637,000	9,881,000
Less valuation allowance	(14,637,000)	(9,881,000)
Total	\$	\$

The provision for income taxes is as follows:

	2006	2005	2004
Current income tax expense	\$	\$	\$
Deferred tax benefit	(4,756,000)	(3,613,000)	(1,956,000)
Increase in valuation allowance	4,756,000	3,613,000	1,956,000
Total	\$	\$	\$

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The Company has a Federal net operating loss carryforward of approximately \$32,200,000 which will begin to expire in 2021. The Company also has state net operating losses of approximately \$21,000,000 which have

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**ATRICURE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

varying expirations ranging from 5 years to 20 years. The Company also has a foreign net operating loss of approximately \$1,100,000 which has no expiration. The Company also has a research and development credit carryforward of approximately \$2,000,000 which will begin to expire in 2021.

**13. RELATED PARTY**

Prior to the acquisition, Enable was a related party with whom the Company transacted business. In January 2002 (amended in 2003), the Company entered into a master development, manufacturing, and supply agreement with Enable. Pursuant to the terms of the agreement, the Company was required to pay Enable a monthly fee of at least \$96,000 for certain product development services during the period from February 1, 2003 to January 31, 2004. After January 31, 2004 there was no specified monthly fee requirement. The agreement expired in January 2005, but was extended to December 2005. The agreement was cancelled as of August 10, 2005 in connection with the acquisition.

The Company entered into a Consulting Agreement, dated as of January 1, 2007, with Michael D. Hooven, its Co-Founder and also one of its directors. Under the terms of the agreement, Mr. Hooven will provide consulting services and advice to the Company 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 will be paid \$12,000 per month. The term of the consulting portion of the agreement is one year; provided, however, that if there is a change of control event, the agreement will terminate automatically upon consummation of the change of control event. Additionally, the agreement contains certain non-compete and non-solicitation provisions which expire on December 31, 2009.

**14. EMPLOYEE BENEFIT PLANS**

The Company sponsors a defined contribution savings and profit sharing retirement plan. Eligible employees were permitted to contribute up to 15% of their eligible compensation, and effective January 1, 2007, eligible employees may contribute up to 50% of their eligible compensation. For every dollar contributed by a participant, the Company will match a fixed percentage set prior to the end of the year (50% of the first 6% for 2006, 2005, and 2004, respectively). The Company may also make discretionary contributions. Total Company matching contributions charged to expense were approximately \$396,700, \$243,500, and \$107,700 in 2006, 2005, and 2004, respectively. No discretionary contributions were paid or charged to expense during 2006, 2005, or 2004.

**15. EQUITY COMPENSATION PLANS**

As of December 31, 2006, the Company had two equity compensation plans: the 2001 Stock Option Plan (the 2001 Plan ) and the 2005 Equity Incentive Plan (the 2005 Plan ). The 2001 plan is no longer used for granting options.

Under the 2005 Plan, the Board of Directors may grant incentive stock options to employees and any parent or subsidiary s employees, and may grant nonstatutory stock options, stock purchase rights, restricted stock, stock appreciation rights, performance units or performance shares to employees, directors and consultants of the Company and any parent or subsidiary s employees, directors and consultants. The administrator (which is made up of the Company s board of directors or a committee of the board) has the power to determine the terms of any awards, including the exercise price of options, the number of shares subject to each award, the exercisability of the awards and the form of consideration.

**Table of Contents****ATRICURE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Options granted under the 2001 and 2005 Plans generally expire 10 years from the date of grant (5 years for persons owning more than 10% of the voting power of all classes of stock). Options granted from the 2001 plan are generally exercisable beginning one year from the date of grant in cumulative yearly amounts of 25% of the shares granted. Options granted from the 2005 plan generally vest at a rate of 25% on the first anniversary date and ratably each month thereafter. Certain options are exercisable upon grant and the underlying unvested shares are subject to the Company's repurchase right as stated in the applicable plan agreement.

