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SEMTECH CORP  
Form SC 13G/A  
February 14, 2006

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Schedule 13G

Under the Securities Exchange Act of 1934  
(Amendment No. 4)\*

SEMTECH CORPORATION

---

(Name of Issuer)

Common Stock

---

(Title of Class of Securities)

816850101

---

(CUSIP Number)

Check the following box if a fee is being paid with this statement \_\_\_\_\_. (A fee is not required only if the filing person: (1) has a previous statement on file reporting beneficial ownership of more than five percent of the class of securities described in Item 1; and (2) has filed no amendment subsequent thereto reporting beneficial ownership of five percent or less of such class.) (See Rule 13d-7.)

\*The remainder of this cover page shall be filled out for a reporting person's initial filing on this form with respect to the subject class of securities, and for any subsequent amendment containing information which would alter the disclosures provided in a prior cover page.

The information required in the remainder of this cover page shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934 ("Act") or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Notes).

(Continued on following page(s))

Page 1 of 5 Pages

CUSIP NO. 816850101

13G

Page 2 of 5 Pages

1 Name of Reporting Person  
S.S. or I.R.S. Identification No. of Above Person

T. ROWE PRICE ASSOCIATES, INC.  
52-0556948

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2 Check the Appropriate Box if a Member of a Group\*

NOT APPLICABLE (a) \_\_\_\_\_  
(b) \_\_\_\_\_

3 SEC Use Only

\_\_\_\_\_

4 Citizenship or Place of Organization

MARYLAND

Number of 5 Sole Voting Power  
\*\*

Shares 1,564,800

Beneficially 6 Shared Voting Power  
\*\*

Owned By Each -0-

Reporting 7 Sole Dispositive Power  
\*\*

Person 7,392,100

With 8 Shared Dispositive Power

-0-

9 Aggregate Amount Beneficially Owned by Each Reporting Person

7,392,100

10 Check Box if the Aggregate Amount in Row (9) Excludes Certain Shares\*

NOT APPLICABLE

11 Percent of Class Represented by Amount in Row 9

10.1%

12 Type of Reporting Person\*

IA

\*SEE INSTRUCTION BEFORE FILLING OUT!

\*\*Any shares reported in Items 5 and 6 are also reported in Item 7.

SCHEDULE 13G

PAGE 3 OF 5

Item 1(a) Name of Issuer:

Reference is made to page 1 of this Schedule 13G

Item 1(b) Address of Issuer's Principal Executive Offices:

200 Flynn Road, Camarillo, California 93012-8790

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Item 2(a) Name of Person(s) Filing:

(1) T. Rowe Price Associates, Inc. ("Price Associates")

(2) \_\_\_\_\_

\_\_\_\_\_ Attached as Exhibit A is a copy of an agreement between the Persons Filing (as specified hereinabove) that this Schedule 13G is being filed on behalf of each of them.

Item 2(b) Address of Principal Business Office:

100 E. Pratt Street, Baltimore, Maryland 21202

Item 2(c) Citizenship or Place of Organization:

(1) Maryland

(2) \_\_\_\_\_

Item 2(d) Title of Class of Securities:

Reference is made to page 1 of this Schedule 13G

Item 2(e) CUSIP Number: 816850101

Item 3 The person filing this Schedule 13G is an:

X Investment Adviser registered under Section 203 of the Investment Advisers Act of 1940

\_\_\_\_\_ Investment Company registered under Section 8 of the Investment Company Act of 1940

Item 4 Reference is made to Items 5-11 on page 2 of this Schedule 13G.

SCHEDULE 13G

PAGE 4 OF 5

Item 5 Ownership of Five Percent or Less of a Class.

X Not Applicable.

\_\_\_\_\_ This statement is being filed to report the fact that, as of the date of this report, the reporting person(s) has (have) ceased to be the beneficial owner of more than five percent of the class of securities.

Item 6 Ownership of More than Five Percent on Behalf of Another Person

(1) Price Associates does not serve as custodian of the assets of any of its clients; accordingly, in each instance only the client or the client's custodian or trustee bank has the right to receive dividends paid with respect to, and proceeds from the sale of, such securities.

The ultimate power to direct the receipt of dividends

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paid with respect to, and the proceeds from the sale of, such securities, is vested in the individual and institutional clients which Price Associates serves as investment adviser. Any and all discretionary authority which has been delegated to Price Associates may be revoked in whole or in part at any time.

Except as may be indicated if this is a joint filing with one of the registered investment companies sponsored by Price Associates which it also serves as investment adviser ("T. Rowe Price Funds"), not more than 5% of the class of such securities is owned by any one client subject to the investment advice of Price Associates.

- (2) With respect to securities owned by any one of the T. Rowe Price Funds, only State Street Bank and Trust Company, as custodian for each of such Funds, has the right to receive dividends paid with respect to, and proceeds from the sale of, such securities. No other person is known to have such right, except that the shareholders of each such Fund participate proportionately in any dividends and distributions so paid.

Item 7 Identification and Classification of the Subsidiary Which Acquired the Security Being Reported on By the Parent Holding Company.

Not Applicable.

Item 8 Identification and Classification of Members of the Group.

Not Applicable.

SCHEDULE 13G  
PAGE 5 OF 5

Item 9 Notice of Dissolution of Group.

Not Applicable.

Item 10 Certification.

By signing below I (we) certify that, to the best of my (our) knowledge and belief, the securities referred to above were acquired in the ordinary course of business and were not acquired for the purpose of and do not have the effect of changing or influencing the control of the issuer of such securities and were not acquired in connection with or as a participant in any transaction having such purpose or effect. T. Rowe Price Associates, Inc. hereby declares and affirms that the filing of Schedule 13G shall not be construed as an admission that Price Associates is the beneficial owner of the securities referred to, which beneficial ownership is expressly denied.

Signature.

After reasonable inquiry and to the best of my (our) knowledge and belief, I (we) certify that the information set forth in this statement is true,

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complete and correct.

Dated: February 14, 2006

T. ROWE PRICE ASSOCIATES, INC.

By: /s/ Henry H. Hopkins  
Henry H. Hopkins, Vice President

Note: This Schedule 13G, including all exhibits, must be filed with the Securities and Exchange Commission, and a copy hereof must be sent to the issuer by registered or certified mail not later than February 14th following the calendar year covered by the statement or within the time specified in Rule 13d-1(b)(2), if applicable.

12/31/2005

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting Common Stock held by non-affiliates of the registrant, based upon the closing sale price of the Common Stock on June 30, 2012, as reported on the NASDAQ Global Market, was \$118.6 million.

As of February 28, 2013 there were 20,896,517 shares of Common Stock, \$.001 par value per share, outstanding.

### DOCUMENTS INCORPORATED BY REFERENCE

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



**Table of Contents**

**TABLE OF CONTENTS**

<b><u>PART I</u></b>		1
	<u>ITEM 1. BUSINESS</u>	1
	<u>ITEM 1A. RISK FACTORS</u>	20
	<u>ITEM 1B. UNRESOLVED STAFF COMMENTS</u>	37
	<u>ITEM 2. PROPERTIES</u>	37
	<u>ITEM 3. LEGAL PROCEEDINGS</u>	37
	<u>ITEM 4. MINE SAFETY DISCLOSURES</u>	37
<b><u>PART II</u></b>		38
	<u>ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	38
	<u>ITEM 6. SELECTED FINANCIAL DATA</u>	40
	<u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	41
	<u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	52
	<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	53
	<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	84
	<u>ITEM 9A. CONTROLS AND PROCEDURES</u>	84
	<u>ITEM 9B. OTHER INFORMATION</u>	87
<b><u>PART III</u></b>		87
	<u>ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	87
	<u>ITEM 11. EXECUTIVE COMPENSATION</u>	87
	<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	87
	<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE</u>	87
	<u>ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	87
<b><u>PART IV</u></b>		88
	<u>ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u>	88
<b><u>SIGNATURES</u></b>		91

**Table of Contents****PART I**

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

**ITEM 1. BUSINESS****Overview**

We are a medical device company and a leader in developing, manufacturing and selling innovative cardiac surgical ablation systems designed to create precise lesions, or scars, in cardiac, or heart, tissue for the treatment of atrial fibrillation, or AF, and systems for the exclusion of the left atrial appendage. We are the only company with a system approved by the United States Food and Drug Administration, or FDA, for the treatment of patients with persistent and long-standing persistent AF undergoing certain concomitant procedures. We have two primary product lines for the ablation of cardiac tissue. Our primary product line for the ablation of cardiac tissue, which accounts for a majority of our revenue, is the AtriCure Synergy Ablation System, or Synergy System, a bipolar ablation clamp system and related radiofrequency ablation devices. We also offer a cryoablation product line, which features reusable and disposable cryoablation devices. Additionally, we offer the AtriClip Gillinov-Cosgrove Left Atrial Appendage System, or AtriClip system, which is designed to safely and effectively exclude the left atrial appendage.

Cardiothoracic surgeons have adopted our radio-frequency, or RF, ablation and cryoablation systems to treat AF in an estimated 125,000 patients since January 2003, and we believe that we are currently the market leader in the surgical treatment of AF. Our products are utilized by cardiothoracic surgeons during concomitant open-heart surgical procedures and also during sole-therapy minimally invasive cardiac ablation procedures. During a concomitant open procedure, the surgeon ablates cardiac tissue and/or excludes the left atrial appendage, secondary, or concomitant, to a primary cardiac procedure such as a valve or coronary bypass. Additionally, although our products are not approved for this specific use, cardiothoracic surgeons have adopted our products as a treatment alternative for AF patients who may be candidates for sole-therapy minimally invasive surgical procedures. Our Synergy System, which includes our Isolator<sup>®</sup> Synergy clamps, a radiofrequency generator and related switchbox, is approved by the FDA for the treatment of patients with persistent and long-standing persistent AF during open-heart concomitant coronary artery bypass grafting and/or valve replacement or repair procedures. To date, none of our other products have been approved or cleared by the FDA for the treatment of other forms of AF or for other uses for the treatment of AF. Additionally, the FDA has not cleared or approved our products for a reduction in the risk of stroke. We anticipate that substantially all of our revenue for the foreseeable future will relate to products we currently sell, or are in the process of developing, which surgeons generally use to ablate cardiac tissue for the treatment of AF or for the exclusion of the left atrial appendage.

AF affects approximately 1% of the population in the United States. It is the most common cardiac arrhythmia, or irregular heartbeat, encountered in clinical practice and accounts for more doctor visits and



## **Table of Contents**

hospital days than any other cardiac arrhythmia. AF is a condition wherein abnormal electrical impulses cause the atria, or upper chambers of the heart, to fibrillate, or quiver, at rapid rates of 400 to 600 beats per minute. As a result of this quivering, blood in the atria may become static, creating an increased risk that a blood clot will form and cause a stroke or other serious complications. If AF persists, patients often progress from experiencing AF intermittently to having AF continuously, a condition that is more difficult to treat. Symptoms of AF may include heart palpitations, dizziness, fatigue and shortness of breath, and these symptoms may be debilitating and life threatening in some cases. Although there is often no specific cause of AF, the condition is often associated with high blood pressure and other forms of heart disease. In most cases, AF is associated with cardiovascular disease, in particular hypertension, congestive heart failure, left ventricular dysfunction, coronary artery disease and valvular disease.

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

We were incorporated in the State of Delaware as AtriCure, Inc. on October 31, 2000 in connection with a spin-off transaction from Enable Medical Corporation, in which shares of our common stock were distributed to the Enable shareholders. The spin-off was intended to allow us to focus on the development of products designed to treat AF and to raise capital for that purpose, while Enable continued its broader research and manufacturing activities. On August 5, 2005, we completed an initial public offering of our common stock. On August 10, 2005, we acquired Enable Medical Corporation, the manufacturer of our Isolator clamps, which are an essential part of our Synergy System. We have two operating subsidiaries: (i) AtriCure Europe B.V., a company incorporated under the laws of the Netherlands in December 2005; and (ii) AtriCure, LLC, a limited liability company organized under the laws of Delaware in October 2012.

## **Market Overview**

AF is the most commonly diagnosed sustained cardiac arrhythmia, and affects more than 5.5 million people worldwide, including more than 3.0 million in the United States, where approximately 160,000 new cases of AF are diagnosed each year. According to data from the Framingham Heart Study, a study originally undertaken by the National Heart Institute (now known as the National Heart, Lung and Blood Institute), it is estimated that the incidence of AF doubles with each decade of an adult's life. At age 40, remaining lifetime risk for AF is 26% for men and 23% for women. AF is an under-diagnosed condition due in large part to the fact that patients with AF often have mild or no symptoms and their AF is only diagnosed when they seek treatment for an associated condition, such as a stroke or heart disease. We believe that increasing awareness of AF and improved diagnostic screening will result in an increased number of patients diagnosed with AF. Also, since the prevalence of AF increases with age, there will likely be an increase in the number of diagnosed AF patients in the United States as the population ages.

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

## **Table of Contents**

AF is a condition that doctors often find difficult to treat and, historically, there has been no widely accepted long-term cure for AF. Doctors typically begin treating AF with drugs, which are often ineffective, not well-tolerated and may be associated with serious side effects. Patients who cannot effectively be treated with drugs may be candidates to undergo catheter-based procedures to treat their AF. To perform a catheter ablation, an electrophysiologist performs the ablation from the inside of the heart using a flexible catheter. The heart is reached via a blood vessel, most commonly through the femoral vein. Catheter-based procedures are often technically challenging, can be associated with serious complications, are generally not indicated for a certain population of AF patients and have been known to yield inconsistent results. Implantable devices, such as pacemakers and defibrillators, are sometimes used to reduce the frequency and symptoms of AF although they are not designed to treat the underlying disease. In the past, an open-heart surgical procedure known as the cut and sew Maze was used to treat AF, but this procedure has not been widely adopted because it is technically challenging, highly invasive and involves long recovery times.

Of the patients undergoing open-heart surgery in the United States, we estimate that 80,000-100,000 are potential candidates for surgical ablation using our ablation products. Of the United States population diagnosed with AF, approximately 12%, or 300,000, of these patients are symptomatic and do not respond to drug therapy or are intolerant to the drugs used to treat AF. For these patients, the cut and sew Maze procedure is typically too invasive and catheter ablation may not be indicated. Accordingly, we believe that there is a large population of under-treated patients for whom their physicians may decide that they would potentially benefit from a minimally invasive or hybrid AF treatment using our Synergy System and related products, and that these patients comprise our largest growth opportunity.

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

### **The AtriCure Solution and Products**

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

Our clinical studies for the use of our products to treat AF are ongoing. Leading cardiothoracic surgeons and electrophysiologists, including those who serve or who have served as consultants to us, have published results of initial clinical studies utilizing our Synergy System. The results of these studies are promising in terms of efficacy, ease of use and safety. Additionally, we have conducted FDA regulated clinical trials which support the safety and efficacy of our Synergy System.

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## Table of Contents

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

Product lines for cardiac tissue ablation:

- 1.) **AtriCure s Synergy Ablation System and Related Radio-Frequency Ablation Devices.** Our Synergy System and related RF devices, such as our multifunctional pens, represent our primary product line and currently generate a substantial majority of our revenue. Physicians may elect to use the Synergy System and related RF devices in both open and minimally invasive procedures. These devices primarily consist of the following products:

**Isolator Bipolar Radio-Frequency Ablation Clamps.** We sell multiple configurations of our Isolator Synergy clamps. One design is for ablation during open-heart procedures and one design is for ablation during minimally invasive procedures. All of our clamps are single-use disposables and have jaws that close in a parallel fashion. The parallel closure compresses the tissues and evacuates the blood and fluids from the energy pathway in order to make the ablation more effective.

**Ablation and Sensing Unit, or ASU.** Our ASU is a compact power generator that uses our proprietary software and delivers bipolar radio-frequency, or RF, energy. The ASU provides the RF energy necessary for our clamps, multifunctional pens and Coolrail linear ablation device. We generally lend our ASU, free of charge, to our direct customers and sell it to our distributors.

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

**Isolator Multifunctional Pens.** Our Isolator multifunctional pens are disposable RF devices that come in two configurations; one that makes linear ablations and one that makes spot ablations. The pens enable surgeons to evaluate cardiac arrhythmias, perform temporary cardiac pacing, sensing, and stimulation and ablate cardiac tissue with the same device. When the multifunctional pens are used with our ASB, surgeons are able to toggle back and forth between temporary pacing, sensing, and stimulation and ablation. Because of their broad range of capabilities, we believe surgeons are generally using one or both of our pen devices in combination with our Isolator clamps during both minimally invasive and open-heart procedures.

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

- 2.) **Cryoablation System.** Our cryoablation offering consists of our ACC2 and *cryoICE*<sup>®</sup> BOX generators along with the *cryoIce* probe and reusable cryo probes which use cryotherapy, or extreme cold, to ablate cardiac tissue. Our cryoablation devices are used with our cryoablation generators and are being adopted by physicians for AF ablation treatment during certain open-heart procedures for which physicians prefer cryoablation over RF ablation. We believe our cryoablation devices provide us with a superior competitive product offering.

Product line for left atrial appendage exclusion:

**AtriClip System.** Our AtriClip system is designed to exclude the left atrial appendage by implanting the device during concomitant open surgical procedures from the outside of the heart, avoiding contact with the circulating blood pool while eliminating blood flow between the left atrial appendage and the atria. We believe that our AtriClip system is potentially safer, more effective and easier to use when permanently excluding the left atrial appendage than current products and techniques. During 2012 we launched a new, minimally invasive, totally thoroscopic version of the AtriClip system.



## **Table of Contents**

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

### **Current AF Treatment Alternatives**

Doctors usually begin treating AF patients with a variety of drugs intended to prevent blood clots, control heart rate or restore the heart to normal sinus rhythm. If a patient's AF cannot be adequately controlled with drug therapy, doctors may perform one of several procedures that vary depending on the severity of the AF symptoms and whether or not the patient suffers from other forms of heart disease. During 2007 the Heart Rhythm Society published an updated expert consensus statement on catheter and surgical ablation for the treatment of AF. The expert consensus concluded that the current indications for the surgical treatment of AF are the following:

Symptomatic AF patients undergoing other cardiac surgery;

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

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

Other treatment alternatives include:

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

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

*Catheter-Based Treatment.* Catheter ablation is an ablation procedure that is typically performed by an electrophysiologist. The ablations are made from the inside of the heart using a flexible catheter. The heart is reached via a blood vessel, most commonly through the femoral vein. Catheter-based AF treatments are often technically challenging, can be associated with serious complications and have been known to yield inconsistent results. In proportion to the prevalence of AF, only a small number of catheter-based AF treatments are performed each year in the United States.

*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.

With the exception of the Synergy System, which may be promoted according to its FDA-approved indication for patients with persistent and long-standing persistent AF undergoing certain open-heart procedures, we may not promote our products specifically for AF. Nevertheless, physicians have adopted our products for use in open-heart and minimally invasive procedures for the treatment of AF. During elective open-heart surgical procedures, such as bypass or valve surgery, cardiothoracic surgeons use our ablation systems to treat patients



## **Table of Contents**

with a pre-existing history of AF. Surgeons report that ablation using our products generally adds approximately 10 to 20 minutes to an open-heart surgical procedure. Surgeons use our products to perform cardiac procedures that may vary depending on the length of time a patient has been diagnosed with AF and whether the patient's AF is intermittent, known as paroxysmal, or more continuous, known as persistent, long-standing persistent or permanent. Patients who have been diagnosed with AF for a longer duration and have non-paroxysmal forms of AF generally receive more extensive ablation procedures than patients who have been diagnosed with AF for a shorter duration or who have paroxysmal AF. Additionally, during an open-heart procedure, physicians may use our AtriClip system to exclude the left atrial appendage, which has been reported to add less than one minute to a procedure. Surgeons using our ablation systems during an open-heart surgical procedure typically perform the following steps:

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

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

For those patients with AF who do not require a concomitant open-heart surgical procedure, surgeons have used our Isolator clamps and related products for minimally invasive AF treatment procedures. These procedures have generally been performed through minimally invasive incisions without the need to place patients on a heart-lung bypass machine. Surgeons have reported that the procedure takes approximately two to three hours and that the average hospitalization period has typically been two to five days. Similar to the open-heart surgical procedure, patients who have non-paroxysmal forms of AF generally require an expanded lesion set that mimics the cut and sew Maze procedure. Our multifunctional pens are often used during these procedures to enable physicians to perform additional ablations.

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

## **Product Development**

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

Our product development initiatives have been partially funded by a variety of grant programs. In April 2010 we received a grant from the State of Ohio through the Global Cardiovascular Innovation Center. Pursuant to the terms of the grant, as amended, we are eligible to receive \$0.5 million in support of defined research and

## **Table of Contents**

development activities through 2012. During 2012 we earned \$0.3 million pursuant to the grant, and to date we have earned \$0.5 million under the grant.

In July 2011 we were awarded a \$1 million grant from the Ohio Third Frontier Commission, a technology-based economic development initiative dedicated to supporting existing industries that are transforming themselves with new globally competitive products and fostering the formation and attraction of new companies in emerging industry sectors in Ohio. The grant will be used to develop and commercialize a left atrial appendage exclusion device for use in minimally invasive standalone procedures. We earned \$0.1 million related to this grant in 2012.

### **Business Strategy**

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

***Provide Training and Education.*** We have recruited and trained sales professionals who have strong backgrounds in the medical device industry to effectively communicate to doctors the unique features and benefits of our technologies as they relate to their cleared indications. Our highly trained sales professionals meet with doctors at leading institutions to provide education and technical training on the technical features and benefits of our products. With the December 2011 approval of our Synergy System for the treatment of AF, our U.S. sales representatives also educate and train physicians on the use of the Synergy System to treat certain AF patients who are undergoing open-heart surgery. Additionally, we instituted a comprehensive training program to train existing and new customers on the use of the Synergy System to treat certain AF patients undergoing open-heart surgery. This FDA approved training program provides for comprehensive training of all new users and an eighteen month window to train existing users. We believe this training and education program will increase awareness about the surgical treatment of AF during open-heart procedures, which we believe will result in market expansion. We also provide medical information on our products in response to information requests from physicians, and we have provided educational grants to institutions that have facilitated the education of doctors concerning the treatment of AF, including the use of our products as an AF treatment alternative. As a result of the educational process, we believe that awareness of our technologies is growing and will result in the increased use of our products.

***Expand International Markets and Enter into New Markets.*** Sales to international customers represented 25% of our total revenue for 2012. Many of the international markets in which we currently do business are underpenetrated markets which present high growth opportunities for our products. Further, we plan to continue to evaluate expansion opportunities in new geographic markets and capitalize on new product introductions.

***New Product Innovation.*** We plan to continue to develop new and innovative products, including those that allow us to enter new market opportunities or expand our growth in existing markets. During 2012 we launched a new, minimally invasive, totally thoracoscopic version of the AtriClip system, which provides a new growth platform. Our product development and growth plans include continued innovation to expand on both new and existing market opportunities.

***Form Relationships with Key Opinion Leaders at Leading Institutions.*** We have formed investigational relationships with key opinion leaders at several leading medical centers who have worked with us as consultants to evaluate and develop our products. Additionally, we have formed an advisory board made up of leading physicians to oversee our AF training programs. Several key opinion leaders have published peer-reviewed data that describes the use of our products as a treatment alternative for AF. These opinion leaders have assisted and continue to assist us with the design and/or evaluation of our products. To date, there have been over 40 peer-reviewed publications that describe our Synergy System's ability to create transmural lesions and/or as an AF treatment alternative in addition to our FDA clinical trials. Key publications and presentations have highlighted



## **Table of Contents**

promising results utilizing our products to treat patients with AF during sole-therapy minimally invasive surgical procedures. Further, initial presentations and publications have described our AtriClip system as a safe and effective means of excluding the left atrial appendage. We believe that these publications and presentations have contributed to and, we expect, will continue to contribute to the expanded adoption of our products.