Under the 2005 Plan, 2,347,817 shares of common stock were reserved for issuance as of December 31, 2006. In addition, the shares reserved for issuance under the 2005 plan include (a) shares reserved but unissued under the 2001 Plan as of August 10, 2005, (b) shares returned to the 2001 Plan as the result of termination of options or the repurchase of shares issued under such plan, and (c) annual increases in the number of shares available for issuance on the first day of each year equal to the lesser of:

3.25% of the outstanding shares of common stock on the first day of the fiscal year;

825,000 shares; or

an amount the Company's board of directors may determine.

As of December 31, 2006, 3,228,479 shares of the Company's common stock were reserved for issuance under the Company's equity compensation plans. On January 1, 2006, 392,676 additional shares were authorized for issuance under the 2005 Equity Incentive Plan representing 3.25% of the outstanding shares on this date.

Activity under the Plans was as follows:

	<b>Number of Shares Outstanding</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at January 1, 2006	1,610,895	\$ 6.33		
Granted	725,894	\$ 8.71		
Forfeited	(345,195)	\$ 10.04		
Exercised	(84,666)	\$ 1.09		
Outstanding at December 31, 2006	1,906,928	\$ 6.79	7.54	\$ 6,553,176
Expected to vest	1,755,469	\$ 6.53	7.42	\$ 6,431,013
Exercisable at December 31, 2006	876,766	\$ 3.41	6.12	\$ 5,483,209

As of December 31, 2006, there were 1,321,551 shares available for future grants under the Plans.

The total intrinsic value of options exercised during the years ended December 31, 2006, 2005, and 2004 was approximately \$505,000, \$471,000, and \$103,000, respectively. Due to the Company's current tax position, no tax benefit was recognized as a result of option exercises for the years ended December 31, 2006, 2005, and 2004. Additionally, there was no impact on operating or financing activities in the Company's

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consolidated statement of cash flows for the years ended December 31, 2006, 2005, and 2004 as a result of the exercise of stock options, other than the recognition of \$92,470, \$42,214, and \$89,183, respectively, in cash receipts as a result of stock option exercises.

The exercise price per share of each option is equal to the fair market value of the underlying share on the date of grant. The Company issues registered shares of common stock to satisfy stock option exercises.

**Table of Contents****ATRICURE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Valuation and Expense Information under FAS 123(R)**

On January 1, 2006, the Company adopted SFAS 123(R), which requires the measurement and recognition of compensation expense for all share-based payment awards made to the Company's employees and directors based on fair values. The following table summarizes stock-based compensation expense related to employee stock options under SFAS 123(R), which was allocated as follows:

	<b>Year Ended December 31, 2006</b>
Cost of revenue	\$ 55,364
Research and development	184,534
Selling, general and administrative	1,018,226
 Total stock-based compensation expense related to employee stock options	 \$ 1,258,124
 Impact on reported basic and diluted loss per share	 \$ 0.10

For the years ended December 31, 2005 and 2004, the Company incurred a charge for stock compensation for employees for options issued with exercise prices below fair market value of approximately \$259,000 and \$327,000, respectively.

In calculating the compensation costs under SFAS 123 and SFAS 123(R), the fair value of the options is estimated on the grant date using the Black-Scholes model considering the following assumptions:

	<b>2006</b>	<b>2005</b>	<b>2004</b>
Risk free interest rate	4.44 - 5.14%	3.75 - 3.99%	2.89 - 3.25%
Expected life of option (years)	6.0	4.0 - 6.0	4.0
Expected volatility of stock	38.06 - 46.00%	0.00 - 57.00%	0.00%
Weighted-average volatility	38.92%	43.48%	0.00%
Dividend yield	0.00%	0.00%	0.00%

The risk-free interest rate assumption is based upon the U.S. treasury yield curve at the time of grant for a time period equal to the expected option life.

Due to the Company's limited operating history, the expected lives and volatility are estimated based on other companies in the industry.

Due to the Company's limited trading history, the Company used the implied volatility of a group of comparable companies, looking at both short and long-dated options in determining the Company's volatility.