***Leverage Product Portfolio, Labeling and Cross-Selling Opportunities.*** We believe we have the most comprehensive offering of cardiac ablation and left atrial appendage exclusion products in the market. Further, we are the only company with a device approved to treat patients with persistent and long-standing persistent AF. We plan to leverage our leading product portfolio and FDA approvals to facilitate cross-selling of our products as well as to drive market share gains through competitive account conversions.

***Expand Adoption of Our Minimally Invasive Products.*** We believe that the catalysts for expanded adoption of our minimally invasive products include procedural advancements, such as the hybrid procedure, and the publication of peer-reviewed articles, which we believe will help validate the successful, long-term use of our products for patients with AF. We believe that ongoing research activities, including clinical trials, new procedural techniques and anticipated presentations and publications will create an increased demand for our minimally invasive products.

### **Clinical Trials**

We received premarket approval ( PMA ) for our Synergy Ablation System for the treatment of AF during concomitant open-heart procedures in December 2011, after conducting our ABLATE clinical trial since 2007. The FDA approved the Synergy Ablation System for the treatment of patients with persistent and long-standing persistent AF during open-heart concomitant coronary artery bypass grafting and/or valve replacement or repair procedures. The PMA included the requirement to implement a 350-patient post-approval study ( PAS ). Additionally, the FDA approval included the requirement to implement a physician training and education program. We submitted a protocol for the PAS to the FDA in February 2012. We received a letter from the FDA regarding deficiencies in the protocol in April 2012, and we responded to the letter in May 2012. The PAS protocol was approved in September 2012.

During the third quarter of 2010 our Dual Epicardial Endocardial Persistent Atrial Fibrillation ( DEEP AF ) clinical trial was approved by the FDA. DEEP AF was a feasibility trial designed to evaluate the safety and effectiveness of our minimally invasive products with catheter mapping and ablation technologies for the treatment of patients with persistent or long-standing persistent AF. The trial was modified during the first quarter of 2011 to include the use of the AtriClip system to exclude the left atrial appendage. Enrollment in the trial was initiated in December 2010 and was closed in November 2011 after it was determined that a staged approach, where the minimally invasive surgical ablation procedure is performed and the catheter optimization is scheduled separately, may be more applicable to a larger number of investigators. The trial was conducted at six U.S. medical centers and enrolled 24 patients. In February 2012 we submitted to the FDA a staged DEEP AF ( Staged DEEP ) protocol which evaluates the effectiveness of a staged approach where a minimally invasive ablation procedure is performed initially and the catheter and mapping optimization procedure is performed on a different day during the same hospitalization. The protocol was conditionally approved by the FDA in March 2012, and final approval was received in June 2012. Enrollment in the Staged DEEP trial was initiated during the third quarter of 2012. We expect to enroll up to 30 patients at six medical centers.

During the fourth quarter of 2011 our stroke clinical trial was approved by the FDA. The 30-patient trial was designed to evaluate the safety and effectiveness of AtriCure's thoracoscopically deployed AtriClip system for the exclusion of the left atrial appendage for stroke prevention in patients with non-valvular AF and for whom long-term oral anticoagulation therapy is considered unsuitable. Recent findings in the research and development of less invasive versions of the AtriClip system have caused us to place this trial on hold while we evaluate our progress and determine our approach to expand AtriClip technologies into the sole-therapy device markets for left atrial appendage exclusion.

## **Table of Contents**

In August 2012 we filed an Investigational Device Exemption ( IDE ) with the FDA for ABLATE II, a sole-therapy clinical trial intended for patients that have failed single or multiple catheter ablation attempts. The trial leverages our existing open, concomitant PMA approval for AF and our AF-approved products and accessory devices to perform a Maze IV ablation treatment. The trial was conditionally approved by the FDA in September 2012. We have reviewed the conditionally approved IDE with several key surgeons and have concluded that an updated protocol would better serve the patient population identified. The protocol update will require a new IDE, which we anticipate to be completed during the second half of 2013.

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

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

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

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

We market and sell our products in selected markets outside of the United States through independent distributors and, in EMEA markets, through our European subsidiary which includes a combination of independent distributors and direct sales personnel. During 2012 and 2011 sales to customers outside of the United States accounted for 25% and 24% of our total revenue, respectively. We have a network of distributors outside of the United States who currently market and sell our products and are located primarily in Europe, Asia, South America and Canada. Our international sales team is led by a Vice President, General Manager, International and has direct sales representatives who sell to customers in markets we sell directly to, such as Germany and the Benelux region. We continue to evaluate opportunities for further expansion into markets outside of the United States.

### **Competition**

Our industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Many of our competitors have significantly greater financial and human resources than we do and have established reputations with our target customers, as well as worldwide distribution channels that are more established and developed than ours. Our primary competitors include Medtronic, Inc., Estech, St. Jude Medical, Inc., nContact, Inc. and Endoscopic Technologies, Inc. We and

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## **Table of Contents**

our competitors provide products that have been adopted by doctors for the off-label treatment of AF. We are the only company with a FDA approval to market a surgical ablation system for the treatment of AF and the only company with a device, whether catheter-based or surgical, cleared to treat certain patients with persistent or long-standing persistent AF. Some of our competitors offer catheter-based treatments, including but not limited to Biosense Webster, Inc. (a subsidiary of Johnson & Johnson), St. Jude Medical, Inc., and Medtronic, Inc. These companies sell products that are used by doctors to treat the population of patients that have AF but are not candidates for open-heart surgery. However, catheter-based treatments often do not effectively treat patients with non-paroxysmal forms of AF, which we believe is a segment of the AF patient population that would benefit from minimally invasive AF procedures.

We believe that we compete favorably against companies that have products used for the surgical treatment of AF during both open-heart and sole-therapy minimally invasive procedures, although we cannot assume that we will be able to continue to do so in the future or that new devices that perform better than our products will not be introduced. We also believe that our products compete favorably when compared to catheter-based treatments for non-paroxysmal forms of AF. Further, we believe our AtriClip system provides an improved treatment alternative for the exclusion of the left atrial appendage.

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

Existing or new competitors may develop technologies and products that are safer, more effective, easier to use or less expensive than our products. To compete effectively, we have to demonstrate that our products are an attractive alternative to other treatments by differentiating our products on the basis of safety, efficacy, performance, ease of use, brand and name recognition, reputation, service and price. We have encountered and expect to continue to encounter potential customers who, due to existing relationships with our competitors, are committed to or prefer the products offered by competitors. Competitive pressures may result in price reductions and reduced gross profit margins for our products over time. Technological advances developed by one or more of our competitors may render our products obsolete or uneconomical.

### **Third-Party Reimbursement**

Payment for patient care in the United States is generally made by third-party payors. These payors include private insurers and government insurance programs, such as Medicare and Medicaid. The Medicare program, the largest single payor in the United States, is a federal health benefit program administered by the Centers for Medicare and Medicaid Services (CMS), and covers certain medical care items and services for eligible beneficiaries, such as individuals over 65 years old, as well as chronically disabled individuals. Reimbursement under Part A of the Medicare program includes hospitals and other institutional services, while Medicare Part B covers physician services. Because Medicare beneficiaries comprise a large percentage of the populations for which our products are used, and private insurers may follow the coverage and payment policies for Medicare, Medicare's coding, coverage and payment policies for cardiothoracic surgical procedures are significant to our business.

Medicare's Part A program pays hospitals for inpatient services, such as cardiothoracic surgery, under the Inpatient Prospective Payment System, or IPPS, which provides a predetermined payment based on the patient's discharge diagnoses and surgical procedure(s). Discharge diagnoses are grouped into Medicare Severity Diagnosis Related Groupings (MS-DRGs). There are several cardiac surgery MS-DRGs associated with the surgical treatment of AF, with and without a concomitant open-heart procedure. When an ablation device and/or LAA exclusion device are used during a concomitant open-heart procedure, Medicare's hospital reimbursement is based upon the patient's primary surgical procedure. Reimbursement for sole-therapy minimally invasive AF

## **Table of Contents**

ablation treatment is also influenced by the patient's severity of illness. Currently, we believe hospital reimbursement rates for sole therapy and concomitant therapy cardiac surgical tissue ablation are adequate to cover the cost of our products. Medicare's coding, coverage, and payment policies are subject to change. As a result, the continuance of current coverage, coding or payment determinations cannot be guaranteed, and any change may have an adverse impact on our business.

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

In addition to the Medicare program, many private payors look to CMS policies as a guideline in setting their coverage policies and payment amounts. The current coverage policies of these private payors may differ from the Medicare program, and payment rates may be higher, lower, or the same as the Medicare program. If CMS or other agencies decrease or limit reimbursement payments to doctors and hospitals, this may negatively impact our business. Additionally, some private payors do not follow the Medicare guidelines and those payors may reimburse only a portion of the cost of cardiac ablation, or not at all. It is our understanding that there has recently been an increase in certain payors declining reimbursement for sole-therapy minimally invasive AF ablation treatment. Physicians, in combination with their professional organizations and societies, are responding and working to secure reimbursement for the procedure to the extent the payor has denied reimbursement.

The FDA generally does not regulate the practice of medicine. Doctors may use our products in circumstances where they deem it medically appropriate, such as for the treatment of AF or the reduction in stroke risk, even though the FDA may not have approved or cleared our products for those indications. In these circumstances, some government or private payors, including some Medicare carriers, may make coverage and payment determinations on a case-by-case basis. Additionally, some government or private payors may deem the treatment of AF using our products for indications not approved or cleared by the FDA to be experimental or not medically necessary and, as such, may not provide coverage or payment.

## **Government Regulation**

Our products are medical devices and are subject to regulation by the FDA, as well as other federal and state regulatory bodies in the United States and comparable authorities in other countries. In December 2011, following FDA approval, we began to market our Synergy System for the treatment of patients with persistent and long-standing persistent AF during open-heart concomitant coronary artery bypass grafting and/or valve replacement or repair procedures during open-heart, concomitant procedures. Prior to obtaining the expanded approval, we marketed the Synergy System under a 510(k) clearance for the ablation of cardiac tissue. We currently market our minimally invasive clamps in the United States under a 510(k) clearance for the ablation of cardiac tissue. Our multifunctional pen and multifunctional linear pen are marketed in the United States under a 510(k) clearance for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias and for the ablation of cardiac tissue. Our cryoablation products are cleared for the cryosurgical treatment of cardiac arrhythmias. We currently market the Lumitip dissector in the United States under a 510(k) clearance for use in the dissection of soft tissues during general, ear, nose and throat, thoracic, urological and gynecological surgical procedures. We market our AtriClip system for exclusion of the left atrial appendage under direct visualization in conjunction with other open-heart procedures. Although our Synergy Ablation System received FDA approval for the treatment of patients with persistent and long-standing persistent AF during open-heart concomitant coronary artery bypass grafting and/or valve replacement or repair procedures, we may not market our other products for the treatment of AF or the reduction of stroke without obtaining additional approvals from the FDA.

## **Table of Contents**

FDA regulations govern nearly all of the activities that we perform, or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses. The activities that the FDA regulates include the following:

product design, development and manufacture;

product safety, testing, labeling and storage;

pre-clinical testing in animals and in the laboratory;

clinical investigations in humans;

premarketing clearance or approval;

record keeping and document retention procedures;

advertising and promotion;

the import and export of products;

product marketing, sales and distribution;

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

corrective actions, removals and recalls.

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

***510(k) Clearance Pathway.*** When 510(k) clearance is required, we must submit a notification to the FDA demonstrating that our proposed device is substantially equivalent to a predicate device, 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

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clinical data. As a practical matter, 510(k) clearance often takes significantly longer than 90 days and may take up to a year or more. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously cleared device or use, the device is automatically placed into Class III, requiring the submission of a PMA. Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, in connection with safety and effectiveness, approval of a PMA. The FDA requires every manufacturer to make the determination regarding a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. We have made modifications to elements of our products which we believe did not require us to seek additional 510(k) clearance.

***Premarket Approval Pathway.*** A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process and is not otherwise exempt. A PMA must be supported by extensive data, including but not limited to technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction, the safety and effectiveness of the device.

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**Table of Contents**

After a PMA is submitted and the FDA has determined that the application is sufficiently complete to permit a substantive review, the FDA will accept the application for filing. The FDA has 180 days to review an accepted PMA, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. Any approvals we receive may be limited in scope or may be contingent upon further post-approval study commitments or other conditions. New PMAs or PMA supplements are required for significant modification to the device, including indicated use, manufacturing process, labeling and design of a device that is approved through the premarket approval process. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel.

***Clinical Trials.*** Clinical trials are required to support a PMA and are sometimes required for 510(k) clearance. In the United States, clinical trials for a significant risk device require the prior submission of an application for an Investigational Device Exemption, or IDE, to the FDA for approval. An IDE application must be submitted before initiating a new clinical study. Some trials require a feasibility study followed by a pivotal trial. An IDE supplement is utilized as a means of obtaining approval to initiate a pivotal trial following the conclusion of a feasibility trial. IDE applications must be supported by appropriate data, such as animal and laboratory testing results, and any available data on human clinical experience, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The animal and laboratory testing must meet the FDA's good laboratory practice requirements.

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

Clinical trials are subject to extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. We are also required to obtain the patients' written informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the United States. Similarly, in Europe, the clinical study must be approved by a local ethics committee and, in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

***Educational Grants.*** Under FDA policy, a device manufacturer may provide financial support, including support by way of unrestricted educational grants, to third-parties for the purpose of conducting medical educational activities. So long as these sponsored programs are independent of the manufacturer providing the grant, the programs would not be regulated as promotional activity by the manufacturer.

## **Table of Contents**

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

whether the intent of the funded activity is to present clearly defined educational content, free from commercial influence or bias;

whether the third-party grant recipient and not the manufacturer has maintained control over selecting the faculty, speakers, audience, activity content and materials;

whether the program focuses on a single product of the manufacturer without a discussion of other relevant existing competitive products or treatment options;

whether there was meaningful disclosure to the audience, at the time of the program, regarding the manufacturer's funding of the program, any significant relationships between the provider, presenters, or speakers and the supporting manufacturer and whether any unapproved uses will be discussed; and

whether there are legal, business, or other relationships between the supporting manufacturer and the provider or its employees that could permit the supporting manufacturer to exert influence over the content of the program.

We seek to ensure that the activities we support pursuant to our educational grants program are in accordance with these criteria for independent educational activities. However, we cannot provide an assurance that the FDA or other government authorities would view the programs we have supported as being independent.

***Pervasive and Continuing Regulation.*** There are numerous regulatory requirements that apply after a product is cleared or approved. These include:

the FDA's Quality System Regulation, or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

labeling regulations and FDA prohibitions against the false or misleading promotion or the promotion of products for uncleared, unapproved or off-label use or indication;

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

medical device reporting, or MDR, regulations which require that manufacturers comply with reporting requirements of the FDA and report if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;

post-approval restrictions or conditions, including post-approval study commitments;



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post-market surveillance regulations which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and

requirements to issue notices of correction or removal, or conduct market withdrawals or recalls where quality or other issues arise. During 2012 we submitted thirteen MDRs to the FDA related to complications during procedures utilizing our products. Of these MDRs, four related to our RF clamps, four related to our pen devices, two related to our AtriClip devices, two related to our Lumitip dissector and one related to our cryoablation generator. There may have been other incidents, including patient deaths, which have occurred during procedures utilizing our products, although we are not aware of any such incidents during the period noted above.

In addition to FDA regulation, the advertising and promotion of medical devices are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, some promotional

## **Table of Contents**

activities for FDA-regulated products have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the Federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

We have registered with the FDA as a medical device manufacturer and listed our devices. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers.

Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other federal or state authorities, which may include any of the following sanctions, among others:

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

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

operating restrictions, partial suspension or total shutdown of production;

suspension or termination of our clinical trials;

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

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

criminal prosecution.

***Fraud, Abuse and False Claims.*** We are directly and indirectly subject to various federal and state laws governing our relationship with healthcare providers and pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG, has issued a series of regulations, known as the safe harbors. These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable element of a safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

The Federal False Claims Act, or FCA, imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the United States Government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity with knowledge of past or present fraud against the federal government to sue on behalf of the government to recover the civil penalties and treble damages. The U.S. Department of Justice, or DOJ, on behalf of the government, has previously alleged that the marketing and promotional practices of pharmaceutical and medical device manufacturers included the off-label promotion of products or the payment of prohibited kickbacks to doctors violated the FCA resulting in the submission of improper claims to federal and state healthcare entitlement programs such as Medicaid. In certain cases, manufacturers have entered into criminal and civil



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**Table of Contents**

settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

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

AdvaMed is one of the primary voluntary United States trade associations for medical device manufacturers. This association has established guidelines and protocols for medical device manufacturers in their relationships with healthcare professionals on matters including research and development, product training and education, grants and charitable contributions, support of third-party educational conferences, and consulting arrangements. Adoption of the AdvaMed Code by a medical device manufacturer is voluntary, and while the OIG and other federal and state healthcare regulatory agencies encourage its adoption and may look to the AdvaMed Code, they do not view adoption of the AdvaMed Code as proof of compliance with applicable laws. We have adopted the AdvaMed Code and incorporated its principles in our standard operating procedures, sales force training programs, and relationships with doctors. Key to the underlying principles of the AdvaMed Code is the need to focus the relationships between manufacturers and healthcare professionals on matters of training, education and scientific research, and limit payments between manufacturers and healthcare professionals to fair market value for legitimate services provided and payment of modest meal, travel and other expenses for a healthcare professional under limited circumstances. We have incorporated these principles into our relationships with healthcare professionals under our consulting agreements, payment of travel and lodging expenses, grant making procedures and sponsorship of third-party conferences. In addition, we have conducted training sessions on these principles. However, we cannot provide any assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws.

***Regulation Outside of the United States.*** Sales of medical devices outside of the United States are subject to foreign governmental regulations which vary substantially from country to country. The time required to obtain certification or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval and the requirements may be different.

In the European Union, various directives and voluntary standards regulate the design, manufacture and labeling of and clinical trials and adverse event reporting for medical devices. Devices may only be placed in the market in the European Union if they comply with the essential requirements of a relevant directive and bear the CE mark. Manufacturers must demonstrate that their devices comply with the relevant essential requirements through a conformity assessment procedure. The method for assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a notified body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment will include a review of documentation relating to the device and may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's device. Successful completion of a conformity assessment procedure allows a manufacturer to issue a declaration of conformity with the requirements of the relevant Directive and affix the CE mark to the device. Devices that bear the CE mark may be commercially distributed throughout the member states of the European Union and other

## **Table of Contents**

countries that comply with or mirror the medical device directives. A notified body has granted us a certificate of compliance with the International Organization for Standardization, (ISO) 13485:2003 Quality Management System. Compliance with this standard establishes the presumption that our quality system conforms with the essential requirements of the relevant directive. We have successfully completed the conformity assessment procedure and affixed the CE Mark to our Isolator clamps, allowing us to commercialize our Isolator clamps in the European Union for the treatment of cardiac arrhythmias, including atrial fibrillation. Our Isolator pen, Coolrail linear pen and Isolator Synergy Access are CE Marked to ablate soft tissue. Our Isolator linear pen is CE marked to ablate cardiac tissue and temporarily pace, sense, record, and stimulate during evaluation of cardiac arrhythmias. Our cryo ablation devices are CE Marked for the treatment of cardiac arrhythmias. Our AtriClip LAA Exclusion System is CE marked for open occlusion of the heart's left atrial appendage.

## **Intellectual Property**

Protection of our intellectual property is a strategic priority for our business and we rely on a combination of patent, copyright, trademark and trade secret laws to protect our interests. Our ability to protect and use our intellectual property rights in the continued development and commercialization of our technologies and products, operate without infringing the proprietary rights of others, and prevent others from infringing our proprietary rights is crucial to our continued success. We will be able to protect our products and technologies from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents, trademarks or copyrights or are effectively maintained as trade secrets, know-how or other proprietary information.

We seek patent protection relating to technologies and products we develop in both the United States and in selected foreign countries. While we own much of our intellectual property, including patents, patent applications, trademarks, trade secrets, know-how and proprietary information, we also license patents and related technology of importance to the commercialization of our products. For example, to continue developing and commercializing our current and future products, we may license intellectual property from commercial or academic entities to obtain the rights to technology that is required for our research, development and commercialization activities.

All of our employees and technical consultants are required to execute confidentiality agreements in connection with their employment and consulting relationships with us. We also generally require them to agree to disclose and assign to us all inventions conceived in connection with their relationship with us. We cannot provide any assurance that employees and consultants will abide by the confidentiality or assignment terms of these agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our products or obtain and use information that we regard as proprietary. We devote significant resources to obtaining patents and other intellectual property and protecting our other proprietary information. If valid and enforceable, these patents may give us a means of blocking competitors from using infringing technology to compete directly with our products. We also have certain proprietary trade secrets that may not be patentable or for which we have chosen to maintain secrecy rather than file for patent protection. With respect to proprietary know-how that is not patentable, we have chosen to rely on trade secret protection and confidentiality agreements to protect our interests.

As of February 28, 2013 we had the following portfolio of patents or patent applications covering our proprietary technologies and products:

44 issued or approved United States patents expiring between 2015 and 2030;

22 United States non-provisional patent applications;

One United States provisional patent application;

Fifteen issued foreign patents; and

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

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## **Table of Contents**

Additionally, as of February 28, 2013 we had twelve trademark registrations covering our product branding, one trademark registration allowed and one pending trademark registration.

### **Manufacturing**

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

Order quantities and lead times for components purchased from outside suppliers are based on our forecasts derived from historical demand and anticipated future demand. Lead times may vary significantly depending on the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the components and subassemblies. To date, we have not experienced significant delays in obtaining any of our components. There are no unique or proprietary processes required in manufacturing our components. We generally do not have contractual obligations that preclude us from developing products or sourcing components from new suppliers.

As a result of regulatory changes in Europe, our ASU and ASB underwent compliance verification in 2012 to determine if they meet new medical device safety standards. The ASU and ASB passed this compliance verification. Similar standards will become effective in the U.S. during 2013. We are in the process of updating our documentation to be compliant with the new standards in the U.S.

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

We regularly audit our suppliers for compliance with QSR and applicable ISO standards. We have been an FDA-registered medical device manufacturer since November 2002. We obtained our CE Mark in June of 2002 and our quality systems and facility practices are certified to ISO 13485:2003; MDD 93/42/EEC, or CE Mark, and CMDCAS, or Canadian regulations. We believe that we are currently in good standing with the FDA. Our current quality system is developed to comply with QSR and ISO standards.

During February 2011 the FDA conducted an inspection of our West Chester, Ohio facility and manufacturing processes. As a result of the inspection, we received a Form FDA 483, Inspectional Observations, which outlined deficiencies observed by the FDA investigators. We have taken corrective and preventive actions where appropriate and in October 2011 we received from the FDA an Establishment Inspection Report which was classified by the FDA as Voluntary Action Indicated. During February 2013 the FDA conducted another

## **Table of Contents**

inspection of our facility and manufacturing processes. No inspectional observations were cited on Form FDA 483 as a result of the inspection. We will continue to be diligent with our quality systems initiatives and continuous improvement activities.