Based on the assumptions noted above, the weighted average estimated fair values of the options granted in the years ended December 31, 2006, 2005, and 2004 were as follows:

	<b>2006</b>	<b>2005</b>	<b>2004</b>
Weighted average fair value of options granted	\$ 3.92	\$ 6.22	\$ 6.22





**Table of Contents****ATRICURE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Non-Employee Stock Compensation***

The Company has issued nonstatutory common stock options to consultants to purchase shares of common stock. Such options vest over a service period ranging from immediately to four years. The fair value at the date of grant, which is subject to adjustment at each vesting date based upon the fair value of the Company's common stock, was determined using the Black-Scholes model with the following assumptions:

	2005	2004
Risk free interest rate	3.25 - 3.69%	1.84 - 3.25%
Expected life of option (years)	2.0 - 10.0	10.0
Expected volatility of stock	0.00 - 57.00%	0.00%
Weighted-average volatility	27.80%	0.00%
Dividend yield	0.00%	0.00%

There were no non-employee stock options granted during 2006.

The values attributable to these options have been amortized over the service period on a graded vesting method and the vested portion of these options was re-measured at each vesting date.

Stock compensation income (expense) with respect to non-employee awards totaled approximately \$212,000, \$(414,000), and \$(687,000) for the years ended December 31, 2006, 2005, and 2004, respectively.

**16. EXERCISE OF WARRANTS**

In August 2006, 17,452 shares of common stock were issued as a result of the cashless exercise of 195,160 warrants with an exercise price of \$5.43 and an average fair value of \$5.96. These warrants were initially granted in connection with the issuance of a convertible note in 2002. There are no outstanding warrants from this grant as of December 31, 2006.

**17. SEGMENT AND GEOGRAPHIC INFORMATION**

The Company considers reporting segments in accordance with SFAS 131, Disclosure about Segments of an Enterprise and Related Information. The Company develops, manufactures, and sells devices designed for the surgical treatment of atrial fibrillation. These devices are developed and marketed to a broad base of hospitals in the United States and internationally. Management considers all such sales to be part of a single operating segment.

Geographic revenue is as follows:

	2006	2005	2004
United States	\$ 34,084,304	\$ 28,281,096	\$ 17,748,472
International	4,158,939	2,675,891	1,408,560
Total	\$ 38,243,243	\$ 30,956,987	\$ 19,157,032

**Table of Contents****ATRICURE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Substantially all of the Company's long-lived assets are located in the United States.

**18. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

(Dollars in thousands, except per share data)

	March 31,		For the Three Months Ended				December 31,	
	2006	2005	June 30, 2006	2005	September 30, 2006	2005	2006	2005
Operating Results:								
Revenue	\$ 8,637	\$ 7,498	\$ 9,649	\$ 7,730	\$ 9,358	\$ 7,170	\$ 10,599	\$ 8,559
Gross profit	7,037	5,578	7,864	5,752	7,472	5,154	8,244	6,416
Loss from operations	(3,369)	(1,411)	(3,554)	(1,361)	(3,391)	(3,777)	(4,455)	(4,301)
Net loss	(3,090)	(2,366)	(3,208)	(2,343)	(3,156)	(3,964)	(4,263)	(4,010)
Loss per share (basic and diluted)	\$ (0.26)	\$ (1.26)	\$ (0.26)	\$ (1.24)	\$ (0.26)	\$ (0.49)	\$ (0.35)	\$ (0.33)

**Table of Contents****SCHEDULE II****VALUATION AND QUALIFYING ACCOUNTS**

	Beginning Balance	Additions	Deductions	Ending Balance
<b>Allowance for doubtful accounts receivable</b>				
Year ended December 31, 2006	\$ 261,707	\$ 81,420	\$	\$ 343,127
Year ended December 31, 2005	\$ 56,779	\$ 204,928	\$	\$ 261,707
Year ended December 31, 2004	\$ 27,877	\$ 28,902	\$	\$ 56,779
<b>Allowance for inventory valuation</b>				
Year ended December 31, 2006	\$ 258,558	\$ 71,462	\$ 235,353	\$ 94,667
Year ended December 31, 2005	\$	\$ 287,052	\$ 28,494	\$ 258,558
Year ended December 31, 2004	\$	\$	\$	\$
<b>Valuation allowance for deferred tax assets</b>				
Year ended December 31, 2006	\$ 9,881,000	\$ 4,756,000	\$	\$ 14,637,000
Year ended December 31, 2005	\$ 6,268,000	\$ 3,661,000	\$ 48,000	\$ 9,881,000
Year ended December 31, 2004	\$ 4,313,000	\$ 1,955,000	\$	\$ 6,268,000