We are subject to numerous federal, state and local laws relating to such matters as laboratory practices, the experimental use of animals, the use and disposal of hazardous or potentially hazardous substances, safe working conditions, manufacturing practices, environmental protection and fire hazard control. We may incur significant costs to comply with those laws and regulations now or in the future, but, as we currently believe we are in compliance with such laws and regulations, we do not expect that continued compliance will have a material impact on our business.

## **Consulting Relationships**

We have developed consulting relationships with a number of scientists and doctors throughout the world to develop our research and development, clinical and training and education teams. We work closely with these thought leaders to understand unmet needs and emerging applications for the treatment of AF.

Most of our consulting agreements provide for fair market value 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. 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. We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our product for non-FDA-approved or off-label, uses .

## **Royalty Agreements**

We have certain royalty agreements in place with terms that include payment of royalties based on product revenue from sales of current products, certain other inventions, improvements or ideas. During 2012 we had royalty agreements with rates of 5% of product revenue related to our AtriClip system and 1.5% of product revenue related to our Lumitip dissector. The agreement for the Lumitip dissector also calls for minimum royalty payments and limits the maximum aggregate in royalties during the term of the agreement. Parties to royalty agreements have the right at any time to terminate the agreement immediately for cause. Royalty expense for each of the years ended December 31, 2012, 2011 and 2010 was \$0.6 million, \$0.5 million and \$0.3 million, respectively.

## **Employees**

We had approximately 230 full-time employees as of February 28, 2013. None of the employees were represented by a labor union or covered by a collective bargaining agreement. We have never experienced any employment-related work stoppages and consider our employee relations to be good although we cannot provide any assurance that we will not experience such work stoppages in the future.

## **Available Information**

Our principal executive offices are located at 6217 Centre Park Drive, West Chester, Ohio and our telephone number is 513-755-4100. We are subject to the reporting requirements under the Securities Exchange Act of 1934. Consequently, we are required to file reports and information with the Securities and Exchange Commission, or SEC, including reports on the following forms: Form 10-K, Form 10-Q, Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. These reports and other information concerning us may be accessed through the SEC's website at <http://www.sec.gov>. You may also find, free of charge, on our website at <http://www.atricure.com>, electronic copies of our Form 10-Ks, Form 10-Qs, Form 8-Ks, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. Such filings are placed on our website as soon

## **Table of Contents**

as reasonably practicable after they are filed or furnished, as the case may be, with the SEC. Our charters for our Audit, Compensation and Nominating and Corporate Governance Committees and our Code of Ethics are available on our website. In the event that we grant a waiver under our Code of Ethics to any of our officers and directors, we will publish it on our website. Information contained in any of our websites is not deemed to be a part of this Form 10-K.

### **ITEM 1A. RISK FACTORS** **Risks Relating To Our Business**

**If our products do not achieve widespread market acceptance in the United States, our operating results will be harmed and we may not achieve profitability.**

Our success will depend, in large part, on the medical community's acceptance of our principal products in the United States, which is the largest revenue market in the world for medical devices. The U.S. medical community's acceptance of our products will depend upon our ability to demonstrate the safety and efficacy, advantages, long-term clinical performance and cost-effectiveness of our products as compared to other products. In addition, acceptance of products for the treatment of AF is dependent upon, among other factors, the level of screening for AF and the awareness and education of the medical community about the surgical treatment of AF, in general, and the existence, effectiveness and, in particular, the safety of our products. Market acceptance and adoption of our products for the treatment of AF also depends on the level of reimbursement to doctors and hospitals for the use of our products.

We cannot predict whether the U.S. medical community will accept our products or, if accepted, the extent of their use. Negative publicity resulting from isolated incidents involving our products or other products related to those we sell could have a significant adverse effect on the overall acceptance of our products. If we encounter difficulties developing a market for our products in the United States, we may not be able to increase our revenue enough to achieve profitability, and our business and operating results will be seriously harmed.

**We rely on our ablation and ablation related products as our primary sources of revenue. If we are not successful in selling these products, or if these products become obsolete, our operating results will be harmed.**

Our ablation products, such as our clamps and related products, generate a large majority of our revenue. We expect that sales of these products will continue to account for a majority of our revenue for the foreseeable future and that our future revenue will depend on the increasing acceptance by the medical community of our products as a standard treatment alternative for the surgical treatment of AF during open-heart surgical procedures and as a sole-therapy minimally invasive procedure. We may not be able to maintain or increase market acceptance of our products for a number of additional reasons, including those set forth elsewhere in this Risk Factors section. In addition, our products may become obsolete prior to the end of their anticipated useful lives or we may introduce new products or next-generation products prior to the end of the useful life of a prior generation, either of which may require us to dispose of existing inventory and related capital instruments and/or write off their value or accelerate their depreciation. Since we believe that doctors are using our ablation and ablation related products only for the surgical treatment of AF, if doctors do not use our products to treat AF, we would lose substantially all of our revenue.

**Worldwide economic conditions may reduce demand for procedures using our products or otherwise result in adverse implications on our business, operating results and financial condition.**

General worldwide economic conditions deteriorated beginning in late 2007 due to the effects of, among other developments, the subprime lending crisis, general credit market crisis, collateral effects on the finance and banking industries, concerns about inflation, slower economic activity, decreased consumer confidence, reduced corporate profits and capital spending, adverse business conditions and liquidity concerns. Although there may



## **Table of Contents**

continue to be signs of an improving economic environment, we are unable to predict the extent to which current or future worldwide economic conditions may impact our business. Specifically, because many procedures using our products are elective, they can be deferred by patients. In addition, patients may not be as willing under current or future economic conditions to take time off from work or spend their money on deductibles and co-payments often required in connection with the procedures that use our products.

Beyond patient demand, any current or future deterioration in worldwide economic conditions, including in particular their effects on the credit and capital markets, may have other adverse implications for our business. For example, our customers' ability to borrow money from their existing lenders or to obtain credit from other sources to purchase our products may be impaired resulting in a decrease in sales. Although we maintain allowances for estimated losses resulting from the inability of our customers to make required payments, we cannot guarantee that we will accurately predict the loss rates we will experience, especially given any continuing turmoil in the worldwide economy. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in our receivable collections and additional allowances may be required, which could adversely affect our operating results. Further, given the economic and political challenges facing Eurozone countries, concerns have been raised regarding the stability and suitability of the Euro as a single currency. The failure of the Euro as a single currency could adversely affect our operating results.

### **Healthcare costs have risen significantly over the past decade. There have been and may continue to be proposals by legislators, regulators and third-party payors to keep, contain or reduce healthcare costs.**

The continuing efforts of governments, insurance companies and other payors of healthcare costs to contain or reduce these costs, combined with closer scrutiny of such costs, could lead to patients being unable to obtain approval for payment from these third-party payors. The cost containment measures that healthcare providers are instituting both in the U.S. and internationally could harm our business. Some healthcare providers in the U.S. have adopted or are considering a managed care system in which the providers contract to provide comprehensive healthcare for a fixed cost per person. Healthcare providers may attempt to control costs by authorizing fewer elective surgical procedures or by requiring the use of the least expensive devices possible, which could adversely affect the demand for our products or the price at which we can sell our products. Some healthcare providers have sought to consolidate and create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide products and services has become and will continue to become more intense. This has resulted and likely will continue to result in greater pricing pressures and the exclusion of certain suppliers from important marketing segments.

### **We face significant uncertainty in the industry due to government healthcare reform.**

The Patient Protection and Affordable Care Act, as amended, (the Patient Act) as well as other healthcare reform have a significant impact on our business. The impact of the Patient Act on the healthcare industry is extensive and includes, among other things, the federal government assuming a larger role in the healthcare system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits. The Patient Act has impacted our business by requiring a 2.3% excise tax on all U.S. medical device sales beginning in January 2013. The increased tax burden will have a significant impact on our results of operations and cash flows. Any healthcare reforms enacted in the future may, like the Patient Act, be phased in over a number of years but, if enacted, could reduce our revenue, increase our costs, or require us to revise the ways in which we conduct business or put us at risk for loss of business. In addition, our results of operations, financial position and cash flows could be materially adversely affected by changes under the Patient Act and changes under any federal or state legislation adopted in the future.

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

Due to current worldwide economic conditions and other factors discussed in this Risk Factors section which may impact our sales results, our quarterly operating results are difficult to predict and may fluctuate significantly from quarter to quarter or from prior year to current year periods, particularly because our sales

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**Table of Contents**

prospects are uncertain. These fluctuations may also affect our annual operating results and may cause those results to fluctuate unexpectedly from year to year.

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

It is critical to the success of our sales efforts to ensure that there are a sufficient number of doctors familiar with, trained on and proficient in the use of our products. While we educate and train doctors as to the skills involved in the proper use of our products, it is not our policy to educate or train them to use any products for the surgical treatment of AF, unless the product is approved for the treatment of AF. Until December 2011 doctors learned to use our products for the treatment of AF through independent training programs sponsored by hospitals and universities and through independent peer-to-peer training among doctors. In December 2011 our Synergy System was approved for the treatment of certain AF patients during certain open-heart procedures. We have a comprehensive physician training program to train all existing users of the Synergy System over an eighteen month period as well as a training and education program for all new users on the use of our Synergy System. We cannot assure you that a sufficient number of doctors will become aware of training programs, or that doctors will dedicate the time, funds and energy necessary to obtain training for themselves or to train others in the use of our products. In addition, our inability to directly train doctors in off-label use exposes us to a risk that our products may not be used correctly and may also expose us to a greater risk of product liability for injuries sustained during procedures utilizing our products.

**Unless and until we obtain additional FDA approval for our products, we will not be able to promote many of our products to treat AF or the reduction in stroke risk, and our ability to maintain and grow our business could be harmed.**

Although our Synergy System received FDA approval for the treatment of AF for certain patients and certain procedures, we have not received FDA clearance or approval to promote many of our products for the treatment of AF or the reduction in stroke risk. See Business Government Regulation. Unless and until we obtain FDA clearance or approval for the use of our products for the treatment of AF or reduction in stroke risk we, and others acting on our behalf, may not promote our products for such uses, make any claim that our system is safe and effective for such uses, or proactively discuss or provide information on the use of our system in connection with such uses. We cannot assure you that future clearances or approvals of our products will be granted or that current or future clearances or approvals will not be withdrawn. Failure to obtain a clearance or approval or loss of an existing clearance or approval, could hurt our ability to maintain and grow our business.

**Unless and until we are able to complete the clinical trials required to support future submissions to the FDA, and unless and until the data generated by such trials supports the use of our products as safe and effective for the treatment of AF or reduction in stroke risk, 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 additional FDA approvals to promote our products for the treatment of AF or reduction in stroke risk, we will need to demonstrate in clinical trials that our products are safe and effective for such use. We cannot assure you that any of our clinical trials will be completed in a timely manner or successfully or that the results obtained will be acceptable to the FDA. In addition, if the results obtained from our clinical trials, any other clinical studies, or clinical or commercial experience indicate that any of our products are not safe or effective, or not as safe or effective as other treatment options, the FDA may not approve our products for the treatment of AF or reduction in stroke risk, adoption of the use of our products may suffer and our business would be harmed.

**We may experience unfavorable publicity relating to our business and our industry. This publicity could have a negative impact on our ability to attract and retain customers, our sales, clinical studies involving our products, our reputation and our stock price.**

We may experience a negative impact on our business from newspaper articles or other media reports relating to, among other things, our compliance with FDA regulations for medical device reporting and concerns

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**Table of Contents**

over disclosure of financial relationships between us and certain of our consultants who are involved with clinical studies and the publication of articles concerning our products. We believe that such publicity would potentially have a negative impact on our clinical studies, business, results of operations and financial condition or cause other adverse effects, including a decline in the price of our stock.

**We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for non-FDA approved, or off-label, uses.**

Our business and future growth depend on the continued use of our products for the treatment of AF or reduction in stroke risk, which, with the exception of our Synergy System's AF approval, are considered off-label use of our products. Under the Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products for off-label uses. Unless the products are FDA cleared, we may not make claims about the safety or effectiveness of our products for the treatment of AF or reduction in stroke risk and may not proactively discuss or provide information on the use of our products for the treatment of AF, except in certain limited scientific and other settings.

These limitations present a material risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales, marketing and/or product support activities, though designed to comply with all FDA requirements, constitute the promotion of our products for a non-FDA approved use in violation of the law. We also face the risk that the FDA or other governmental authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities. Investigations concerning the promotion of off-label uses and related issues, including our settlement with the DOJ (see further discussion in Item 3, "Legal Proceedings" of this Form 10-K), are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law, we may face significant fines and penalties and may be required to substantially change our sales, promotion, grant and educational activities. There is also a possibility that we could be enjoined from selling some or all of our products for any non-FDA approved use. In addition, as a result of an enforcement action against us or our executive officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid. Also, our failure to comply with the terms of the settlement agreement with the DOJ or the related corporate integrity agreement could result in additional action by the DOJ or the OIG, in fines or penalties or in restrictions on our sales, promotion, grant or educational activities.

**The use of products we sell may result in injuries or other adverse events that lead to product liability suits, which could be costly to our business or our customers' businesses.**

The use of products we sell may result in a variety of serious complications, including damage to the heart, internal bleeding, death or other adverse events, potentially leading to product liability claims. Serious complications, including death, have been encountered in connection with the surgical treatment of AF, including in connection with a limited number of sole-therapy minimally invasive procedures in which our products were used. If products we sell are defectively designed, manufactured or labeled, contain inadequate warnings, contain defective components or are misused, we may become subject to costly litigation by our customers or their patients. We carry product liability insurance that is limited in scope and amount and may not be adequate to fully protect us against product liability claims. We could be required to pay damages that exceed our insurance coverage. Any product liability claim, with or without merit, could result in an increase in our product insurance rates or our inability to secure coverage on reasonable terms, if at all. Even in the absence of a claim, our insurance rates may rise in the future. Any product liability claim, even a meritless or unsuccessful one, would be time-consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, withdrawal of clinical trial participants, injury to our reputation and loss of revenue. Any of these events could negatively affect our earnings and financial condition.

## **Table of Contents**

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

The medical device industry, including the market for the treatment of AF, is highly competitive, subject to rapid technological change and significantly affected by new product introductions and promotional activities of its participants. We cannot assure you that our products will compete effectively against drugs, catheter-based ablation, implantable devices, other ablation systems, other products or techniques to exclude the left atrial appendage, or other surgical AF treatments, which may be more well-established among doctors and hospitals. We anticipate that new or existing competitors may develop competing products, procedures and/or clinical solutions. There are few barriers to prevent new entrants or existing competitors from developing products to compete directly with ours. Some companies also compete with us to attract qualified scientific and technical personnel as well as funding. Some of our competitors have greater financial, manufacturing, marketing and research and development capabilities than we have or may obtain FDA approval for the use of their products before we do. The introduction of new products, procedures, clinical solutions or our competitors obtaining FDA approvals may result in price reductions, reduced margins or loss of market share and may render our products obsolete, which could adversely affect our net revenue and future profitability.

### **Our intellectual property rights may not provide meaningful commercial protection for our products, which could enable third-parties to use our technology or methods, or very similar technology or methods, and could reduce our ability to compete.**

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our patent applications may not issue as patents at all or in a form that will be advantageous to us. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. Although we have taken steps to protect our intellectual property and proprietary technology, we cannot assure you that third-parties will not be able to design around our patents or, if they do infringe upon our technology, that we will be successful in or will have sufficient resources to pursue a claim of infringement against those third-parties. We believe that third-parties may have developed or are developing products that could infringe upon our patent rights. Any pursuit of an infringement claim by us may involve substantial expense or diversion of management attention. In addition, although we have generally entered into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, investigators and advisors, such agreements may be breached, may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. Additionally, as is common in the medical device industry, some of these individuals were previously employed at other medical equipment or biotechnology companies, including our competitors. Although no claims are currently pending against us, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers.

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

## **Table of Contents**

**The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights and any litigation or claim against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation.**

Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Any patent dispute, even one without merit or an unsuccessful one, would be time-consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, the disruption of development and marketing efforts, injury to our reputation and loss of revenue. Litigation also puts our patent applications at risk of being rejected and our patents at risk of being invalidated or interpreted narrowly, and may provoke third parties to assert claims against us. Any of these events could negatively affect our earnings and financial condition.

In the event of a patent dispute, if a third-party's patents were upheld as valid and enforceable and we were found to be infringing, we could be prevented from selling our products unless we were able to obtain a license to use technology or ideas covered by such patent or are able to redesign our system to avoid infringement. A license may not be available at all or on terms acceptable to us, and we may not be able to redesign our products to avoid any infringement. Modification of our products or development of new products could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. If we are not successful in obtaining a license or redesigning our products, we may be unable to sell our products and our business could suffer.

**The increase in cost of medical malpractice premiums to doctors and hospitals or the lack of malpractice insurance coverage due to the use of our products by doctors for an off-label indication may cause certain doctors or hospitals to decide not to use our products and may damage our ability to grow and maintain the market for our system.**

Insurance carriers have been raising premiums charged for medical malpractice insurance due, at least in part, to increased risks associated with off-label procedures, including higher damage awards for successful plaintiffs. Insurance carriers may continue to raise premiums or they may deny malpractice coverage for procedures performed using products such as ours on an off-label basis. If this trend continues or worsens, our revenue may fall as doctors or hospitals decide against purchasing our products due to the cost or unavailability of insurance coverage.

**We have a history of net losses and we may never become profitable.**

We have incurred net losses each year since our inception, including net losses of \$7.5 million in 2012, \$5.5 million in 2011, \$3.8 million in 2010, \$16.5 million in 2009, \$10.2 million in 2008, \$11.3 million in 2007, \$13.7 million in 2006 and \$12.7 million in 2005. As of December 31, 2012, we had an accumulated deficit of \$110.8 million.

Our net losses have resulted principally from costs and expenses relating to sales and promotional efforts, research and development, seeking regulatory clearances and approvals, goodwill impairment, litigation and settlement costs associated with the DOJ investigation and general operating expenses. We expect to continue to make substantial expenditures and to potentially incur additional operating losses in the future as we further develop and commercialize our products, including completing clinical trials and seeking regulatory clearances and approvals. If sales of our products do not continue to grow as we anticipate, we will not be able to achieve profitability. Our expansion efforts may prove more expensive than we currently anticipate, and we may not succeed in increasing our revenue sufficiently to offset these higher expenses. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and accumulated deficit, and we may never become profitable.

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**Table of Contents**

**Our federal tax net operating loss and general business credit carryforwards generated prior to the initial public offering of our common stock will be limited or may expire, which could result in greater future income tax expense and adversely impact future cash flows because we experienced an ownership change of more than 50 percentage points upon the initial public offering of our common stock.**

In connection with our initial public offering in August 2005, we experienced an ownership change as defined by Section 382 of the Internal Revenue Code of 1986. Section 382 imposes limitations ( Section 382 limitation ) on a company's ability to use net operating loss and general business credit carryforwards if a company experiences a more-than-50-percent ownership change over a three-year testing period. The Section 382 limitation could limit the availability of our net operating loss and general business credit carryforwards to offset any future taxable income, which may increase our future income tax expense and adversely impact future cash flows. We had federal income tax net operating loss and general business credit carryforwards at August 5, 2005 that, if not utilized to reduce our taxable income, will begin to expire in 2021. In addition, if the company were to experience a second ownership change of more than 50 percentage points in a future period, the company's NOL carryforward at the date of the original ownership change would be subject to a second Section 382 limitation. In addition, the company's NOLs generated subsequent to the original ownership change would be subject to the second Section 382 limitation. Since December 31, 2005 the company has generated additional net operating loss and general business credit carryforwards of \$41.5 million and \$2.4 million, respectively, which, 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 investments, including additional cash generated from a 2012 amendment to our credit facility and a January 2013 public offering of common stock will be sufficient to meet our projected capital requirements for at least the next 12 months. Our current loan agreement (the Agreement ) with Silicon Valley Bank (the Bank ), as amended, includes a term loan and a revolving credit facility under which we can borrow a maximum of \$20 million. We have borrowed the maximum amount of \$10 million under the term loan. We can borrow the lesser of the amount available pursuant to a borrowing base formula and \$10.0 million under the revolving loan facility. Based on our current borrowing base, we have availability of approximately \$5.3 million. The Agreement is secured by all of our assets, including intellectual property. The term loan and revolving loan mature on February 1, 2017 and April 30, 2014, respectively. Interest on the term loan accrues at a rate of 6.75% per year, and interest on the revolving loans will accrue at a fluctuating rate equal to the Bank's announced prime rate of interest plus between 0.25% and 1.25%, depending on our Liquidity Ratio (as defined in the Agreement). The common stock offering generated \$27.1 million in net proceeds through the issuance of 4.0 million shares.

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

Our Agreement contains covenants that include, among others, covenants that limit our ability to dispose of assets, enter into mergers or acquisitions, incur indebtedness, incur liens, pay dividends or make distributions on our capital stock, make investments or loans, and enter into certain affiliate transactions, in each case subject to customary exceptions for a credit facility of this size and type. Additional covenants apply when we have outstanding borrowings under the revolving loan facility or when we achieve specific covenant milestones. The occurrence of an event of default could result in an increase to the applicable interest rate by 3.0%, an acceleration of all obligations under the Agreement, an obligation to repay all obligations in full, and a right by the Bank to exercise all remedies available to it under the Agreement and related agreements including the Guaranty and Security Agreement. If we are unable to pay those amounts, the Bank could proceed against the collateral granted to it pursuant to the credit facility.

If we need to raise additional funds, we cannot be certain that such funds will be available to us on acceptable terms, if at all. Furthermore, if we issue equity securities to raise additional funds, our existing stockholders may experience dilution, and if we issue equity or debt securities, such securities may have rights,

## **Table of Contents**

preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our future products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise funds on acceptable terms, we may not be able to expand our operations, develop new products, take advantage of future opportunities or respond to competitive pressures or unanticipated customer requirements.

### **We rely upon single and limited source third-party suppliers and third-party logistics providers, making us vulnerable to supply problems and price fluctuations which could harm our business.**

We currently rely on single and limited source third-party vendors for the manufacture of many of the components used in our products. For example, we rely on one vendor to manufacture our ASU and ASB. It would be a time consuming and lengthy process to secure these products from an alternative supplier. In addition, in some cases there are relatively few alternative sources of supply for certain other components that are critical to our products. We also rely on a third party to handle our warehousing and logistics functions for EMEA markets on our behalf and a single supplier (a CRO), to administer our clinical trials and related activities.

Our reliance on outside manufacturers and suppliers also subjects us to risks that could harm our business, including:

we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;

we may have difficulty timely locating and qualifying alternative suppliers;

switching components may require product redesign and new submissions to the FDA which could significantly delay production or, if the FDA refuses to approve the changes, completely eliminate our ability to manufacture or sell our products;

our suppliers manufacture products for a range of customers, and fluctuations in demand for the products those suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and

our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

Identifying and qualifying additional or replacement suppliers for any of the components used in our products or a replacement warehousing and logistics provider, if required, may not be accomplished quickly and could involve significant additional costs. Any interruption or delay in the supply of components, materials or warehousing and logistics, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products and could therefore have a material adverse effect on our business, financial condition and results of operations. Any disruption to our relationship with our CRO could result in a delay in our clinical trials, which could also delay product approvals.

As a result of regulatory changes in Europe, our ASU and ASB underwent compliance verification in 2012 to determine if they meet new medical device safety standards. The ASU and ASB passed this compliance verification. Similar standards will become effective in the U.S. during 2013. We are in the process of updating our documentation to be compliant with the new standards in the U.S. If the ASU and ASB do not meet the revised safety guidelines, it would have a material and substantial impact on the sale of RF devices in the U.S.

### **An inability to forecast future revenue or estimate life cycles of products may result in inventory-related charges that would negatively affect our gross margins and results of operations.**

To mitigate the risk of supply interruptions, we may choose to maintain excess inventory of our products or component parts. Managing our inventory levels is important to our cash position and results of operations and is more challenging in the current economic environment. As we grow and expand our product offerings, managing





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**Table of Contents**

our inventory levels becomes more difficult, particularly as we expand into new product areas and bring product enhancements to market. While we rely on our information technology systems for inventory management and to effectively manage accounting and financial functions, our information technology systems may fail to adequately perform these functions or may experience an interruption. An excessive amount of inventory reduces our cash available for operations and may result in excess or obsolete materials. Conversely, inadequate inventory levels may make it difficult for us to meet customer product demand, resulting in decreased revenue. An inability to forecast future revenue or estimated life cycles of products may result in inventory-related charges that would negatively affect our gross margins and results of operations.

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

Our manufacturing facility and the manufacturing facility of any of our third-party component manufacturers, critical suppliers or third-party sterilization facility are required to comply with the FDA's Quality System regulation, or QSR, which sets forth minimum standards for the procedures, execution and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our Isolator system and other products we sell. The FDA may evaluate our compliance with the QSR, among other ways, through periodic announced or unannounced inspections which could disrupt our operations and interrupt our manufacturing. If in conducting an inspection of our manufacturing facility or the manufacturing facility of any of our third-party component manufacturers, critical suppliers or third-party sterilization facility, FDA investigators observe conditions or practices believed to violate the QSR, the investigators may document their observations on a Form FDA-483 that is issued at the conclusion of the inspection. A manufacturer that receives an FDA-483 may respond in writing and explain any corrective actions taken in response to the inspectional observations. The FDA will typically review the facility's written response and may re-inspect to determine the facility's compliance with the QSR and other applicable regulatory requirements. Failure to take adequate and timely corrective actions to remedy objectionable conditions listed on an FDA-483 could result in the FDA taking administrative or enforcement actions. Among these may be the FDA's issuance of a Warning Letter to a manufacturer, which informs it that the FDA considers the observed violations to be of regulatory significance that, if not corrected, could result in further enforcement action. FDA enforcement actions, which include seizure, injunction and criminal prosecution, could result in total or partial suspension of a facility's production and/or distribution, product recalls, fines, suspension of the FDA's review of product applications and the FDA's issuance of adverse publicity. Thus, an adverse inspection could force a shutdown of our manufacturing operations or a recall of our products. Adverse inspections could also delay FDA approval of our products and could have an adverse effect on our production, sales and profitability.

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

**Table of Contents**

**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;

pre-market clearance or approval;

record keeping and document retention procedures;

product advertising, sales and promotion;

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

product corrective actions, removals and recalls; and

product import and export.

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

If a serious failure to comply with applicable regulatory requirements was determined, it could result in enforcement action by the FDA or other state or federal agencies, including the DOJ, which may include any of the following sanctions, among others:

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

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

operating restrictions, partial suspension or total shutdown of production;

suspension or termination of our clinical trials;

refusing or delaying our pending requests for 510(k) clearance or PMAs, new intended uses or modifications to existing products;

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

criminal prosecution.

If any of these events were to occur, we could lose customers and our production, product sales, business, results of operations and financial condition would be harmed.

We are also subject to medical device reporting regulations that require us to file reports with the FDA if our products reasonably are the cause of or contribute to an adverse event, death, serious injury or, in the event of

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**Table of Contents**

product malfunction, that if it were to recur, would likely cause or contribute to a death or serious injury. We have a history of submitting medical device reports to the FDA involving our products, including patient deaths, which were categorized as outcomes based on physician judgment, not on the failure of our devices. There have also been other incidents, including patient deaths, which have occurred during procedures using our products that we have not, and believe were not required to be, reported to the FDA because we and our physician consultants determined that our products did not cause or contribute to the outcomes in these incidents. If the FDA disagrees with us, however, and determines that we should have submitted reports for these adverse events, we could be subject to significant regulatory fines or other penalties. In addition, the number of medical device reports we make, or the magnitude of the problems reported, could cause the FDA or us to terminate or modify our clinical trials or recall or cease the sale of our products, and could hurt commercial acceptance of our products.

**Modifications to our products may require new clearances or approvals or require us to cease promoting or to recall the modified products until such clearances or approvals are obtained and the FDA may not agree with our conclusions regarding whether new clearances or approvals were required.**

Any modification to a 510(k)-cleared device that would constitute a change in its intended use, design or manufacture, could require a new 510(k) clearance or, possibly, submission and FDA approval of a PMA. The FDA requires every medical device company to make the determination as to whether a new 510(k) is to be filed, but the FDA may review any medical device company's decision. We have made modifications to our products but do not believe such modifications required us to submit an additional 510(k). The FDA may not agree with our decisions regarding whether new clearances or approvals were required.

If the FDA were to disagree with us and require us to submit a new 510(k), PMA or a different type of PMA supplement for then existing modifications, we could be required to cease promoting or to recall the modified product until we obtain clearance or approval. In addition, we could be subject to significant regulatory fines or other penalties. Furthermore, our products could be subject to recall if 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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**Table of Contents**

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

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

federal and state healthcare fraud and abuse laws or laws protecting the privacy of patient medical information, including the Health Insurance Portability and Accountability Act, or HIPAA, which protects medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting reasonably necessary to accomplish the intended purpose, and, although we are not a covered entity under HIPAA, as a business associate of covered entities through our contractual agreements with them, we are required to implement and maintain policies, procedures and reasonable and appropriate security measures to protect individually identifiable health information we receive from covered entities;

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

similar and other regulations outside the United States.

Certain federal and state laws regarding Medicare, Medicaid and physician self-referrals are broad and we may be required to change one or more of our practices to be in compliance with these laws. Healthcare fraud and abuse regulations are complex and even minor, inadvertent irregularities in submissions can potentially give rise to claims that a statute has been violated. Any violations of these laws could result in a material adverse effect on our business, financial condition and results of operations. For example, if we were found to be in violation of the Federal False Claims Act, we would likely face significant fines and penalties and would likely be required to change substantially our sales, promotion, grant and educational activities. There is also a possibility that we could face an injunction that would prohibit in whole or in part our current business activities, and, as a result of enforcement actions against us or our senior officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations. In October 2008, the DOJ initiated an investigation of our marketing and promotional practices. Although we admitted to no wrongdoing and believe there was no wrongdoing on the part of us or our employees, during 2010 this investigation resulted in a financial settlement of \$4.4 million (which includes interest based on payment terms), and we agreed to a corporate integrity agreement that provides certain ongoing compliance and reporting obligations. Additionally, we incurred substantial legal costs through the investigation and settlement process.

If our past or present operations are found to be in violation of any of the laws described above or the other governmental regulations to which we, our distributors or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from Medicare, Medicaid and other government programs and the curtailment or restructuring of our operations. If we are required to obtain permits or licensure under these laws that we do not already possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them

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**Table of Contents**

have not been fully or clearly interpreted by the regulatory authorities or the courts, and their provisions are subject to a variety of interpretations and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

**Adverse changes in payors' policies toward coverage and reimbursement for surgical AF treatment would harm our ability to promote and sell our products.**

Third-party payors are increasingly exerting pressure on medical device companies to reduce their prices. Even to the extent that the treatment of AF using our products is reimbursed by private payors and governmental payors, adverse changes in payors' policies toward coverage and reimbursement for surgical AF treatment would also harm our ability to promote and sell our products. Payors continue to review their policies and can, without notice, deny coverage for treatments that include the use of our products. Because each third-party payor individually approves coverage and reimbursement, obtaining these approvals may be time-consuming and costly. In addition, third-party payors may require us to provide scientific and clinical support for the use of our products. Alternatively, government or private payors may deem the treatment of AF utilizing our products (other than the Synergy System for its cleared indications) experimental or not medically necessary and, as such, not provide coverage. Adverse changes in coverage and reimbursement for surgical AF treatment could harm our business and reduce our revenue.

**We have traditionally had limited long-term clinical data regarding the safety and efficacy of our products. Any long-term data that is generated may not be positive or consistent with our limited short-term data, which would affect the rate at which our products are adopted by the medical community.**

Important factors upon which the efficacy of our products will be measured include long-term data on the number of patients that continue to experience AF or stroke following treatment with our products and the number of patients that have serious complications resulting from AF treatment or stroke reduction treatment using our products. While we believe we are now well-positioned to provide sufficient long-term data regarding the efficacy of our products for the treatment of AF going forward, such data could, nevertheless, identify unexpected safety issues. We cannot provide any assurance that the data collected during our clinical trials will be compelling to the medical community because it may not be scientifically meaningful and may not demonstrate that procedures utilizing our products are an attractive option when compared against data from alternative procedures and products. In addition, the long-term effects of ablation system procedures and left atrial appendage exclusion are not known. Negative long-term data would affect the use of our products and harm our business and prospects.

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

Doing business outside of the United States exposes us to risks distinct from those we face in our domestic operations. For example, our operations outside of the United States are subject to different regulatory laws and requirements in each jurisdiction where we operate or have sales. Our failure, or the failure of our distributors, to comply with current or future foreign regulatory requirements, or the assertion by foreign authorities that we or they have failed to comply, could result in adverse consequences, including enforcement actions, fines and penalties, recalls, cessation of sales, civil and criminal prosecution, and the consequences could be disproportionate to the relative contribution of our international operations to our results of operations. Moreover, if political or economic conditions deteriorate in these countries, or if any of these countries are affected by a natural disaster or other catastrophe, our ability to conduct our international operations or collect on international accounts receivable could be limited and our costs could be increased, which could negatively affect our operating results. Engaging in business outside of the United States inherently involves a number of other difficulties and risks, including, but not limited to:

export restrictions and controls relating to technology;

pricing pressure that we may experience internationally;

**Table of Contents**

difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

political and economic instability;

consequences arising from natural disasters and other similar catastrophes, such as hurricanes, tornados, earthquakes, floods and tsunamis;

potentially adverse tax consequences, tariffs and other trade barriers;

the need to hire additional personnel to promote our products outside of the United States;

international terrorism and anti-American sentiment;

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

difficulty in obtaining and enforcing intellectual property rights.

In addition, our business practices in foreign countries comply with U.S. law, including the Foreign Corrupt Practices Act ( FCPA ). We have a compliance program in place designed to reduce the likelihood of potential violations of the FCPA and other U.S. laws. If violations were to occur, they could subject us to fines and other penalties as well as increased compliance costs.

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

**Our manufacturing operations are conducted at a single location, and any disruption at our manufacturing facility could increase our expenses and decrease our revenue.**

All of our manufacturing operations are conducted at a single location in West Chester, Ohio. While we take precautions at this location, we do not maintain a backup manufacturing facility, making us dependent on our current facility for the continued operation of our business. A natural or other disaster could damage or destroy our manufacturing equipment and cause substantial delays in our manufacturing operations, which could lead to additional expense and decreased revenue due to lack of supply. The insurance we maintain may not be adequate to cover our losses in any particular case. With or without insurance, damage to our facility or our other property, due to a natural disaster or casualty event, could have a material adverse effect on our business, financial condition and results of operations.

**We rely on independent distributors to market and sell our products in certain markets outside of the United States, and a failure of our independent distributors to successfully market our products in these markets or any disruption in their ability to do so may adversely impact our sales.**

We depend on third-party distributors to sell our products in certain markets outside of the United States and if these distributors do not perform, we may be unable to increase or maintain our level of international revenue. Over the long term, we intend to continue to grow our business outside of the United States, and to do so we will need to attract additional distributors or hire direct sales personnel to expand the territories in which we sell our products. Independent distributors may terminate their relationship with us or devote insufficient sales efforts to our products. We are not able to control our independent distributors, and they may not be successful in implementing our marketing plans. In addition, many of our independent distributors outside of the United States initially obtain and maintain foreign regulatory approval for sale of our products in their respective countries. Our failure to maintain our relationships with our independent distributors outside of the United States, or our failure to recruit and retain additional skilled independent distributors in these locations, could have an adverse effect on our operations. Turnover among our independent distributors, even if replaced, may adversely affect our short-term financial results while we transition to new

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independent distributors or direct personnel. Fluctuations in foreign currency exchange rates including, in particular, any strengthening of the U.S. dollar may cause our independent sales distributors to seek longer payment terms to offset the higher prices they are paying



## **Table of Contents**

in local currency for our products. The ability of these third-party distributors to market and sell our products could also be adversely affected by unexpected events, including, but not limited to, power failures, nuclear events, natural or other disasters and war or terrorist activities. In addition, in light of the worldwide economic crisis, the ability of our distributors to borrow money from their existing lenders or to obtain credit from other sources to purchase our products may be impaired or our distributors could experience a significant change in their liquidity or financial condition, all of which could impair their ability to distribute our products and eventually lead to distributor turnover.

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

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

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

We are highly dependent on the skills and experience of our President and Chief Executive Officer, Michael H. Carrel, and certain other officers and key employees. We do not have any insurance in the event of the death or disability of our key personnel. Our officers and key employees, with the exception of our President and Chief Executive Officer, Senior Vice President, R&D, Operations and QA and Vice President and General Manager International, do not have employment agreements and they may terminate their employment and work elsewhere without notice and without cause or good reason. Currently we have non-compete agreements with our officers and other employees. Due to the specialized knowledge that each of our officers possesses with respect to our products and our operations and the limited pool of people with relevant experience in the medical device field, the loss of service of one or more of these individuals could significantly affect our ability to operate and manage our business. The announcement of the loss of one or more of our key personnel could negatively affect our stock price.

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

## **Table of Contents**

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

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

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

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

Because we operate within the medical device segment of the healthcare industry, our stock price is likely to be volatile. The market price of our common stock may have and has had a history of substantial fluctuation due to a variety of factors, including, but not limited to:

doctor and patient acceptance of the surgical treatment of AF or reduction in stroke risk using our products;

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

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

the timing of orders received;

delays or interruptions in manufacturing or shipping of our products;

pricing of our products;

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

investigations, claims or allegations by regulatory agencies, such as the Department of Justice and Financial Industry Regulatory Authority;

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

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additions to or departures of our key personnel;

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

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

variations in our quarterly financial and operating results;

failure to achieve or maintain an effective healthcare compliance environment;

## **Table of Contents**

changes in accounting principles; and

failure to achieve and maintain an effective internal control environment.

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

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

### **Sales of common stock by us in a capital raising transaction may dilute your ownership of common stock and cause a decline in the market price of our common stock.**

We may need to raise capital in the future to fund our operations or new initiatives. If we raise funds by issuing equity securities, our stock price may decline and our existing shareholders may experience significant dilution. Furthermore, we may enter into financing transactions at prices that represent a substantial discount to market price. A negative reaction by investors and securities analysts to any sale of our equity securities could result in a decline in the trading price of our common stock. In January 2013 we raised funds through a public offering of 4.0 million shares of common stock which increased the outstanding share count to approximately 20.9 million shares.

### **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.

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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

## **Table of Contents**

members of our management team, these provisions could, in turn, affect any attempt to replace the current management team. If a change of control or change in management is delayed or prevented, you may lose an opportunity to realize a premium on your shares of common stock or the market price of our common stock could decline.

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

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

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

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act), and the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act). We are also subject to certain provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the Dodd-Frank Act). These requirements may place a strain on our systems and resources. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight is required. While the Dodd-Frank Act requires the SEC to adopt certain rules and regulations relating to our public disclosures, corporate governance and executive compensation, among other things, we expect such rules and regulations will require significant attention from management. Compliance with all of these laws, rules and regulations 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**

The Company maintains its headquarters in West Chester, Ohio in three leased facilities totaling approximately 51,400 square feet. The facilities contain the Company's administrative, regulatory, engineering and product development, manufacturing and distribution functions. The monthly rent for this space is approximately \$40,000. All West Chester leases will expire in August 2013. Internationally, the Company maintains office space in the Netherlands. The monthly rent for this lease is approximately \$8,500 and the lease will expire in October 2013. The Company believes that its existing facilities are adequate to meet its immediate needs and that suitable additional space will be available in the future on commercially reasonable terms as needed.

### **ITEM 3. LEGAL PROCEEDINGS**

The Company is not party to any material pending or threatened litigation. We may from time to time become a party to additional legal proceedings. See Note 10, Commitments and Contingencies, to our Consolidated Financial Statements.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

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

Our common stock is traded on the NASDAQ Global Market under the symbol ATRC. The following table sets forth the high and low closing sales price of our common stock for 2012 and 2011:

	Price Range	
	High	Low
<b>2012</b>		
First Quarter	\$ 11.96	\$ 9.10
Second Quarter	\$ 9.85	\$ 7.96
Third Quarter	\$ 9.88	\$ 6.54
Fourth Quarter	\$ 7.65	\$ 5.91

	Price Range	
	High	Low
<b>2011</b>		
First Quarter	\$ 11.52	\$ 9.62
Second Quarter	\$ 14.50	\$ 11.58
Third Quarter	\$ 14.44	\$ 9.05
Fourth Quarter	\$ 12.17	\$ 8.54

As of February 28, 2013, the closing price of our common stock on the NASDAQ Global Market was \$8.88 per share, and the number of stockholders of record was 40.

**Dividend Policy**

The Company has not declared or paid any dividends on its capital stock since incorporation. Furthermore, pursuant to the credit facility, the Company is currently subject to certain restrictions on its ability to pay dividends. The Company currently expects to retain future earnings, if any, for use in the operation and expansion of the business and does not anticipate paying any cash dividends in the foreseeable future.

**Table of Contents**

**Performance Graph**

The following graph compares the cumulative total stockholder return on our common stock with the cumulative total return of the NASDAQ Composite and the NASDAQ Medical Equipment Index for the period beginning on January 1, 2008 and ending on December 31, 2012.

\* This graph assumes that \$100.00 was invested on December 31, 2007 in our common stock, the NASDAQ Composite Index and the NASDAQ Medical Equipment Index, and that all dividends are reinvested. No dividends have been declared or paid on our common stock. Stock performance shown in the above chart for our common stock is historical and should not be considered indicative of future price performance.

	12/31/08	12/31/09	12/31/10	12/31/11	12/31/12
AtriCure, Inc.	\$ 16.93	\$ 46.07	\$ 78.34	\$ 84.67	\$ 52.63
NASDAQ Composite	\$ 59.03	\$ 82.25	\$ 97.32	\$ 98.63	\$ 110.78
NASDAQ Medical Equipment	\$ 53.91	\$ 75.19	\$ 78.88	\$ 89.14	\$ 97.76



**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, 2012, 2011 and 2010 and the balance sheet data as of December 31, 2012 and 2011 are derived from our audited financial statements included in this Form 10-K. The statement of operations data for the years ended December 31, 2009 and 2008 and the balance sheet data as of December 31, 2010, 2009 and 2008 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.

	2012	Year Ended December 31,			2008
		2011	2010	2009 <sup>(1)</sup>	
(in thousands, except per share data)					
<b>Operating Results:</b>					
Revenue	\$ 70,247	\$ 64,402	\$ 59,006	\$ 54,534	\$ 55,257
Gross profit	50,014	46,996	45,388	41,783	42,033
Gross margin	71.2%	73.0%	76.9%	76.6%	76.1%
Net loss	(7,534)	(5,456)	(3,792)	(16,495)	(10,167)
Basic and diluted net loss per share	(0.47)	(0.35)	(0.25)	(1.13)	(0.72)
Weighted average shares outstanding	16,190	15,672	15,095	14,564	14,191
<b>Financial Position:</b>					
Cash, cash equivalents and short-term investments	\$ 12,000	\$ 14,183	\$ 12,571	\$ 15,722	\$ 11,448
Restricted cash and cash equivalents					6,000
Working capital	16,334	20,384	17,613	19,545	17,997
Total assets	32,431	33,859	33,716	34,982	43,369
Long-term debt and capital leases	6,407	4,926	662	2,670	6,037
Stockholders' equity	12,500	15,615	16,736	17,090	29,119

- (1) As a result of a reduction in our market capitalization during the first quarter of 2009, we believed an indication of impairment existed and, as such, performed an interim analysis of our goodwill as of March 31, 2009 as required by FASB Accounting Standards Codification (ASC) 350, Goodwill and Other Intangible Assets (ASC 350). The analysis concluded that the carrying value of our goodwill exceeded the estimated fair value, and, as such, a full impairment loss of \$6.8 million was recognized during 2009. Also during 2009, we recorded \$4.0 million in expense related to a settlement with the DOJ. See Note 10, Commitments and Contingencies, to our Consolidated Financial Statements.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the accompanying financial statements and notes thereto contained in Item 8, Financial Statements and Supplementary Data, to provide an understanding of our results of operations, financial condition and cash flows. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those set forth under Item 1A Risk Factors, the cautionary statement regarding forward-looking statements at the beginning of Part I and elsewhere in this Form 10-K.

**Overview**

We are a medical device company and a leader in developing, manufacturing and selling innovative cardiac surgical ablation systems designed to create precise lesions, or scars, in cardiac, or heart, tissue for the treatment of atrial fibrillation ( AF ), and systems for the exclusion of the left atrial appendage. We are the only company with a system cleared by the United States Food and Drug Administration ( FDA ), for the treatment of patients with persistent and long-standing persistent AF. We have two primary product lines for the ablation of cardiac tissue. Our primary product line for the ablation of cardiac tissue is the AtriCure Synergy Ablation System ( Synergy System ), a bipolar ablation clamp system and related radiofrequency ( RF ) ablation devices. We also offer a cryoablation product line, which features reusable and disposable cryoablation devices. Additionally, we offer the AtriClip Gillinov-Cosgrove Left Atrial Appendage System ( AtriClip System ), which is designed to safely and effectively exclude the left atrial appendage.

Cardiothoracic surgeons have adopted our RF and cryo ablation systems to treat AF in an estimated 125,000 patients since January 2003, and we believe that we are currently the market leader in the surgical treatment of AF. Our products are utilized by cardiothoracic surgeons during concomitant open-heart surgical procedures and also during sole-therapy minimally invasive cardiac ablation procedures. During a concomitant open procedure, the surgeon ablates cardiac tissue and/or excludes the left atrial appendage, secondary, or concomitant, to a primary cardiac procedure such as a valve or coronary bypass. Additionally, cardiothoracic surgeons have adopted our products as a treatment alternative for AF patients who may be candidates for sole-therapy minimally invasive surgical procedures. Our Synergy System, which includes our Isolator<sup>®</sup> Synergy clamps, a radiofrequency generator and related switchbox, is cleared by the FDA for the treatment of patients with persistent and long-standing persistent AF during open-heart concomitant coronary artery bypass grafting and/or valve replacement or repair procedures. During 2012 product sales of the Synergy System in the United States ( U.S. ) represented approximately 39% of our U.S. revenue. To date, none of our other products have been approved or cleared by the FDA for the treatment of other forms of AF or for other uses for the treatment of AF. Additionally, the FDA has not cleared or approved our products for a reduction in the risk of stroke. We anticipate that substantially all of our revenue for the foreseeable future will relate to products we currently sell, or are in the process of developing, which surgeons generally use to ablate cardiac tissue for the treatment of AF or for the exclusion of the left atrial appendage.