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

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this Form 10-K was carried out under the supervision and with the participation of our management, including our chief executive officer. Based on that evaluation, our chief executive officer has concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

**Changes in Internal Control Over Financial Reporting**

During the twelve-month period ended December 31, 2006, there has not occurred any change in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Securities Exchange Act of 1934) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. However, as previously announced, during the third quarter of 2006, our Vice President and Chief Financial Officer resigned. We believe that the resignation was in no way related to our internal controls, financial statements, financial performance or financial condition. All of the control processes formerly performed by our Chief Financial Officer were transitioned to and performed by other individuals, including our Chief Executive Officer until a successor was named in January 2007. During that time our President and Chief Executive Officer continued to work with our controller to manage our finances and all finance functions reported directly to our President and Chief Executive Officer.

**ITEM 9B. OTHER INFORMATION**

None.

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**PART III**

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

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2007 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of 2006 (the Proxy Statement ).

**ITEM 11. EXECUTIVE COMPENSATION**

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

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

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

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE**

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

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

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

**Table of Contents****PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

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

<b>Exhibit No.</b>	<b>Description</b>
1.1 <sup>(1)</sup>	Underwriting Agreement, dated as of August 5, 2005, between AtriCure, Inc., the Selling Stockholders as named therein and the Underwriters as named therein.
2.1 <sup>(2)</sup>	Agreement and Plan of Merger, dated as of February 14, 2005, between AtriCure, Inc. and Enable Medical Corporation (exhibits and schedules have been omitted but will be furnished supplementally to the Securities and Exchange Commission upon request).
2.1.1 <sup>(3)</sup>	First Amendment to Agreement and Plan of Merger between AtriCure, Inc. and Enable Medical Corporation.
3.2*	Amended and Restated Certificate of Incorporation.
3.4*	Second Amended and Restated Bylaws.
4.1 <sup>(2)</sup>	Amended and Restated Investors Rights Agreement, dated June 6, 2002 between AtriCure, Inc. and each of the signatory Investors.
4.1.1 <sup>(2)</sup>	Amendment No. 1 to Amended and Restated Investors Rights Agreement, dated March 8, 2005 between AtriCure, Inc. and each of the signatory Investors.
4.4 <sup>(3)</sup>	Specimen common stock certificate.
4.5 <sup>(2)</sup>	Specimen of warrant certificate issued to former Series B preferred shareholders.
4.6 <sup>(2)</sup>	Specimen of warrant certificate issued to Lighthouse Capital Partners V, L.P.
10.1 <sup>(2)</sup> #	2001 Stock Option Plan.
10.2 <sup>(3)</sup> #	2005 Equity Incentive Plan.
10.3 <sup>(3)</sup>	Development Agreement, dated as of June 1, 2005, between AtriCure, Inc. and Stellartech Research Corporation.
10.4 <sup>(3)</sup>	Manufacturing Agreement, dated as of June 1, 2005, between AtriCure, Inc. and Stellartech Research Corporation.
10.6 <sup>(2)</sup>	Lease Agreement, dated as of December 18, 2000, between AtriCure, Inc. and Allen Road Properties Limited Liability Company.
10.6.1 <sup>(2)</sup>	Agreement to Improve Lease Premises, First Amendment to Lease Dated December 18, 2000, dated as of May 28, 2002, between AtriCure, Inc. and Allen Road Properties Limited Liability Company.
10.6.2 <sup>(2)</sup>	Agreement to Expand Leased Premises and Extend Lease, Second Amendment to Lease Dated December 18, 2000, dated as of April 8, 2004, between AtriCure, Inc. and Allen Road Properties Limited Liability Company.
10.7 <sup>(2)</sup>	Loan and Security Agreement No. 4631, dated as of March 8, 2005, by and between Lighthouse Capital Partners V, L.P. and AtriCure, Inc.