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

The December 2011 approval of our Synergy System included the requirement to implement a 350-patient post-approval study ( PAS ). The trial is designed to evaluate the long-term treatment effect of our Synergy Ablation System in persistent and long-standing persistent AF patients undergoing open-heart procedures. We

**Table of Contents**

submitted protocol for the PAS to the FDA in February 2012, and it was approved in September 2012. More than 100 patients have been enrolled in the trial. The FDA approval also included the requirement to implement a physician training and education program for existing and new users. Approximately 800 physicians have been trained through the education program.

We are also conducting a Staged DEEP clinical trial. We submitted a Staged DEEP AF trial protocol to the FDA in February 2012. The trial evaluates the effectiveness of a staged approach, where a minimally invasive ablation procedure is performed initially and the catheter and mapping optimization procedure is performed on a different day during the same hospitalization. Final approval was received in June 2012. Enrollment in the Staged DEEP trial was initiated during the third quarter of 2012, and there are currently fourteen patients enrolled. We expect to enroll up to 30 patients at six medical centers during the course of the trial.

During 2012 we introduced our BOA Pro device, a minimally invasive device for the surgical exclusion of the left atrial appendage. We also re-launched our Coolrail device, a disposable linear RF ablation device designed to allow physicians to create an expanded cardiac ablation lesion set during minimally invasive procedures.

Our financial position was strengthened by our public offering of approximately 4.0 million shares of common stock in January 2013, which generated net proceeds of \$27.1 million. We believe our current cash position will support the execution of our strategic plan.

**Results of Operations*****Year Ended December 31, 2012 compared to December 31, 2011***

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, 2012		Year Ended December 31, 2011	
	Amount	% of Revenue (dollars in thousands)	Amount	% of Revenue
Revenue	\$ 70,247	100.0%	\$ 64,402	100.0%
Cost of revenue	20,233	28.8%	17,406	27.0%
Gross profit	50,014	71.2%	46,996	73.0%
Operating expenses:				
Research and development expenses	12,147	17.3%	11,857	18.4%
Selling, general and administrative expenses	45,065	64.1%	39,870	61.9%
Total operating expenses	57,212	81.4%	51,727	80.3%
Loss from operations	(7,198)	-10.2%	(4,731)	-7.3%
Other expense:				
Interest expense	(802)	-1.1%	(814)	-1.2%
Interest income	11	0.0%	16	0.0%
Other	505	0.7%	104	0.1%
Other expense	(286)	-0.4%	(694)	-1.1%
Loss before income tax expense	(7,484)	-10.6%	(5,425)	-8.4%
Income tax expense	50	-0.1%	31	-0.1%
Net loss	\$ (7,534)	-10.7%	\$ (5,456)	-8.5%

**Revenue.** Total revenue increased 9.1% (10.3% on a constant currency basis), from \$64.4 million in 2011 to \$70.2 million in 2012. Constant currency basis amounts are calculated by applying previous period foreign



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**Table of Contents**

currency exchange rates to each of the comparable periods. Revenue from sales to customers in the United States increased \$3.7 million, or 7.5%, and revenue from sales to international customers increased \$2.2 million, or 14.0% (18.9% on a constant currency basis). The increase in sales to customers in the United States was primarily due to increased sales of ablation-related open-heart products of \$2.2 million and increased sales of the AtriClip system of \$1.4 million. This increase was partially offset by a reduction in sales of products used in minimally invasive standalone cardiac ablation procedures. The increase in international revenue was primarily due to an increase in product sales in direct European markets, Russia and Asia.

**Cost of revenue and gross margin.** Cost of revenue increased \$2.8 million, from \$17.4 million in 2011 to \$20.2 million in 2012. The increase in cost of revenue was primarily due to an increase in revenue and an increase in product cost primarily due to an increase in resources being dedicated to manufacturing-related activities. As a percentage of revenue, cost of revenue increased from 27.0% for the year ended December 31, 2011 to 28.8% for the year ended December 31, 2012. Gross margin for 2012 and 2011 was 71.2% and 73.0%, respectively. The decrease in gross margin was primarily due to:

an increase in manufacturing costs and inefficiencies primarily associated with transitioning to the manufacturing of PMA approved products;

an increased mix of international sales, which carry lower gross margins;

slight pressure on ASPs, primarily in our clamp and clip products; and

an increase in capital equipment sales, primarily the ORLab, which have a lower gross margin than our single-use products.

**Research and development expenses.** Research and development expenses increased \$0.3 million, from \$11.9 million in 2011 to \$12.1 million in 2012. As a percentage of revenue, research and development expenses decreased from 18.4% in 2011 to 17.3% in 2012. The increase in research and development expenses was primarily due to:

a \$0.1 million increase in clinical trial spending, primarily driven by the Post Approval Study to support the December 2011 FDA clearance of our Synergy System for the treatment of AF;

a \$0.2 million increase in other clinical and regulatory supporting activities;

the impact of a \$0.3 million sale of a patent in 2011; and

a \$0.3 million decrease in costs related to product development activities, primarily in headcount and share-based compensation expense.

**Selling, general and administrative expenses.** Selling, general and administrative expenses increased \$5.2 million, or 13.0%, from \$39.9 million in 2011 to \$45.1 million in 2012. The increase in selling, general and administrative expenses was primarily due to:

a \$2.0 million increase in training expenditures related to the December 2011 FDA clearance of our Synergy System for the treatment of AF;

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\$1.6 million in expenses related to the departure of the Company's Chief Financial Officer and Chief Executive Officer; and

a \$1.6 million increase in general and administrative expenses.

**Net interest expense.** Net interest expense was \$0.8 million for 2012 and 2011. Net interest expense primarily represents interest expense related to amounts outstanding on our term loan, amortization of the debt discount related to the warrants issued in conjunction with the term loan and amortization of debt issuance costs.

**Other income.** Other income consists primarily of foreign currency transaction gains and losses, grant income and non-employee option gains and losses related to the fair market value change for fully vested options

**Table of Contents**

outstanding for consultants which are accounted for as free-standing derivatives. Other income totaled \$0.5 million for 2012 and \$0.1 million for 2011.

**Year Ended December 31, 2011 compared to December 31, 2010**

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,		2010	
	2011	% of Revenue	Amount	% of Revenue
	Amount	(dollars in thousands)	Amount	
Revenue	\$ 64,402	100.0%	\$ 59,006	100.0%
Cost of revenue	17,406	27.0%	13,618	23.1%
Gross profit	46,996	73.0%	45,388	76.9%
Operating expenses:				
Research and development expenses	11,857	18.4%	11,531	19.5%
Selling, general and administrative expenses	39,870	61.9%	37,049	62.8%
Total operating expenses	51,727	80.3%	48,580	82.3%
Loss from operations	(4,731)	-7.3%	(3,192)	-5.4%
Other expense:				
Interest expense	(814)	-1.2%	(862)	-1.5%
Interest income	16	0.0%	22	0.1%
Other	104	0.1%	259	0.4%
Other expense	(694)	-1.1%	(581)	-1.0%
Loss before income tax expense	(5,425)	-8.4%	(3,773)	-6.4%
Income tax expense	31	-0.1%	19	0.0%
Net loss	\$ (5,456)	-8.5%	\$ (3,792)	-6.4%

**Revenue.** Revenue increased \$5.4 million, or 9.1% (8.5% on a constant currency basis), from \$59.0 million in 2010 to \$64.4 million in 2011. Revenue from sales to customers in the United States increased \$1.4 million, or 3.0%, and revenue from sales to international customers increased \$4.0 million, or 34.7% (31.1% on a constant currency basis). The increase in sales to customers in the United States was primarily due to increased sales of the AtriClip system of \$3.2 million, a new product offering that was released at the end of the second quarter of 2010. This increase was partially offset by a reduction in revenue from ablation-related products, which we believe was primarily due to a reduction in minimally invasive standalone cardiac ablation procedures. The increase in international revenue was primarily due to:

an increase in sales to European customers, primarily in our direct markets, including the benefit of transitioning the Benelux region to a direct market during the third quarter of 2010;

an increase in sales in Asia; and

foreign currency exchange fluctuations.

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**Cost of revenue and gross margin.** Cost of revenue increased \$3.8 million, from \$13.6 million in 2010 to \$17.4 million in 2011. The increase in cost of revenue was primarily due to an increase in revenue, an increased mix of capital equipment sales, an increase in scrap and manufacturing variances and costs associated with the discontinuance of manufacturing our Coolrail and Cryo1 devices. As a percentage of revenue, cost of revenue increased from 23.1% for the year ended December 31, 2010 to 27.0% for the year ended December 31, 2011. Gross margin for 2011 and 2010 was 73.0% and 76.9%, respectively. The decrease in gross margin was primarily due to:

increased manufacturing costs, scrap and inefficiencies driven primarily by new products and the anticipation of transitioning to the manufacturing of PMA approved products;



## Table of Contents

an increased mix of AtriClip and disposable cryo ablation device sales, which have lower gross margins than our other single-use products;

costs associated with the discontinuance of the manufacturing of our Coolrail and Cryo1 devices, which have been replaced with our Multifunctional Linear Pen and *cryoICE* devices, respectively; and

an increased mix of international sales.

**Research and development expenses.** Research and development expenses increased \$0.3 million, from \$11.5 million in 2010 to \$11.9 million in 2011. As a percentage of revenue, research and development expenses decreased from 19.5% in 2010 to 18.4% in 2011. The increase in research and development expenses was primarily due to:

a \$0.9 million increase in third party clinical and regulatory consulting costs, due primarily to an increase in clinical and regulatory activities;

a \$0.4 million increase in clinical trial spending, primarily due to an increase in enrollment related expense related to the DEEP AF and ABLATE AF clinical trials during 2011; and

a \$0.9 million reduction in external product design and development expenses, due primarily to a reduction in development and research related activities and new product introductions as compared to 2010.

**Selling, general and administrative expenses.** Selling, general and administrative expenses increased \$2.8 million, or 7.6%, from \$37.0 million in 2010 to \$39.9 million in 2011. The increase was primarily attributable to a \$2.4 million increase in sales and marketing expenses, primarily due to a \$2.0 million increase in headcount-related and travel expenses driven by an increase in average worldwide sales and marketing headcount of seven sales and marketing personnel in support of our growth initiatives.

**Net interest expense.** Net interest expense was \$0.8 million for 2011 and 2010. Net interest expense primarily represents interest expense related to amounts outstanding on our term loan, amortization of the debt discount related to the warrants issued in conjunction with the term loan and amortization of debt issuance costs.

**Other income (expense).** Other income (expense) consists primarily of foreign currency transaction gains (losses), grant income and non-employee option expense related to the fair market value change for fully vested options outstanding for consultants which are accounted for as free-standing derivatives. In 2011, other income of \$0.1 million included:

\$52,000 of grant income;

\$30,000 of income related to foreign currency transaction gains; and

\$23,000 for certain non-employee option income due to a decrease in the fair market value of the options.  
In 2010, other income of \$0.3 million included:

\$0.6 million of grant income, primarily due to a non-recurring, one-time grant from the United States Internal Revenue Service of \$0.5 million;

\$0.2 million of expenses related to foreign currency transaction losses, due to partial settlements of intercompany balances; and

\$0.2 million for certain non-employee option expenses due to an increase in the fair market value of the options.

**Liquidity and Capital Resources**

As of December 31, 2012 we had cash, cash equivalents and short-term investments of \$12.0 million and short-term and long-term debt of \$8.3 million, resulting in a net cash position of \$3.7 million. We had unused

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**Table of Contents**

borrowing capacity of approximately \$5.3 million under our revolving credit facility. Substantially all cash is held by United States institutions. We had net working capital of \$16.3 million and an accumulated deficit of \$110.8 million as of December 31, 2012.

**Cash flows used in operating activities.** Net cash used in operating activities was \$1.9 million during 2012. The primary net uses of cash for operating activities were as follows:

the net loss of \$7.5 million, offset by \$5.5 million of non-cash expenses, including \$3.5 million of share-based compensation and \$1.9 million of depreciation; and

a net decrease in cash used related to changes in operating assets and liabilities of \$0.1 million, due primarily to the following:

an increase in accounts receivable of \$0.4 million due primarily to an increase in sales during the fourth quarter of 2012 as compared to the fourth quarter of 2011;

a decrease in inventory of \$0.9 million due primarily to more effective inventory planning; and

a \$0.2 million reduction in accounts payable and accrued liabilities due primarily to the timing of payments.

**Cash flows provided by investing activities.** Net cash used in investing activities was \$2.8 million during 2012. The primary uses of cash were:

use of cash of \$3.0 million related to the purchase of equipment, which consisted primarily of loans of our RF and cryo generators to our customers; and

net proceeds of \$0.2 million related to the maturity of available-for-sale securities.

**Cash flows provided by financing activities.** Net cash provided by financing activities during 2012 was \$2.7 million, which was primarily due to net proceeds from the modified SVB term loan borrowing of \$3.9 million, proceeds from stock option exercises of \$0.7 million and proceeds from the issuance of common stock under the employee stock purchase plan of \$0.6 million, partially offset by shares repurchased for payment of taxes on stock awards of \$0.4 million and debt payments of \$2.0 million.

**Credit facility.** Our Loan and Security Agreement with Silicon Valley Bank ( SVB ), as amended, restated, and modified (the Agreement ) provides for a term loan and a revolving credit facility under which we may borrow a maximum of \$20.0 million. As of December 31, 2012 we had no borrowings under the revolving credit facility, and we had borrowing availability of approximately \$5.3 million. The applicable borrowing rate on the revolving facility is 0.25% to 1.25% above the prime rate, as determined by a liquidity ratio. Also, as of December 31, 2012, \$8.3 million was outstanding under the term loan, which included \$2.0 million classified as current maturities of long-term debt. The term loan has a five year term, and principal payments in the amount of \$0.2 million, together with accrued interest, are due and payable monthly. The term loan accrues interest at a fixed rate of 6.75%.

The Agreement contains covenants that include, among others, covenants that limit our ability to dispose of assets, enter into mergers or acquisitions, incur indebtedness, incur liens, pay dividends or make distributions on our capital stock, make investments or loans, and enter into certain affiliate transactions, in each case subject to customary exceptions for a credit facility of this size and type. Additional covenants apply when we have outstanding borrowings under the revolving loan facility or when we achieve specific covenant milestones. Financial covenants include a minimum EBITDA, a limitation on capital expenditures, and a minimum liquidity ratio. Further, a minimum fixed charge ratio applies when we achieve specific covenant milestones. The occurrence of an event of default could result in an increase to the applicable interest rate by 3.0%, an acceleration of all obligations under the Agreement, an obligation to repay all obligations in full, and a right by SVB to exercise all remedies available to it under the Agreement and related agreements including the Guaranty



## **Table of Contents**

and Security Agreement. As of and for the period ended December 31, 2012 we were in compliance with all of the financial covenants of our amended and modified credit facility. In addition, if the guarantee by the Export-Import Bank of the United States ceases to be in full force and effect, we must repay all loans under the Export-Import agreement.

The effective interest rate on borrowings under the modified term loan, including debt issuance costs, is 7.6%. We had an outstanding letter of credit of \$0.3 million issued to our corporate credit card program provider which was due to expire on July 31, 2011. This letter of credit was cancelled in June 2011, and no letters of credit were outstanding at December 31, 2012. See Note 9, *Indebtedness*, to our Consolidated Financial Statements.

**Uses of liquidity and capital resources.** Our future capital requirements depend on a number of factors, including 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, costs associated with clinical trials and securing regulatory approval for new products, costs associated with required training programs and post-approval clinical studies, costs associated with prosecuting, defending and enforcing our intellectual property rights, and possible acquisitions and joint ventures. Global economic turmoil may adversely impact our revenue, access to the capital markets or future demand for our products.

In July 2011 we filed a shelf registration statement with the SEC, which will allow us to sell any combination of senior or subordinated debt securities, common stock, preferred stock, warrants, depositary shares and units in one or more offerings should we choose to do so in the future. In January 2013 we sold approximately 4.0 million shares of common stock under the shelf registration which resulted in net proceeds of approximately \$27.1 million.

We believe that our current cash, cash equivalents and short-term investments, along with the cash we raised in January 2013 and the cash we expect to generate or use for operations or access via our credit facility, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next twelve months. Significant cash needs over the next twelve months include debt service of approximately \$2.5 million (\$0.2 million per month plus interest) on our outstanding term loan and payments under our settlement agreement with the DOJ and Relator of approximately \$1.2 million. 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 revised or additional credit facility. The sale of additional equity or convertible debt securities could result in further 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.

## **Contractual Obligations and Commitments**

### *DOJ Settlement*

On February 2, 2010 we entered into a settlement agreement among the Company, the DOJ, the OIG and the Relator in the DOJ investigation and *qui tam* complaint ( *Settlement Agreement* ). The Settlement Agreement and dismissal of the *qui tam* complaint definitively resolve all claims related to the DOJ investigation and *qui tam* complaint. We have not admitted nor will we admit to any wrongdoing in connection with the settlement.

The Settlement Agreement provided that we would pay a settlement amount of approximately \$3.8 million (total payments based on the settlement inclusive of interest are approximately \$4.2 million) and legal fees to counsel for the Relator of \$0.2 million. Payment of the settlement amount is being made over a five-year period. A majority of the amount payable is payable during the fourth and fifth years. Payments of the Relator's legal fees are being made in ratable quarterly payments over four years with the first payment made in February 2010.

**Table of Contents**

As part of the resolution, we also entered into a five-year Corporate Integrity Agreement with OIG. This agreement acknowledges the existence of our corporate compliance program and provides for certain other compliance-related activities during the five-year term of the agreement. Those activities include specific written standards, monitoring, training, education, independent review, disclosure and reporting requirements.

*Purchase Agreements*

On June 15, 2007 we entered into a purchase agreement with MicroPace Pty Ltd Inc., ( MicroPace ). The agreement, as amended, provides for MicroPace to produce a derivative of one of their products tailored for the cardiac surgical environment, known as the MicroPace ORLab for worldwide distribution by us. Pursuant to the terms of the amended agreement, in order to retain exclusive distribution rights, we were required to purchase a minimum of 40 units during the period December 1, 2010 through December 31, 2011 to extend exclusivity through 2012 and an additional 40 units during 2012 to extend exclusivity through December 31, 2013. Units purchased in excess of yearly minimums reduce future minimum purchase requirements. A total of 56 units were purchased between December 1, 2010 and December 31, 2011, thereby extending exclusive distribution rights through December 31, 2012. A total of 60 units were purchased during 2012, fulfilling the purchase requirement to extend exclusive distribution rights through 2013. We anticipate entering into another purchase agreement with MicroPace to extend our distribution rights beyond 2013.

In April 2012 we entered into a development and manufacturing services agreement with Stellartech Research Corporation ( Stellartech ). Under the terms of the agreement, Stellartech will provide development services for the next generation of our radio frequency generators and will manufacture at least the first 300 units of the product. The agreement also establishes Stellartech as the exclusive supplier of the generators during the initial three years after product completion. There is no minimum purchase requirement beyond the initial 300 units.

*Distributor Termination*

In July 2010 we terminated a distributor agreement with a European distributor. Under the terms of the agreement we paid the distributor a termination fee, repurchased saleable disposable product inventory and assigned the distributor's capital equipment to AtriCure Europe BV. Additionally, we entered into a consulting agreement with the distributor to provide ongoing consulting services through September 30, 2012. In exchange for these services, beginning October 1, 2010, the distributor earned 0.1 million (approximately \$0.1 million) per quarter for a total of 0.4 million (approximately \$0.5 million).

The following sets forth our approximate aggregate obligations at December 31, 2012 for future payments under contracts and other contingent commitments (in thousands):

<b>Contractual Obligations</b>	<b>Total</b>	<b>Less than 1 year</b>	<b>1-3 years</b>	<b>3-5 years</b>
Long-term debt and capital leases <sup>(1)</sup>	\$ 9,660	\$ 2,544	\$ 4,666	\$ 2,450
DOJ settlement <sup>(2)</sup>	2,300	1,175	1,125	
Operating leases <sup>(3)</sup>	600	583	17	
Royalty obligations <sup>(4)</sup>	1,124	724	400	
Obligations to fund research grants	459	459		
Total contractual obligations	\$ 14,143	\$ 5,485	\$ 6,208	\$ 2,450

(1) Long-term debt represents principal repayment related to our term loan that matures in 2016. Interest on the term loan accrues at a rate of 6.75% per year and is included above with monthly principal payments of \$0.2 million. Capital leases consist of principal and interest payments related to computer equipment.

(2) The DOJ settlement provides that we pay a settlement amount of \$4.0 million, which represents the net present value of the settlement amount to be paid to the DOJ, the Relator, and Relator's counsel (total payments based on the settlement inclusive of interest are \$4.4 million and payable over five years).

(3) Represents lease commitments under various operating leases.

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## **Table of Contents**

- (4) Represents minimum payments required under the terms of a royalty agreement, not to exceed in aggregate \$2.0 million in royalties from January 1, 2010 through December 31, 2015. Through 2012, \$0.6 million had been paid. Also represented is another royalty agreement which is a total royalty of 5% of product sales and was estimated using 2012 sales. See Note 10, *Commitments and Contingencies* to our Consolidated Financial Statements.

### **Off-Balance-Sheet Arrangements**

As of December 31, 2012 we had operating lease agreements not recorded on the Consolidated Balance Sheets. Operating leases are utilized in the normal course of business.

### **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 sales returns and allowances, accounts receivable, inventories and share-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.

***Share-Based Employee Compensation*** We account for share-based compensation for all employee share-based payment awards, including stock options, restricted stock, performance shares and stock purchases related to an employee stock purchase plan, based on their estimated fair values. We estimate the fair value of options on the date of grant using the Black-Scholes option pricing model (Black-Scholes model). Our determination of fair value of share-based payment awards 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 and the peer group's expected stock price volatility over the term of the awards and actual and projected employee stock option exercise behaviors. For non-employee options, the fair value at the date of grant is subject to adjustment at each vesting date based upon the fair value of our common stock. The fair value of our market-based performance option grants is estimated at the date of grant using a Monte-Carlo simulation. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in our Consolidated Statement of Operations. The expense has been reduced for estimated forfeitures.

We estimate the fair value of restricted stock and performance share awards based upon the grant date closing market price of our common stock. Our determination of fair value is affected by our stock price as well as assumptions regarding the number of shares expected to be granted, and, in the case of performance shares, the likelihood that the performance measures will be achieved.

We also have an employee stock purchase plan ( *ESPP* or the *Plan* ) which is available to all eligible employees as defined by the Plan. Under the *ESPP*, shares of our common stock may be purchased at a discount. We estimate the number of shares to be purchased under the Plan and record compensation expense based upon the fair value of the stock at the beginning of the purchase period using the Black-Scholes model.

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**Table of Contents**

We have historically issued stock options to non-employee consultants as a form of compensation for services provided to us. Because these options do not contain specific performance provisions, there is no measurement date of fair value until the options vest. Therefore, the fair value of the options granted and outstanding prior to their vesting date is remeasured each reporting period and recorded as compensation expense. Because the options require settlement by our delivery of registered shares and because the tax withholding provisions in the awards allow the options to be partially net-cash settled, these options, when vested, are no longer eligible for equity classification and are, thus, subsequently accounted for as derivative liabilities under FASB ASC 815 until the awards are ultimately either exercised or forfeited. Accordingly, the vested non-employee options are classified as liabilities, and their fair value is remeasured using the Black-Scholes model at each reporting period.

**Revenue Recognition** Revenue is generated primarily from the sale of our disposable surgical devices. Pursuant to our standard terms of sale, revenue is recognized when title to the goods and risk of loss transfers to customers and there are no remaining obligations that will affect customers' 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 generally do not maintain any post-shipment obligations to the recipients of the products. No installation, calibration or testing of this equipment is performed by AtriCure subsequent to shipment to the customer in order to render it operational. Cost of freight for shipments made to customers is included in cost of revenue. Sales and other value-added taxes collected from customers and remitted to governmental authorities are excluded from revenue. We sell our products primarily through a direct sales force and through a wholly-owned subsidiary, AtriCure Europe B.V. Terms of sale are generally consistent for both end-users and distributors except that payment terms are generally net 30 days for end-users and net 60 days for distributors.

We account for revenue in accordance with FASB ASC 605, Revenue Recognition (ASC 605). We determine 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: (i) there is 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) collectability is reasonably assured.

**Allowance for Uncollectible Accounts Receivable** We evaluate the collectability of accounts receivable in order to determine the appropriate reserve for doubtful accounts. In determining the amount of the reserve, we consider the aging of account balances, historical credit losses, customer-specific information, and other relevant factors. We periodically review accounts receivable and adjust the allowance based on current circumstances and charge off uncollectible receivables against the allowance when all attempts to collect the receivable have failed. Our history of write-offs against the allowance has not been significant.

**Inventories** Our inventories are stated at the lower of cost or market using the first-in, first-out cost method (FIFO) and consist of raw materials, work in process and finished goods. We adjust our inventory reserve estimate based on product usage quarterly for excess, slow moving and obsolete inventory as well as inventory with a carrying value in excess of its net realizable value. Our industry is characterized by rapid product development and frequent new product introductions. Uncertain timing of product approvals, variability in product launch strategies and variation in product utilization all impact excess and obsolete inventory.

**Property and Equipment** We state property and equipment at cost less accumulated depreciation. Depreciation is computed using the straight-line method for financial reporting purposes and applied over the estimated useful lives of the assets. Included in property and equipment are generators and other capital equipment (such as our switchbox units and cryosurgical consoles) that are loaned at no cost to direct customers that use our disposable products. These generators are depreciated over a period of one to three years, which approximates their useful lives, and such depreciation is included in cost of revenue. We estimate the useful lives of this equipment based on anticipated usage by our customers and the timing and impact of our expected new technology rollouts. To the extent we experience changes in the usage of this equipment or the introductions of new technologies, the estimated useful lives of this equipment may change in a future period.



## **Table of Contents**

**Income Taxes** We compute income taxes 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 our assets and liabilities. Deferred taxes are measured using provisions of currently enacted tax laws. We record a valuation allowance against deferred tax assets when it is more likely than not that such assets will not be fully realized, and we account for tax credits as a reduction of income taxes in the year in which the credit originates.

Our estimate of the valuation allowance for deferred tax assets requires us to make significant estimates and judgments about 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 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. In evaluating whether to record a valuation allowance, the applicable accounting standards deem that the existence of cumulative losses in recent years is a significant piece of objectively verifiable negative evidence that must be overcome by objectively verifiable positive evidence to avoid the need to record a valuation allowance. We have recorded a full valuation allowance against our net deferred tax assets as it is more likely than not that the benefit of the deferred tax assets will not be recognized in future periods.

## **Recent Accounting Pronouncements**

In May 2011 the FASB issued FASB Accounting Standards Update ( ASU ) 2011-04, Fair Value Measurement. The ASU is the result of joint efforts by the FASB and IASB to develop a single, converged fair value framework, that is, converged guidance on how (not when) to measure fair value and on what disclosures to provide about fair value measurements. While the ASU is largely consistent with existing fair value measurement principles in U.S. GAAP, it expands ASC 820's existing disclosure requirements for fair value measurements and makes other amendments. Some of the amendments could change how the fair value measurement guidance in ASC 820 is applied. The ASU is effective for interim and annual reporting periods beginning after December 15, 2011. The Company has evaluated the provisions of ASU 2011-04 and has determined that it does not have a material impact on the Company's fair value disclosures.

In June 2011 the FASB issued new guidance in ASU 2011-05, Presentation of Comprehensive Income, which revises the manner in which entities present comprehensive income in their financial statements. This new guidance requires entities to report components of comprehensive income in either (1) a continuous statement of comprehensive income or (2) two separate but consecutive statements. It is effective for interim and annual reporting periods beginning after December 15, 2011. The Company adopted the single continuous statement presentation approach. In December 2011 the FASB issued ASU 2011-12, Comprehensive Income: Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No.2011-05. The Company has evaluated the provisions of ASU 2011-05 that were deferred and has determined that they would not have a material impact on the Company's financial reporting.

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

The Company has financial instruments accounted for as free-standing derivatives related to certain of the Company's share-based payment arrangements that are outside the scope of FASB ASC 718 and are subject to FASB ASC 815, which requires fully vested stock options held by certain non-employee consultants to be accounted for as liability awards until these awards are exercised or forfeited. The fair value of these awards is remeasured at each reporting period until the awards are settled or expire. Income (expense) recorded based on the remeasurement of these options was approximately \$0.2 million, \$23,000 and (\$0.2) million for 2012, 2011 and 2010, respectively. As of December 31, 2012, stock options to acquire 38,000 shares of common stock held by non-employee consultants remained unexercised, and a liability of \$0.1 million was included in accrued liabilities in the accompanying Consolidated Balance Sheet. The Company is exposed to the volatility of the market price of its stock. If the market price of AtriCure stock was \$1 higher as of December 31, 2012, the Company would have recorded approximately \$21,000 in additional expense related to these awards.

The Company is exposed to various market risks, which include potential losses arising from adverse changes in market rates and prices, such as foreign exchange fluctuations and changes in interest rates. Borrowings under the term loan with Silicon Valley Bank bear interest at a rate of 6.75% per year. Interest on the revolving loan will accrue at a fluctuating rate equal to the Bank's announced prime rate of interest, subject to a floor of 4.0%, plus between 0.25% to 1.25%, depending on the Company's Liquidity Ratio (as defined in the Amended Agreement). As of December 31, 2012, our effective borrowing rate was 7.6% and the carrying value and fair value of the outstanding balance under the term loan was \$8.3 million. Based upon this debt level, a 10.0% increase in the interest rate would not have resulted in a material impact to our financial results.

For the years ended December 31, 2012 and 2011, products sold by AtriCure Europe, B.V. accounted for 13.6% and 13.5%, respectively, of the Company's total revenue. Since such revenue was primarily denominated in Euros, the Company is exposed to exchange rate fluctuations between the Euro and the U.S. Dollar. To date, the effect of the foreign exchange rate fluctuations on AtriCure's financial results has not been significant. For the years ended December 31, 2012 and 2011, foreign currency transaction (losses) gains of \$(0.1) million and \$30,000, respectively, were recorded in connection with partial settlements of the intercompany receivable balance with the subsidiary. For revenue 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 products are priced in Euros, the Company will receive less in U.S. Dollars than was received before the rate increase went into effect. If products are priced 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 the Company's price not being competitive in a market where business is transacted in Euros. The Euro to U.S. dollar conversion rate fluctuations may impact our reported revenue and expenses.

The Company currently invests its cash primarily in money market accounts, U.S. government agencies and securities, corporate bonds and commercial paper. Although the Company believes its cash to be invested in a conservative manner, with cash preservation being the primary investment objective, the value of the securities held will fluctuate with changes in the financial markets including, among other things, changes in interest rates, credit quality and general volatility. This risk is managed by investing in high quality investment grade securities with short-term maturities.

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalent balances. Certain of AtriCure's cash and cash equivalents balances exceed FDIC insured limits or are invested in money market accounts with investment banks that are not FDIC insured. The Company places its cash and cash equivalents in what it believes to be credit-worthy financial institutions. As of December 31, 2012 \$10.8 million of the cash and cash equivalents balance was in excess of the FDIC limits.

**Table of Contents**

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

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<i>Financial Statements:</i>	
<u>Report of Independent Registered Public Accounting Firm</u>	54
<u>Consolidated Balance Sheets</u>	55
<u>Consolidated Statements of Operations and Comprehensive Loss</u>	56
<u>Consolidated Statements of Stockholders' Equity</u>	57
<u>Consolidated Statements of Cash Flows</u>	58
<u>Notes to Consolidated Financial Statements</u>	59
<i>Financial Statement Schedule:</i>	
<u>Schedule II Valuation and Qualifying Accounts</u>	82

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

AtriCure, Inc. and subsidiaries

West Chester, Ohio

We have audited the accompanying consolidated balance sheets of AtriCure, Inc. and subsidiaries (the Company) as of December 31, 2012 and 2011, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. 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 the 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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 AtriCure, Inc. and subsidiaries at December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, 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.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2012, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 8, 2013 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Cincinnati, Ohio

March 8, 2013

**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****DECEMBER 31, 2012 and 2011****(In Thousands, Except Per Share Amounts)**

	2012	2011
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 7,753	\$ 9,759
Short-term investments	4,247	4,424
Accounts receivable, less allowance for doubtful accounts of \$49 and \$37, respectively	9,948	9,514
Inventories	5,718	6,563
Other current assets	873	933
Total current assets	28,539	31,193
Property and equipment, net	3,430	2,351
Intangible assets	32	45
Other assets	430	270
Total Assets	\$ 32,431	\$ 33,859
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 5,103	\$ 5,270
Accrued liabilities	5,073	3,996
Current maturities of debt and capital leases	2,029	1,543
Total current liabilities	12,205	10,809
Long-term debt and capital leases	6,407	4,926
Other liabilities	1,319	2,509
Total Liabilities	19,931	18,244
Commitments and contingencies (Note 10)		
Stockholders Equity:		
Common stock, \$.001 par value, 90,000 shares authorized and 16,896 and 16,369 issued and outstanding, respectively	17	16
Additional paid-in capital	123,157	118,853
Accumulated other comprehensive income (loss)	77	(37)
Accumulated deficit	(110,751)	(103,217)
Total Stockholders Equity	12,500	15,615
Total Liabilities and Stockholders Equity	\$ 32,431	\$ 33,859

See accompanying notes to consolidated financial statements.



**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****YEARS ENDED DECEMBER 31, 2012, 2011 and 2010****(In Thousands, Except Per Share Amounts)**

	<b>2012</b>	<b>2011</b>	<b>2010</b>
Revenue	\$ 70,247	\$ 64,402	\$ 59,006
Cost of revenue	20,233	17,406	13,618
Gross profit	50,014	46,996	45,388
Operating expenses:			
Research and development expenses	12,147	11,857	11,531
Selling, general and administrative expenses	45,065	39,870	37,049
Total operating expenses	57,212	51,727	48,580
Loss from operations	(7,198)	(4,731)	(3,192)
Other income (expense):			
Interest expense	(802)	(814)	(862)
Interest income	11	16	22
Other	505	104	259
Loss before income tax expense	(7,484)	(5,425)	(3,773)
Income tax expense	50	31	19
Net loss	\$ (7,534)	\$ (5,456)	\$ (3,792)
Basic and diluted net loss per share	\$ (0.47)	\$ (0.35)	\$ (0.25)
Weighted average shares outstanding basic and diluted	16,190	15,672	15,095
Comprehensive loss:			
Unrealized gains (losses) on investments	\$ (1)	\$ 2	\$ (3)
Foreign currency translation adjustment	115	(119)	(61)
Other comprehensive income (loss)	114	(117)	(64)
Net loss	(7,534)	(5,456)	(3,792)
Comprehensive loss	\$ (7,420)	\$ (5,573)	\$ (3,856)

See accompanying notes to consolidated financial statements.

**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY****YEARS ENDED DECEMBER 31, 2012, 2011, and 2010****(In Thousands)**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
	Shares	Amount				
Balance December 31, 2009	15,353	\$ 15	\$ 110,900	\$ (93,969)	\$ 144	\$ 17,090
Issuance of common stock under equity incentive plans	214	0	232			232
Issuance of common stock under employee stock purchase plan	97	0	498			498
Non-employee stock option fair market value adjustment			19			19
Share-based employee compensation expense			2,753			2,753
Other comprehensive loss					(64)	(64)
Net loss				(3,792)		(3,792)
Balance December 31, 2010	15,664	15	114,402	(97,761)	80	16,736
Issuance of common stock under equity incentive plans	631	1	860			861
Issuance of common stock under employee stock purchase plan	74	0	669			669
Non-employee stock option fair market value adjustment			8			8
Share-based employee compensation expense			2,931			2,931
Reclassification of non-employee option liability			(17)			(17)
Other comprehensive loss					(117)	(117)
Net loss				(5,456)		(5,456)
Balance December 31, 2011	16,369	16	118,853	(103,217)	(37)	15,615
Issuance of common stock under equity incentive plans	438	1	258			259
Issuance of common stock under employee stock purchase plan	89	0	627			627
Share-based employee compensation expense			3,468			3,468
Reclassification of non-employee option liability			(49)			(49)
Other comprehensive income					114	114
Net loss				(7,534)		(7,534)
Balance December 31, 2012	16,896	\$ 17	\$ 123,157	\$ (110,751)	\$ 77	\$ 12,500

See accompanying notes to consolidated financial statements.



**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS****YEARS ENDED DECEMBER 31, 2012, 2011 and 2010****(In Thousands)**

	<b>2012</b>	<b>2011</b>	<b>2010</b>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (7,534)	\$ (5,456)	\$ (3,792)
<b>Adjustments to reconcile net loss to net cash (used in) provided by operating activities:</b>			
Share-based compensation expense	3,468	2,939	2,772
Depreciation	1,886	1,878	2,164
Amortization of deferred financing costs	100	97	111
Write-off of deferred financing costs and discount on long-term debt		153	
Amortization of discount on long-term debt		22	185
Amortization of intangible assets	13	44	199
Amortization/accretion on investments	12	61	
(Gain) loss on disposal of equipment	40	56	(37)
Gain on sale of intellectual property		(300)	
Change in allowance for doubtful accounts	1	28	(16)
<b>Changes in assets and liabilities:</b>			
Accounts receivable	(417)	(199)	(2,300)
Inventories	865	(923)	(850)
Other current assets	57	(17)	525
Accounts payable	(132)	788	893
Accrued liabilities	(97)	(976)	(237)
Other non-current assets and non-current liabilities	(198)	(181)	350
<b>Net cash used in operating activities</b>	<b>(1,936)</b>	<b>(1,986)</b>	<b>(33)</b>
<b>Cash flows from investing activities:</b>			
Purchases of equipment	(2,985)	(1,522)	(1,814)
Proceeds from sale of equipment	24	89	5
Purchases of available-for-sale securities	(9,236)	(12,649)	(11,124)
Maturities of available-for-sale securities	9,400	16,506	9,598
Proceeds from sale of intellectual property		300	
<b>Net cash (used in) provided by investing activities</b>	<b>(2,797)</b>	<b>2,724</b>	<b>(3,335)</b>
<b>Cash flows from financing activities:</b>			
Payments on debt and capital leases	(8,096)	(4,046)	(2,227)
Proceeds from borrowings of debt	10,000	7,500	
Payment of debt fees and premium on retirement of debt	(127)	(81)	(68)
Proceeds from issuance of common stock under employee stock purchase plan	627	669	499
Proceeds from stock option exercises	659	1,588	353
Shares repurchased for payment of taxes on stock awards	(401)	(783)	
<b>Net cash provided by (used in) financing activities</b>	<b>2,662</b>	<b>4,847</b>	<b>(1,443)</b>
Effect of exchange rate changes on cash	65	(57)	137
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(2,006)</b>	<b>5,528</b>	<b>(4,674)</b>
Cash and cash equivalents beginning of period	9,759	4,231	8,905

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Cash and cash equivalents end of period	\$ 7,753	\$ 9,759	\$ 4,231
<b>Supplemental cash flow information:</b>			
Cash paid for interest	\$ 607	\$ 405	\$ 418
Cash paid for income taxes	14	30	30
<b>Non-cash investing and financing activities:</b>			
Accrued purchases of property and equipment	10	44	62
Receivable related to sale of property and equipment			89
Assets acquired through capital lease	65	60	
Capital lease asset early termination	13		

See accompanying notes to consolidated financial statements.

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**Table of Contents**

**ATRICURE, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(In Thousands, Except Per Share Amounts)**

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

**Nature of the Business** AtriCure, Inc. (the Company or AtriCure) was incorporated in the State of Delaware on October 31, 2000. The Company develops, manufactures and sells devices designed primarily for the surgical ablation of cardiac tissue and devices for the exclusion of the left atrial appendage. The Company sells its products to hospitals and medical centers globally.

**Principles of Consolidation** The Consolidated Financial Statements include the accounts of the Company, AtriCure, LLC, the Company's wholly-owned subsidiary organized in the State of Delaware, and AtriCure Europe B.V., the Company's wholly-owned subsidiary incorporated in the Netherlands. All intercompany accounts and transactions have been eliminated in consolidation.

**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 Consolidated Financial Statements.

**Investments** The Company places its investments primarily in U.S. Government agencies and securities, corporate bonds and commercial paper. The Company classifies all investments as available-for-sale. Investments with maturities of less than one year are classified as short-term investments. 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 and includes them in interest income or expense in the Consolidated Statements of Operations.

**Revenue Recognition** The Company accounts for revenue in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 605, Revenue Recognition (ASC 605). The Company determines 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) there is 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) collectability is reasonably assured.

Revenue is generated from the sale of the Company's surgical devices. The Company's surgical devices consist primarily of individual disposable handpieces and equipment generators. The Company's customers need the combination of the generator and the handpieces to have a functional system. The Company believes that the generator and handpiece are considered a single unit of accounting under ASC 605 because neither the generator nor handpiece have value to the customer on a standalone basis. Therefore, because the customer needs both the generator and handpiece to have a functional system, revenue is recognized upon the later of delivery of the generator or the handpiece.

Pursuant to the Company's standard terms of sale, 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 customers' 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 generally does not maintain any 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 and handling revenue of \$723, \$664 and \$657 in 2012, 2011 and 2010, respectively. Cost of freight for shipments made to customers is included in cost of revenue. Sales and other value-added taxes collected from customers and remitted to governmental authorities are excluded from revenue.

**Table of Contents**

**ATRICURE, INC. AND SUBSIDIARIES**

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

**(In Thousands, Except Per Share Amounts)**

The Company sells its products primarily through a direct sales force and through AtriCure Europe B.V. Terms of sale are generally consistent for both end-users and distributors except that payment terms are generally net 30 days for end-users and net 60 days for distributors.

***Sales Returns and Allowances*** The Company maintains a provision for sales returns and allowances to account for potential returns of defective or damaged products, products shipped in error and price adjustments. The Company estimates such provision quarterly based primarily on a specific identification basis, in addition to estimating a general reserve. Increases to the provision result in a reduction of revenue. The provision is included in accrued liabilities in the Consolidated Balance Sheets.

***Allowance for Uncollectible Accounts Receivable*** The Company evaluates the collectability of accounts receivable in order to determine the appropriate reserve for doubtful accounts. In determining the amount of the reserve, the Company considers aging of account balances, historical credit losses, customer-specific information and other relevant factors. An increase to the allowance for doubtful accounts results in a corresponding increase in expense. The Company reviews accounts receivable and adjusts the allowance based on current circumstances and charges off uncollectible receivables against the allowance when all attempts to collect the receivable have failed. The Company's history of write-offs against the allowance has not been significant.

***Inventories*** Inventories are stated at the lower of cost or market using the first-in, first-out cost method ( FIFO ) and consist of raw materials, work in process and finished goods. The Company's industry is characterized by rapid product development and frequent new product introductions. Uncertain timing of product approvals, variability in product launch strategies and variation in product utilization all impact excess and obsolete inventory. An inventory reserve based on product usage is estimated and recorded quarterly 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 a product is destroyed. The Company's history of write-offs against the reserve has not been significant.

***Property and Equipment*** Property and equipment is stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method of depreciation for financial reporting purposes and applied over the estimated useful lives of the assets. The estimated useful life by major asset category is the following: machinery and equipment is three to seven years, computer and other office equipment is three years, furniture and fixtures is three to seven years and leasehold improvements and equipment leased under a capital lease are the shorter of their useful life or remaining lease term. The Company reassesses useful lives of property and equipment annually, and assets are retired if they are no longer being used. Maintenance and repair costs are expensed as incurred.

Included in property and equipment are generators and other capital equipment (such as the Company's switchbox units and cryosurgical consoles) that are loaned at no cost to direct customers that use the Company's disposable products. These generators are depreciated over a period of one to three years, which approximates their useful lives, and such depreciation is included in cost of revenue. The estimated useful lives of this equipment are based on anticipated usage by our customers and the timing and impact of expected new technology rollouts by the Company. To the extent the Company experiences changes in the usage of this equipment or introductions of new technologies, the estimated useful lives of this equipment may change in a future period. Depreciation related to these generators was \$1,081, \$1,294 and \$1,369 in 2012, 2011 and 2010, respectively. As of December 31, 2012 and 2011, the net carrying amount of loaned equipment included in net property and equipment in the Consolidated Balance Sheets was \$2,197 and \$1,204, respectively.

***Impairment of Long-Lived Assets*** The Company reviews property and equipment for impairment using its best estimates based on reasonable and supportable assumptions and projections.

**Table of Contents**

**ATRICURE, INC. AND SUBSIDIARIES**

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

**(In Thousands, Except Per Share Amounts)**

**Intangible Assets** Intangible assets with determinable useful lives are amortized on a straight-line basis over the estimated periods benefited, which have ranged from four to eight years.

**Other Income** Other income consists primarily of foreign currency transaction gains and losses, grant income and non-employee option gains and losses related to the fair market value change for fully vested options outstanding for consultants which are accounted for as free-standing derivatives. The Company recorded foreign currency transaction (losses) gains of (\$83), \$30 and (\$171) for the years ended December 31, 2012, 2011 and 2010, respectively, in connection with settlements of its intercompany balance with its subsidiary.

The Company periodically is awarded grants to support research and development activities. The Company recognizes grant income when the funds are earned. The Company recorded grant income of \$409, \$52 and \$595 during 2012, 2011 and 2010, respectively.

The Company has historically issued stock options to non-employee consultants as a form of compensation for services provided to the Company. Because the non-employee options require settlement by the Company's delivery of registered shares and because the tax withholding provisions in the awards allow the options to be partially net-cash settled, these options, when vested, are no longer eligible for equity classification and are, thus, subsequently accounted for as derivative liabilities under FASB ASC 815 until the awards are ultimately either exercised or forfeited. Accordingly, the vested non-employee options are classified as liabilities and remeasured at fair value through earnings at each reporting period. During the years ended December 31, 2012, 2011 and 2010, \$179, \$23 and \$(165), respectively, of income (expense) was recorded as a result of the remeasurement of the fair value of these fully vested stock options.

**Income Taxes** Income taxes are computed using the asset and liability method in accordance with FASB ASC 740 *Income Taxes* (ASC 740), 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 of 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. In evaluating whether to record a valuation allowance, the applicable accounting standards deem that the existence of cumulative losses in recent years is a significant piece of objectively verifiable negative evidence that must be overcome by objectively verifiable positive evidence to avoid the need to record a valuation allowance. The Company has recorded a full valuation allowance against its net deferred tax assets as it is more likely than not that the benefit of the deferred tax assets will not be recognized in future periods.