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.8 <sup>(2)</sup>	Master Development, Manufacturing and Supply Agreement, Second Amended and Restated, dated as of March 19, 2003 by and between Enable Medical Corporation and AtriCure, Inc.
10.9 <sup>(2)</sup>	Technology Transfer Agreement, dated as of May 25, 2001, by and between AtriCure, Inc. and Enable Medical Corporation.
10.10 <sup>(3)</sup>	Development and License Agreement, dated as of July 15, 2005, by and between AtriCure, Inc. and UST Inc.
10.11	Royalty Agreement, dated as of November 21, 2005, by and between AtriCure, Inc. and Randall K. Wolf, M.D.
10.12 <sup>(5)</sup>	Agreement, dated as of July 18, 2006, by and between AtriCure, Inc. and the Cleveland Clinic.
10.13 <sup>(6)#</sup>	Consulting Agreement, dated as of January 1, 2007, between AtriCure, Inc. and Michael D. Hooven.
10.14 <sup>(7)#</sup>	Employment Agreement, dated as of January 5, 2007, between AtriCure, Inc. and Julie A. Piton.
10.15 <sup>(8)#</sup>	Employment Agreement, dated as of February 9, 2007, between AtriCure, Inc. and David J. Drachman.
21	Subsidiaries of the Registrant
23.1	Consent of Deloitte & Touche LLP
31.1	Rule 13a-14(a) Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification pursuant to 18 U.S.C. Section 1350 by the Chief Executive Officer, as adopted, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Incorporated by reference to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on April 20, 2005, which was declared effective on August 4, 2005.

<sup>(1)</sup> Incorporated by reference to our Annual Report on Form 10-K filed on March 31, 2006.

<sup>(2)</sup> Incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on June 14, 2005, which was declared effective on August 4, 2005.

<sup>(3)</sup> Incorporated by reference to Amendment No. 2 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on July 7, 2005, which was declared effective on August 4, 2005.

<sup>(4)</sup> Incorporated by reference to Amendment No. 3 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on July 19, 2005, which was declared effective on August 4, 2005.

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Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

# Compensatory plan or arrangement.

**Table of Contents****SIGNATURES**

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

**AtriCure, Inc.**  
(REGISTRANT)

Date: April 2, 2007

/s/ David J. Drachman  
**David J. Drachman**

**President and Chief Executive Officer**

**(Principal Executive and Principal Financial Officer)**

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this Form 10-K has been signed by the following persons on behalf of the registrant and in the capacities indicated on April 2, 2007:

Signature	Title(s)
/s/ Richard M. Johnston	<b>Richard M. Johnston</b>
<b>Richard M. Johnston</b>	<i>Chairman of the Board</i>
/s/ David J. Drachman	<b>David J. Drachman</b>
<b>David J. Drachman</b>	<i>Chief Executive Officer (principal executive and financial officer)</i>
/s/ Michael D. Hooven	<b>Michael D. Hooven</b>
<b>Michael D. Hooven</b>	<i>Director</i>
/s/ Donald C. Harrison	<b>Donald C. Harrison</b>
<b>Donald C. Harrison</b>	<i>Director</i>
/s/ Elizabeth D. Krell	<b>Elizabeth D. Krell</b>
<b>Elizabeth D. Krell</b>	<i>Director</i>
/s/ Mark R. Lanning	<b>Mark R. Lanning</b>
<b>Mark R. Lanning</b>	<i>Director</i>



/s/ Karen P. Robards

**Karen P. Robards**

/s/ Lee R. Wrubel

**Lee R. Wrubel**

**Karen P. Robards**

*Director*

**Lee R. Wrubel**

*Director*

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