**Net Loss Per Share** Basic and diluted net loss per share is computed in accordance with FASB ASC 260 *Earnings Per Share* (ASC 260) by dividing the net loss by the weighted average number of common shares

**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)**

outstanding during the period. Since the Company has experienced net losses for all periods presented, net loss per share excludes the effect of 3,676, 2,949 and 3,408 stock options, restricted stock and performance based shares as of December 31, 2012, 2011, and 2010, respectively, because they 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.

**Comprehensive Loss and Accumulated Other Comprehensive Income (Loss)** In addition to net loss, comprehensive loss includes foreign currency exchange rate adjustments and unrealized gains and losses on investments.

Accumulated other comprehensive income (loss) consisted of the following:

	Unrealized Gains (Losses) on Short-Term and Long-Term Investments	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance as of December 31, 2009	\$ 3	\$ 141	\$ 144
Current-period change	(3)	(61)	(64)
Balance as of December 31, 2010	0	80	80
Current-period change	2	(119)	(117)
Balance as of December 31, 2011	2	(39)	(37)
Current-period change	(1)	115	114
Balance as of December 31, 2012	\$ 1	\$ 76	\$ 77

**Research and Development Costs** Research and development costs are expensed as incurred. These costs include compensation and other internal and external costs associated with the development and research related to new products or concepts, preclinical studies, clinical trials and cost of products used in trials and tests.

**Share-Based Employee Compensation** The Company follows FASB ASC 718 Compensation-Stock Compensation (ASC 718), to record share-based compensation for all employee share-based payment awards, including stock options, restricted stock, performance shares and stock purchases related to an employee stock purchase plan, based on estimated fair values. The Company's share-based compensation expense recognized under ASC 718 for the years ended December 31, 2012, 2011 and 2010 was \$3,468, \$2,931 and \$2,753, respectively, on a before and after tax basis.

FASB ASC 718 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. The expense has been reduced for estimated forfeitures. FASB ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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 and the peer group's expected stock price volatility over the term of the awards and actual and projected employee

stock option exercise behaviors. For non-employee options, the fair value at the date of grant

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**Table of Contents**

**ATRICURE, INC. AND SUBSIDIARIES**

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

**(In Thousands, Except Per Share Amounts)**

is subject to adjustment at each vesting date based upon the fair value of the Company's common stock. The fair value of our market-based performance option grants is estimated at the date of grant using a Monte-Carlo simulation. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in our Consolidated Statement of Operations. The expense has been reduced for estimated forfeitures.

The Company estimates the fair value of restricted stock and performance share awards based upon the grant date closing market price of the Company's common stock. The Company's determination of fair value is affected by the Company's stock price as well as assumptions regarding the number of shares expected to be granted and, in the case of performance shares, the likelihood that the performance measures will be achieved.

The Company also has an employee stock purchase plan (ESPP or the Plan) which is available to all eligible employees as defined by the Plan. Under the ESPP, shares of the Company's common stock may be purchased at a discount. The Company estimates the number of shares to be purchased under the Plan and records compensation expense based upon the fair value of the stock at the beginning of the purchase period using the Black-Scholes model.

The Company has historically issued stock options to non-employee consultants as a form of compensation for services provided to the Company. The Company accounts for the options granted to non-employees prior to their vesting date in accordance with ASC 505-50, Equity-Based Payments to Non-Employees. Because these options do not contain specific performance provisions, there is no measurement date of fair value until the options vest. Therefore, the fair value of the options granted and outstanding prior to their vesting date is remeasured each reporting period. During the years ended December 31, 2012, 2011 and 2010, \$0, \$8 and \$19, respectively, of expense was recorded as a result of the remeasurement of these unvested stock options.

Fully vested options to acquire 38 and 34 shares of common stock held by non-employee consultants remained unexercised as of December 31, 2012 and 2011, respectively. A liability of \$78 and \$208 was included in accrued liabilities in the Consolidated Balance Sheets as of December 31, 2012 and 2011, respectively.

**Use of Estimates** The preparation of the financial statements in conformity with GAAP 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 revenue and expense during the reporting period. Actual results could differ from those estimates.

**Fair Value Disclosures** The book value of the Company's financial instruments, including cash and cash equivalents, accounts receivable, short-term investments, short and long-term other assets, accounts payable, accrued expenses, other liabilities and fixed interest rate debt, approximate their fair values. The Company classifies cash as Level 1 within the fair value hierarchy. Accounts receivable, short-term other assets, accounts payable and accrued expenses are also classified as Level 1. The carrying amounts of these assets and liabilities approximate their fair value due to their relatively short-term nature. Other assets and other liabilities are classified as Level 1 within the fair value hierarchy. Cash equivalents and short-term investments are classified as Level 2 within the fair value hierarchy (see Note 3 Fair Value for further information). Fixed interest rate debt fair value is determined by calculating the net present value of future debt payments and is classified as Level 2. Significant unobservable inputs with respect to the fair value measurement of the Level 3 non-employee stock options are developed using Company data. Validations of unobservable inputs are performed to the extent the Company has experience. When an input is changed, the Black-Scholes model is updated and the results are analyzed for reasonableness.



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**Table of Contents**

**ATRICURE, INC. AND SUBSIDIARIES**

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

**(In Thousands, Except Per Share Amounts)**

**2. RECENT ACCOUNTING PRONOUNCEMENTS**

In May 2011 the FASB issued Accounting Standards Update ( ASU ) 2011-04, Fair Value Measurement. The ASU is the result of joint efforts by the FASB and IASB to develop a single, converged fair value framework, that is, converged guidance on how (not when) to measure fair value and on what disclosures to provide about fair value measurements. While the ASU is largely consistent with existing fair value measurement principles in U.S. GAAP, it expands ASC 820's existing disclosure requirements for fair value measurements and makes other amendments. Some of the amendments could change how the fair value measurement guidance in ASC 820 is applied. The ASU is effective for interim and annual reporting periods beginning after December 15, 2011. The Company has evaluated the provisions of ASU 2011-04 and has determined that it does not have a material impact on the Company's fair value disclosures.

In June 2011 the FASB issued new guidance in ASU 2011-05, Presentation of Comprehensive Income, which revises the manner in which entities present comprehensive income in their financial statements. This new guidance requires entities to report components of comprehensive income in either (1) a continuous statement of comprehensive income or (2) two separate but consecutive statements. It is effective for interim and annual reporting periods beginning after December 15, 2011. The Company adopted the single continuous statement presentation approach. In December 2011 the FASB issued ASU 2011-12, Comprehensive Income: Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No.2011-05. The Company has evaluated the provisions of ASU 2011-05 that were deferred and has determined that they do not have a material impact on the Company's financial reporting.

**3. FAIR VALUE**

FASB ASC 820, Fair Value Measurements and Disclosures, ( ASC 820 ) defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date. An active market for the asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis. The valuation under this approach does not entail a significant degree of judgment.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The valuation technique for the Company's Level 2 assets is based on quoted market prices for similar assets from observable pricing sources at the reporting date.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date. The fair value of the Company's Level 3 derivatives are estimated on the grant date using the Black-Scholes model and they are revalued at the end of each reporting period using the Black-Scholes model.



**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)**

In accordance with ASC 820, the following table represents the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2012:

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)	Total
<b>Assets:</b>				
Money market funds	\$	\$ 5,261	\$	\$ 5,261
Commercial paper		3,247		3,247
U.S. government agencies and securities	1,000			1,000
Corporate bonds				
Total assets	\$ 1,000	\$ 8,508	\$	\$ 9,508
<b>Liabilities:</b>				
Derivative instruments	\$	\$	\$ 78	\$ 78
Total liabilities	\$	\$	\$ 78	\$ 78

There were no changes in the levels of financial assets and liabilities during the twelve months ended December 31, 2012.

In accordance with ASC 820, the following table represents the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2011:

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)	Total
<b>Assets:</b>				
Money market funds	\$	\$ 7,417	\$	\$ 7,417
Commercial paper		400		400
U.S. government agencies and securities	2,507			2,507
Corporate bonds		1,517		1,517
Total assets	\$ 2,507	\$ 9,334	\$	\$ 11,841
<b>Liabilities:</b>				
Derivative instruments	\$	\$	\$ 208	\$ 208

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Total liabilities	\$	\$	\$	208	\$	208
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The fair value of the Level 3 liabilities is estimated using the Black-Scholes model including the following assumptions:

	As of December 31, 2012	As of December 31, 2011
Risk-free interest rate	0.23% - 0.74%	0.12% - 0.86%
Expected life of option (years)	1.75 - 5.10	0.97 - 5.11
Expected volatility of stock	70.00%	71.00%
Dividend yield	0.00%	0.00%

The Company has historically issued stock options to non-employee consultants as a form of compensation for services provided to the Company. When these non-employee options fully vest, the awards no longer fall within the scope of ASC 505-50. Because the options require settlement by the Company's delivery of registered shares and because the tax withholding provisions in the awards allow the options to be partially net-cash settled, these vested

**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)**

options are no longer eligible for equity classification and are accounted for as derivative liabilities under FASB ASC 815 ( Derivatives and Hedging ) until the awards are ultimately either exercised or forfeited. Accordingly, the vested non-employee options are classified as liabilities and remeasured at fair value through earnings at each reporting period. In calculating the fair value of the options, they are estimated on the grant date using the Black-Scholes model subject to change in stock price utilizing assumptions of risk-free interest rate, contractual life of option, expected volatility, weighted average volatility and dividend yield. Due to the lack of certain observable market quotes the Company utilizes valuation models that rely on some Level 3 inputs. Specifically, during 2010, the Company's estimate of volatility was weighted 75% and 25% between the Company's implied volatility and the implied volatility of a group of comparable companies, respectively. Beginning January 1, 2011, the Company's estimate of volatility was based solely on the Company's trading history.

The following table represents the company's Level 3 fair value measurements using significant other unobservable inputs for derivative instruments as of December 31:

	2012	2011	2010
Beginning Balance January 1	\$ 208	\$ 268	\$ 180
Total gains/losses (realized/unrealized) included in earnings	(179)	(23)	165
Purchases (exercises)	(50)	(55)	(77)
Reclassification from equity to liability when fully vested	99	18	
Ending Balance December 31	\$ 78	\$ 208	\$ 268
Gains (losses) included in earnings (or changes in net assets attributable to the change in unrealized gains/losses relating to assets held at reporting date)	\$ 179	\$ 23	\$ (165)

**4. INVESTMENTS**

As of December 31, 2012 the Company had no long-term investments. Short-term investments as of December 31, 2012 consisted of the following:

	Cost Basis	Unrealized Gains	Fair Value
U.S. Government agencies and securities	\$ 999	\$ 1	\$ 1,000
Commercial paper	3,247	0	3,247
Total	\$ 4,246	\$ 1	\$ 4,247

Money market funds are included in cash and cash equivalents and not included in investments.

As of December 31, 2011, the Company had no long-term investments. Short-term investments as of December 31, 2011 consisted of the following:

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	<b>Cost Basis</b>	<b>Unrealized Gains (Losses)</b>	<b>Fair Value</b>
U.S. Government agencies and securities	\$ 2,506	\$ 1	\$ 2,507
Commercial paper	400	0	400
Corporate bonds	1,516	1	1,517
<b>Total</b>	<b>\$ 4,422</b>	<b>\$ 2</b>	<b>\$ 4,424</b>

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

**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)****5. INTANGIBLE ASSETS**

Intangible assets with definite lives are amortized over their estimated useful lives. The following table provides a summary of the Company's intangible assets with definite lives:

	<b>Proprietary Manufacturing Technology</b>	<b>Non-Compete Agreement</b>	<b>Trade Name</b>	<b>Total</b>
Net carrying amount as of December 31, 2009	\$ 131	\$ 70	\$ 87	\$ 288
Amortization	(131)	(13)	(55)	(199)
Net carrying amount as of December 31, 2010		57	32	89
Amortization		(12)	(32)	(44)
Net carrying amount as of December 31, 2011		45		45
Amortization		(13)		(13)
Net carrying amount as of December 31, 2012	\$	\$ 32	\$	\$ 32

Amortizable intangible assets are being amortized over eight years for a non-compete arrangement. Trade name usage and proprietary manufacturing technology intangible assets were amortized over four and five year periods, respectively. For the years ended December 31, 2012, 2011 and 2010, amortization expense related to intangible assets with definite lives was \$13, \$44 and \$199, respectively.

Future amortization expense related to intangible assets with definite lives is projected as follows:

<b>Year</b>	<b>Amortization</b>
2013	\$ 13
2014	12
2015	7
Total	\$ 32

In December 2011 the Company entered into a patent purchase agreement with Nu Energy Solutions LLC in which it received proceeds of \$300 in connection with the sale of certain intellectual property. Pursuant to the agreement, the Company agreed to sell its Bipolar Tissue Grasping Apparatus and Tissue Welding Method patent. The Company recorded the gain on sale of \$300 in research and development expenses in the Consolidated Statements of Operations.

**6. INVENTORIES**

Inventories consisted of the following at December 31:

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	2012	2011
Raw materials	\$ 3,066	\$ 3,233
Work in process	675	509
Finished goods	1,977	2,821
Inventories	\$ 5,718	\$ 6,563



**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)****7. PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following at December 31:

	<b>2012</b>	<b>2011</b>
Machinery, equipment and vehicles	\$ 7,489	\$ 6,424
Computer and other office equipment	1,538	1,236
Furniture and fixtures	212	347
Leasehold improvements	165	150
Equipment under capital leases	226	267
Construction in progress	68	207
<b>Total</b>	<b>9,698</b>	<b>8,631</b>
Less accumulated depreciation	(6,268)	(6,280)
<b>Property and equipment, net</b>	<b>\$ 3,430</b>	<b>\$ 2,351</b>

Property and equipment depreciation expense was \$1,886, \$1,878 and \$2,164 for the years ended December 31, 2012, 2011 and 2010, respectively.

**8. ACCRUED LIABILITIES**

Accrued liabilities consisted of the following at December 31:

	<b>2012</b>	<b>2011</b>
Accrued commissions	\$ 1,464	\$ 1,297
Accrued settlement reserve (current portion)	1,120	704
Accrued bonus	487	162
Other accrued liabilities	483	417
Accrued taxes and value-added taxes payable	366	449
Accrued vacation	349	353
Accrued severance	224	16
Accrued payroll	153	167
Withheld FICA	126	105
Accrued royalty	118	78
Sales/returns allowance trade	105	40
Accrued non-employee stock options	78	208
<b>Total</b>	<b>\$ 5,073</b>	<b>\$ 3,996</b>

**9. INDEBTEDNESS**

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

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	2012	2011
Credit facility	\$ 8,333	\$ 6,375
Capital leases	103	94
Total debt and capital leases	8,436	6,469
Less: Current maturities	(2,029)	(1,543)
Total long-term debt and capital leases	\$ 6,407	\$ 4,926

**Table of Contents**

**ATRICURE, INC. AND SUBSIDIARIES**

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

**(In Thousands, Except Per Share Amounts)**

The Company has had a debt agreement with Silicon Valley Bank ( SVB ) which includes a term loan and revolving credit facility since May 1, 2009. SVB received a warrant to purchase shares of the Company's common stock in connection with the term loan in the original agreement. The agreement was modified in November 2009 and March 2010 to amend, among other things, the financial covenants in the agreement and waive a compliance violation which occurred during February 2010. The agreement was amended again in September 2010 in an Amended and Restated Loan and Security Agreement with SVB and an Export-Import Bank Loan and Security Agreement (collectively, Amended Agreement ) which increased the credit facility to approximately \$14,000 and increased the Company's borrowing capacity under the revolving loan facility. The Amended Agreement was to mature on April 30, 2012 and was secured by all of the Company's assets, including intellectual property.

On March 15, 2011 the Company and SVB entered into a First Loan Modification Agreement (the First Loan Modification Agreement ) and an Export-Import Bank First Loan Modification Agreement (the First Ex-Im Agreement and, collectively with the First Loan Modification Agreement, the First Modification Agreements ) which set forth certain amendments to the Company's credit facility with SVB. The First Loan Modification Agreement provided for a new \$7,500 term loan. The proceeds from the term loan were used to repay the amount outstanding under the existing SVB term loan of \$2,500. The balance was invested in short-term investments. The new term loan has a five-year term, and principal payments in the amount of \$125, together with accrued interest, are due and payable monthly. The modified term loan accrues interest at a fixed rate of 6.75%.

The First Modification Agreements also provided for a two-year extension of the maturity date of the existing revolving credit facility from April 30, 2012 to April 30, 2014. The applicable borrowing rate was reduced to 0.25% to 1.25% above the prime rate. The maximum borrowing amount under the revolving facility remained at \$10,000.

On February 2, 2012 the Company and SVB entered into a Second Loan Modification Agreement (the Second Loan Modification Agreement ) and an Export-Import Bank Second Loan Modification Agreement (the Second Ex-Im Agreement and, collectively with the Second Loan Modification Agreement, the Second Modification Agreements ) which set forth certain amendments to the Company's credit facility with SVB. The Second Modification Agreements provided for a new \$10,000 term loan in addition to the \$10,000 revolving loan. The proceeds from the term loan were used to repay the amount outstanding under the existing SVB term loan of \$6,125. The balance was invested in cash and cash equivalents and short-term investments. The new term loan has a five year term, and principal payments in the amount of \$167, together with accrued interest, are due and payable monthly. The modified term loan accrues interest at a fixed rate of 6.75%.

The Second Modification Agreements also provided for a change to a Liquidity Ratio covenant to replace the existing Adjusted Quick Ratio covenant. The applicable borrowing rate on the revolving facility is 0.25% to 1.25% above the prime rate, as determined by the Liquidity Ratio.

The Amended Agreement, as modified, contains covenants that include, among others, covenants that limit the Company's and its subsidiaries ability to dispose of assets, enter into mergers or acquisitions, incur indebtedness, incur liens, pay dividends or make distributions on the Company's capital stock, make investments or loans, and enter into certain affiliate transactions, in each case subject to customary exceptions for a credit facility of this size and type. As a result, the Company has not declared or paid any dividends on its capital stock and expects to retain future earnings, if any, for use in the operation and expansion of the business and does not anticipate paying any cash dividends in the foreseeable future. Additional covenants apply when the Company

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**Table of Contents**

**ATRICURE, INC. AND SUBSIDIARIES**

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

**(In Thousands, Except Per Share Amounts)**

has outstanding borrowings under the revolving loan facility or when the Company achieves specific covenant milestones. Financial covenants under the credit facility, as amended, include a minimum EBITDA, a limitation on capital expenditures and a minimum adjusted quick ratio and affect the Company's borrowing availability under the revolving credit facility. Further, a minimum fixed charge ratio applies when the Company achieves specific covenant milestones. The occurrence of an event of default could result in an increase to the applicable interest rate by 3.0%, an acceleration of all obligations under the Amended Agreement, an obligation of the Company to repay all obligations in full and a right by SVB to exercise all remedies available to it under the Amended Agreement and related agreements including the Guaranty and Security Agreement. As of and for the period ended December 31, 2012, the Company was in compliance with all of the financial covenants of the amended and modified credit facility. In addition, if the guarantee by the Export-Import Bank of the United States ceases to be in full force and effect, the Company must repay all loans under the Export-Import agreement.

In May 2012 the Company and SVB entered into a Third Loan Modification Agreement (the Third Loan Modification Agreement) which sets forth certain amendments to the Company's credit facility with the Bank. The Third Loan Modification Agreement increases the Company's subsidiary investment limit from \$10,000 to \$12,000 from the effective date through September 30, 2012 and reduces the subsidiary investment limit back to \$10,000 thereafter.

Effective September 26, 2012 the Company and SVB entered into a Fourth Loan Modification Agreement (the Fourth Loan Modification Agreement) which sets forth certain amendments to the Company's credit facility with the Bank. The Fourth Loan Modification Agreement eliminates the restriction on investments by the Company in its wholly owned subsidiary, AtriCure Europe, B.V. (AtriCure Europe). In connection with the Fourth Loan Modification Agreement, AtriCure Europe executed certain guaranty and security documents pursuant to which AtriCure Europe guaranteed the Company's obligations under the credit facility and pledged certain of its assets as security for the credit facility.

Effective January 30, 2013 the Company and SVB entered into a Joinder and Fifth Loan Modification Agreement (the Fifth Loan Modification Agreement) and an Export-Import Bank Joinder and Third Loan Modification Agreement (the Third Ex-Im Agreement) and, collectively with the Fifth Loan Modification Agreement, the Modification Agreements) which set forth certain amendments to the Company's credit facility with the Bank. The Modification Agreements add the Company's wholly-owned subsidiary, AtriCure, LLC, as a borrower, and the Fifth Loan Modification Agreement modifies the Company's timing for submitting a forecast to the Bank and decreases the EBITDA amount the Company must achieve to meet the minimum EBITDA covenant.

As of December 31, 2012 the Company had no borrowings under the revolving credit facility and borrowing availability of \$5,303. Also as of December 31, 2012, the Company had \$8,333 outstanding under its term loan, which includes \$2,000 classified as current maturities of long-term debt. As of December 31, 2011, the Company had no borrowings under its revolving credit facility and borrowing availability of \$8,870. Also as of December 31, 2011, the Company had \$6,375 outstanding under its term loan, which included \$1,500 classified as current maturities of long-term debt.

The Warrant that was issued with the initial SVB agreement had been recorded as a discount on long-term debt at its fair value and was being amortized over the term of the loan. Accelerated amortization expense of \$79 was recorded in March 2011 due to the credit facility modification. For the years ended December 31, 2012 and 2011, amortization expense related to the debt discount totaled \$0 and \$22, respectively. In addition to the accelerated amortization of the Warrant, the Company also recorded \$74 of expense related to deferred financing costs and other fees as a result of the credit facility modification in March 2011.

**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)**

As of December 31, 2012 the effective interest rate on borrowings under the modified term loan, including debt issuance costs, was 7.6%, and the book value of the Company's fixed interest rate debt approximated fair value. In June 2011 the Company cancelled an outstanding letter of credit for \$250 issued to its corporate credit card program provider which was to expire on July 31, 2011. No letters of credit were outstanding as of December 31, 2012 and 2011.

As of December 31, 2012 the Company had capital leases for computer equipment that expire at various terms through 2016. The cost of the assets under lease was \$226. The assets are depreciated over their estimated useful lives, which equal the terms of the leases. Accumulated amortization on the capital leases was \$125 at December 31, 2012.

Maturities on long-term debt, including capital lease obligations are as follows:

<b>Year</b>	<b>Amount</b>
2014	\$ 2,032
2015	2,026
2016	2,016
2017	333
<b>Total</b>	<b>\$ 6,407</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 2014. Future minimum lease payments under non-cancelable operating leases are as follows:

<b>Year</b>	<b>Amount</b>
2013	\$ 583
2014	17
<b>Total</b>	<b>\$ 600</b>

Rent expense was approximately \$769, \$685 and \$668 in 2012, 2011, and 2010, respectively.

**Royalty Agreements.** The Company has certain royalty agreements in place with terms that include the payment of royalties based on product revenue from sales of current products. One royalty agreement, which was effective January 1, 2010, has a rate of 1.5% of product sales and includes minimum quarterly payments of \$50 through 2015 and a maximum of \$2,000 in total royalties over the term of the agreement. Another royalty agreement, which was effective in 2003 and has a term of at least twenty years, has royalty rates of 5% of product sales. Parties to the royalty agreements have the right at any time to terminate the agreement immediately for cause. Royalty expense of \$603, \$505 and \$332 was recorded as part of cost of revenue for the years ended December 31, 2012, 2011 and 2010, respectively.

**Purchase Agreement.** On June 15, 2007 the Company entered into a purchase agreement with MicroPace Pty Ltd Inc., ( MicroPace ). The agreement, as amended, provides for MicroPace to produce a derivative of one of their products tailored for the cardiac surgical environment, known as the MicroPace ORLab for worldwide distribution by the Company. Pursuant to the terms of the amended agreement, in order for the

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Company to retain exclusive distribution rights, the Company was required to purchase a minimum of 40 units during the period December 1, 2010 through December 31, 2011 to extend exclusivity through 2012 and an

**Table of Contents**

**ATRICURE, INC. AND SUBSIDIARIES**

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

**(In Thousands, Except Per Share Amounts)**

additional 40 units during 2012 to extend exclusivity through December 31, 2013. Units purchased in excess of yearly minimums reduce future minimum purchase requirements. A total of 56 units were purchased by the Company between December 1, 2010 and December 31, 2011, thereby extending exclusive distribution rights through December 31, 2012. A total of 60 units were purchased by the Company during 2012, fulfilling the purchase requirement to extend exclusive distribution rights through 2013.

In April 2012 the Company entered into a development and manufacturing services agreement with Stellartech Research Corporation (Stellartech). Under the terms of the agreement, Stellartech will provide development services for the next generation of the Company's radio frequency generators and will manufacture at least the first 300 units of the product. The agreement also establishes Stellartech as the exclusive supplier of the generators during the initial three years after product completion. There is no minimum purchase requirement beyond the initial 300 units.

**Distributor Termination.** In July 2010 the Company terminated a distributor agreement with a European distributor. Under the terms of the agreement the Company paid the distributor a termination fee, repurchased saleable disposable product inventory and assigned the distributor's capital equipment to AtriCure Europe BV. Additionally, the Company entered into a consulting agreement with the distributor to provide ongoing consulting services through September 30, 2012. In exchange for these services, beginning October 1, 2010, the distributor earned \$50 (approximately \$65) per quarter for a total of \$400 (approximately \$528).

**Chief Financial Officer and Chief Executive Officer Resignations.** The Company's Vice President, Finance and Administration and Chief Financial Officer (CFO) resigned effective April 30, 2012. In connection with the resignation, the CFO and AtriCure entered into an agreement pursuant to which the CFO is entitled to receive: (i) all accrued and unpaid base salary through the effective date of the resignation; (ii) payment for any accrued and unused vacation; (iii) continued vesting of all stock options and restricted stock until April 30, 2013; and (iv) twelve (12) months base salary (\$250).

On August 2, 2012, the Company's Chief Executive Officer and President (CEO) notified the Company that he was resigning from his positions with the Company. Pursuant to his Employment Agreement, the CEO continued to serve as Chief Executive Officer and President of the Company through September 30, 2012. The CEO's term as a member of the Company's Board of Directors ended effective August 2, 2012. In connection with the resignation, the CEO and AtriCure entered into an agreement pursuant to which he is entitled to receive: (i) all accrued and unpaid base salary through the effective date of the resignation; (ii) payment for any accrued and unused vacation; (iii) continued vesting of all stock options and restricted stock until March 31, 2013; and (iv) six (6) months base salary (\$225).

The Company recorded a total of approximately \$1.6 million in expense related to the departure of the Company's Chief Financial Officer and Chief Executive Officer.

**Legal.** The Company is not party to any material pending or threatened litigation, except as described below:

**Class Action Lawsuits**

AtriCure, Inc. and certain of its current and former officers were named as defendants in a purported securities class action lawsuit in 2007. The suit alleged violations of the federal securities laws and sought 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. Although the Company admitted no wrongdoing, it

**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)**

recorded a liability of \$2,000 in December 2009 which represented an estimate of the potential defense and/or settlement costs. In addition, the Company recorded a related receivable of \$2,000 from its insurance carrier for the potential defense and/or settlement costs, as recovery was expected beyond a reasonable doubt. In October 2010 the parties signed a Definitive Stipulation of Settlement agreement for \$2,000, which was subject to notice to the class as well as approval by the court, which occurred in May 2011. The Company's insurance carrier paid the claim in full in June 2011.

In December 2008 AtriCure, Inc. and certain of its current executive officers were named in a putative class action lawsuit. The plaintiffs alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder and sought unspecified damages against AtriCure, Inc. and certain of its current executive officers. The plaintiffs alleged, among other things, that the defendants issued materially false and misleading statements that failed to disclose that the Company improperly promoted certain products to physicians and caused the filing of false claims for reimbursement. In March 2010 the court granted in part and denied in part the Company's motion to dismiss and, in particular, dismissed the claim that the Company caused the filing of false claims for reimbursement. In October 2010 the court ordered final approval of the settlement for \$2,750, which was funded by the Company's insurance carrier.

**Department of Justice Investigation**

In October 2008 the Company received a letter from the Department of Justice ( DOJ ) informing the Company that it was conducting an investigation for potential False Claims Act ( FCA ) and common law violations relating to its surgical ablation devices. Specifically, the letter stated that the DOJ was investigating the Company's marketing practices utilized in connection with its surgical ablation system to treat AF, a specific use outside the FDA's 510(k) clearance. The letter also stated that the DOJ was investigating whether the Company instructed hospitals to bill Medicare for cardiac surgical ablation using incorrect billing codes. The Company cooperated with the investigation and operated its business in the ordinary course during the investigation. In December 2009 the Company reached a tentative settlement with the DOJ to resolve the investigation and recorded a liability and charged operating expenses for a total of \$3,956, which represented the net present value of the proposed settlement amount to be paid to the DOJ, the Relator, and Relator's counsel (total payments based on the settlement inclusive of interest were estimated to be \$4,350, payable over five years).

The settlement was finalized pursuant to the preliminary terms in February 2010, and the Company entered into a settlement agreement with the DOJ, the Office of the Inspector General ( OIG ), and the Relator in the *qui tam* complaint discussed below. The settlement agreement definitively resolved all claims related to the DOJ investigation. The Company did not admit nor will it admit to any wrongdoing in connection with the settlement. As of December 31, 2012 the Company had made \$2,050 in payments (including interest), and had a liability related to this settlement totaling \$2,229, of which \$1,120 was classified as current.

As part of the resolution, the Company also entered into a five year Corporate Integrity Agreement with the OIG. This agreement acknowledges the existence of the Company's corporate compliance program and provides for certain other compliance-related activities during the five year term of the agreement. Those activities include specific written standards, monitoring, training, education, independent review, disclosure and reporting requirements.

***Qui Tam* Complaint**

In July 2009 a copy of a *qui tam* complaint against the Company was unsealed. The *qui tam* complaint, filed in the U.S. District Court for the Southern District of Texas, was originally filed by the Relator in August 2007. The complaint, which was related to the DOJ investigation, alleged a cause of action under the FCA relating to



**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)**

the Company's alleged marketing practices in connection with its surgical cardiac ablation devices. In August 2009 the DOJ declined to intervene in the *qui tam* complaint. The *qui tam* complaint was settled in February 2010 in accordance with the DOJ settlement agreement above.

The Company may from time to time become a party to additional legal proceedings.

**11. INCOME TAXES**

The Company files federal, state, and foreign income tax returns in jurisdictions with varying statutes of limitations. Income taxes are computed using the asset and liability method in accordance with FASB ASC 740 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. The Company has recorded a full valuation allowance against its net deferred tax assets as it is more likely than not that the benefit of the deferred tax assets will not be recognized in future periods. Tax credits are accounted for as a reduction of income taxes in the year in which the credit originates. The Company does not expect any significant unrecognized tax benefits to arise over the next twelve months and is fully reserved.

The detail of deferred tax assets and liabilities at December 31 is as follows:

	2012	2011
Deferred tax assets (liabilities):		
Net operating loss carryforward	\$ 22,974	\$ 20,819
Research and development credit carryforward	3,603	3,597
Equity compensation	4,082	3,473
Intangible assets	757	832
Accruals and reserves	269	295
Inventory	228	271
Fixed assets	(230)	28
Other, net	2	1
Subtotal	31,685	29,316
Less valuation allowance	(31,685)	(29,316)
Total	\$	\$

The Company's provision for income taxes is as follows:

	2012	2011	2010
Current income tax expense	\$ 50	\$ 31	\$ 19
Deferred tax benefit	(2,336)	(2,005)	(1,118)
Increase in valuation allowance	2,336	2,005	1,118
Total income tax expense	\$ 50	\$ 31	\$ 19

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The Company has a federal net operating loss carryforward of \$63,807 which will begin to expire in 2021 and state net operating loss carryforwards of \$26,875 which have varying expirations ranging from 5 years to 20 years. The Company also has a foreign net operating loss carryforward of approximately \$8,613 which will begin to expire in 2016. Additionally, the Company has a federal research and development credit carryforward of \$3,603 which will begin to expire in 2022.

**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)**

The Company's 2012, 2011 and 2010 effective income tax rates differ from the federal statutory rate as follows:

	2012		2011		2010	
Federal tax at statutory rate	34.00%	\$ (2,483)	34.00%	\$ (1,844)	34.00%	\$ (1,290)
Federal R&D credit	0.08	(6)	6.11	(332)	9.03	(343)
Valuation allowance	(31.98)	2,336	(37.09)	2,012	(29.45)	1,118
State income taxes	0.67	(49)	2.90	(157)	(3.12)	118
Foreign NOL rate change	1.40	(102)			(3.29)	125
Foreign tax rate differential	(1.94)	142	(1.49)	81	(3.63)	138
Other	(2.91)	212	(5.00)	271	(4.04)	153
Effective tax rate	(0.68)%	\$ 50	(0.57)%	\$ 31	(0.50)%	\$ 19

The Company's pre-tax book loss for AtriCure, Inc. and its subsidiary, AtriCure Europe B.V., was (\$5,909) and (\$1,575), respectively, for 2012, (\$4,530) and (\$895), respectively, for 2011 and (\$2,240) and (\$1,533), respectively, for 2010.

The Company currently has not had to accrue interest and penalties related to unrecognized tax benefits. However, when or if the situation occurs, the Company will recognize interest and penalties within the income tax expense (benefit) line in the accompanying Consolidated Statements of Operations and Comprehensive Loss and within the related tax liability line in the Consolidated Balance Sheets.

**12. CONCENTRATIONS**

During fiscal 2012, 2011 and 2010 approximately 19.6%, 20.9% and 19.4%, respectively, of the Company's total net revenue was derived from its top ten customers. During 2012, 2011, and 2010 no customer accounted for more than 10% of the Company's revenue.

The Company maintains cash and cash equivalents balances which at times exceed FDIC limits. As of December 31, 2012 \$10,835 of the cash and cash equivalents balance was in excess of the FDIC limits.

**13. EMPLOYEE BENEFIT PLANS**

The Company sponsors the AtriCure, Inc. 401(k) Plan, a defined contribution plan covering substantially all employees of the Company (the Plan). The Plan was amended effective September 1, 2011 to reflect modifications to the Plan due to a change in Plan Administrator. Eligible employees may contribute up to \$17 of their pre-tax annual compensation (up to \$22 for participants over age 50). During 2012 and 2011, the Company made matching contributions of 25% of the first 6% of employee contributions to the Plan. Employer contributions to the Plan were suspended during 2010. The Company's matching contributions expensed during 2012 and 2011 were \$234 and \$221, respectively. Additional amounts may be contributed to the Plan at the discretion of the Company's board of directors. No such discretionary contributions were made during 2012, 2011 or 2010.

**14. EQUITY COMPENSATION PLANS**

The Company has several share-based incentive plans: the 2001 Stock Option Plan (the 2001 Plan), the 2005 Equity Incentive Plan (the 2005 Plan) and the 2008 Employee Stock Purchase Plan (the ESPP).



**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)****2001 Plan and 2005 Plan**

The 2001 Plan is no longer used for granting incentives. 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, 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 (currently the Compensation Committee of the Board of Directors) 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.

Options granted under the 2001 Plan and the 2005 Plan generally expire ten years from the date of grant. 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 of the grant and ratably each month thereafter. Restricted stock awards granted under the 2005 Plan vest 25% annually over four years from date of grant.

As of December 31, 2012 6,344 shares of common stock had been reserved for issuance under the 2005 Plan. The shares authorized 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 the 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 shares; or

an amount the Company's Board of Directors may determine.

On January 1, 2012 an additional 532 shares were authorized for issuance under the 2005 Plan, representing 3.25% of the outstanding shares on that date. As of December 31, 2012 there were 432 shares available for future grants under the plans.

Activity under the plans during 2012 was as follows:

	Number of Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
<b>Stock Options</b>				
Outstanding at January 1, 2012	2,536	\$ 9.00		
Granted	972	7.15		
Cancelled or forfeited	(109)	10.62		
Exercised	(227)	2.90		
Outstanding at December 31, 2012	3,172	\$ 8.81	5.19	\$ 1,479

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Vested and expected to vest	3,071	\$ 8.86	5.06	\$ 1,433
Exercisable at December 31, 2012	1,966	\$ 9.58	3.20	\$ 971

**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)**

	<b>Number of Shares Outstanding</b>	<b>Weighted Average Grant Date Fair Value</b>
<b>Restricted Stock</b>		
Outstanding at January 1, 2012	403	\$ 7.68
Awarded	293	7.69
Forfeited	(49)	8.36
Released	(143)	6.61
Outstanding at December 31, 2012	504	\$ 7.93

Activity under the plans during 2011 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>
<b>Stock Options</b>				
Outstanding at January 1, 2011	2,787	\$ 7.82		
Granted	264	12.26		
Cancelled or forfeited	(78)	8.06		
Exercised	(437)	3.63		
Outstanding at December 31, 2011	2,536	\$ 9.00	5.72	\$ 6,667
Vested and expected to vest	2,514	\$ 8.98	5.69	\$ 6,635
Exercisable at December 31, 2011	1,970	\$ 9.07	4.94	\$ 5,002

	<b>Number of Shares Outstanding</b>	<b>Weighted Average Grant Date Fair Value</b>
<b>Restricted Stock</b>		
Outstanding at January 1, 2011	372	\$ 4.39
Awarded	189	11.61
Forfeited	(38)	5.75
Released	(120)	4.27
Outstanding at December 31, 2011	403	\$ 7.68

The total intrinsic value of options exercised during the years ended December 31, 2012, 2011 and 2010 was \$1,338, \$3,403 and \$312, respectively. As a result of the Company's tax position, no tax benefit was recognized related to the stock option exercises. For 2012, 2011 and 2010, \$659, \$1,588 and \$353, respectively, in cash proceeds were included in the Company's Consolidated Statements of Cash Flows as a result of the exercise of stock options. The total fair value of performance shares vested during 2012, 2011 and 2010 was \$99, \$1,243 and \$0, respectively. The total fair value of restricted stock vested during 2012, 2011 and 2010 was \$1,292, \$1,457 and \$981, respectively.

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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 and restricted stock grants.



**Table of Contents**

**ATRICURE, INC. AND SUBSIDIARIES**

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

**(In Thousands, Except Per Share Amounts)**

The Company recognized expense related to stock options and restricted stock for 2012, 2011, and 2010 of \$3,211, \$2,617 and \$2,178, respectively. As of December 31, 2012 there was \$9,118 of unrecognized compensation costs related to non-vested stock option and restricted stock arrangements (\$5,571 relating to stock options and \$3,547 relating to restricted stock). This cost is expected to be recognized over a weighted-average period of 3.2 years for stock options and 2.7 years for restricted stock.

The Company awarded 225 performance options to its new President and CEO when he joined the Company in November 2012. The options expire ten years from the date of grant and vest in increments of 25 shares when the volume adjusted weighted average closing price of the common stock of the Company as reported by NASDAQ (or any other exchange on which the common stock of the Company is listed) for 30 consecutive days equals or exceeds each of \$10.00 per share, \$12.50 per share, \$15.00 per share, \$17.50 per share, \$20.00 per share, \$25.00 per share, \$30.00 per share, \$35.00 per share and \$40.00 per share. In accordance with FASB ASC 718, a Monte Carlo simulation was performed to estimate the fair values, vesting terms and vesting probabilities for each tranche of options. Expense calculated using these estimates is being recorded over the estimated vesting terms. The Company recognized expense of \$36 related to the performance options in 2012. As of December 31, 2012 there was \$787 of unrecognized compensation costs related to non-vested performance options. This cost is expected to be recognized over a weighted-average period of 2.45 to 5.22 years. None of the market conditions were met as of December 31, 2012; therefore, none of the performance options were exercisable.

In conjunction with the departure of the Company's Chief Financial Officer on April 30, 2012, the Company extended the vesting terms of the share-based compensation of this former employee. This extension resulted in a modification per FASB ASC 718. As such, the Company recorded \$396 in incremental compensation expense during the second quarter of 2012.

In conjunction with the departure of the Company's Chief Executive Officer on September 30, 2012, the Company extended the vesting terms of the share-based compensation of this former employee. This extension resulted in a modification per FASB ASC 718. As such, the Company recorded \$522 in incremental compensation expense during the third quarter of 2012.

The Company has issued performance shares to certain employees and consultants to incent and reward them for the achievement of specified performance over various service periods. The participants receive awards for a specified number of shares of the Company's common stock at the beginning of the award period, which entitles the participants to the shares at the end of the award period if achievement of the specified metrics and service requirements occurs. The Company released 10 and 111 performance shares (gross) during 2012 and 2011, respectively, related to the participants' achievement of certain specified metrics. In accordance with FASB ASC 718, the Company estimates the number of shares to be issued based upon the probability that the performance metric and service period will be achieved. The fair value of the estimated award, based on the market value of the Company's stock on the date of award, is expensed over the award period. The probability of meeting the specified metrics is reviewed quarterly. During 2012, 2011 and 2010 the Company recognized expense related to the performance shares of \$0, \$40 and \$380 respectively. As of December 31, 2012, there was no unrecognized compensation cost related to non-vested share-based compensation arrangements associated with performance shares.

***Employee Stock Purchase Plan (ESPP)***

During the second quarter of 2008 the Company established its 2008 Employee Stock Purchase Plan ( ESPP ) which is available to eligible employees as defined in the ESPP. Under the ESPP, shares of the Company's common stock may be purchased at a discount (currently 15%) of the lesser of the closing price of

**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)**

the Company's common stock on the first trading day or the last trading day of the offering period. The offering period (currently six months) and the offering price are subject to change. Participants may not purchase more than \$25 of the Company's common stock in a calendar year and, effective January 1, 2009, may not purchase more than 1.5 shares during an offering period. Beginning on January 1, 2009 and on the first day of each fiscal year thereafter during the term of the ESPP, the number of shares available for sale under the ESPP shall be increased by the lesser of (i) two percent (2%) of the Company's outstanding shares of common stock as of the close of business on the last business day of the prior calendar year, not to exceed 600 shares, or (ii) a lesser amount determined by the Board of Directors. At December 31, 2012, there were 774 shares available for future issuance under the ESPP. Share-based compensation expense with respect to the ESPP was \$257, \$273 and \$194 for 2012 and 2011, and 2010, respectively.

**Valuation and Expense Information Under FASB ASC 718**

The following table summarizes share-based compensation expense related to employee share-based compensation under FASB ASC 718 for 2012, 2011 and 2010. This expense was allocated as follows:

	2012	2011	2010
Cost of revenue	\$ 272	\$ 161	\$ 146
Research and development expenses	267	474	537
Selling, general and administrative expenses	2,929	2,296	2,070
Total	\$ 3,468	\$ 2,931	\$ 2,753

In calculating compensation expense, the fair value of the options is estimated on the grant date using the Black-Scholes model including the following assumptions:

	2012	2011	2010
Risk-free interest rate	0.65 - 1.37%	1.59 - 2.78%	1.79 - 2.88%
Expected life of option (years)	5.38 to 7.14	6.00 to 6.25	6.00 to 6.25
Expected volatility of stock	69.00 - 71.00%	71.00 - 72.00%	66.00 - 71.00%
Weighted-average volatility	69.50%	71.58%	69.30%
Dividend yield	0.00%	0.00%	0.00%

For grants made before December 31, 2010 the Company's estimate of volatility was weighted between the Company's trading history and other companies in the industry. Beginning January 1, 2011 the Company's estimate of volatility is based solely on the Company's trading history. 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. The simplified method was utilized in determining the expected life of options prior to January 1, 2012. Since January 1, 2012 the Company has estimated the expected terms of options using historical employee exercise behavior adjusted for abnormal activity.

The fair value of restricted stock awards is based on the market value of the Company's stock on the date of the awards.

Based on the assumptions noted above, the weighted average estimated grant date fair value per share of the stock options and restricted stock granted for 2012, 2011 and 2010 was as follows:

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	<b>2012</b>	<b>2011</b>	<b>2010</b>
Stock options	\$ 4.65	\$ 8.01	\$ 3.59
Restricted stock	7.69	11.61	5.69

**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)**

In calculating compensation expense for performance options, the fair value of the options is estimated on the grant date using a Monte Carlo simulation including the following assumptions:

Strike price	\$ 5.91
Contractual term	10.00
Expected volatility of stock	69.60%
Expected rate of return	1.75%
Dividend yield	0.00%

The estimated contractual term is estimated considering that the performance options were issued to a high ranking executive of the Company and that they will be held until expiration. Expected volatility is estimated based on the Company's trading history. The expected rate of return assumption is based upon the U.S. treasury yield curve at the time of grant for the expected option life.

Based on the assumptions noted above, the estimated grant date fair value per share of the performance options granted in 2012 was as follows:

	<b>Price Target</b>	<b>Fair Value</b>
Tranche 1	\$ 10.00	\$ 4.32
Tranche 2	12.50	4.30
Tranche 3	15.00	4.27
Tranche 4	17.50	4.23
Tranche 5	20.00	4.19
Tranche 6	25.00	4.10
Tranche 7	30.00	4.01
Tranche 8	35.00	3.92
Tranche 9	40.00	3.83

***Non-Employee Stock Compensation***

The Company has issued nonstatutory common stock options to consultants to purchase shares of common stock as a form of compensation for services provided to the Company. Such options vest over a service period ranging from immediately to four years. After January 1, 2006 all stock options to non-employee consultants have a four year vesting period and vest at a rate of 25% on the first anniversary date of the grant and ratably each month thereafter.

The Company accounts for the options granted to non-employees prior to their vesting date in accordance with ASC 505-50, *Equity-Based Payments to Non-Employees*. Because these options do not contain specific performance provisions, there is no measurement date of fair value until the options vest. Therefore, the fair value of the options granted and outstanding prior to their vesting date is remeasured each reporting period. The fair value was determined using the Black-Scholes model. There were no non-employee stock options granted during 2012 and 2011. The values attributable to the non-vested portion of the non-employee stock options have been amortized over the service period on a graded vesting method and the vested portion of these stock options was remeasured at each vesting date. Stock compensation expense with respect to unvested non-employee stock options totaled \$0, \$8 and \$19 for 2012, 2011 and 2010, respectively.

Once these non-employee stock option grants have fully vested, the awards no longer fall within the scope of ASC 505-50. Because the stock options require settlement by the Company's delivery of registered shares and because the tax withholding provisions in the awards allow the stock options to be partially net-cash settled, these vested stock options are no longer eligible for equity classification and are, thus, accounted for as derivative



**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)**

liabilities under FASB ASC 815 until the stock options are ultimately either exercised or forfeited. Accordingly, the vested non-employee stock options are classified as liabilities and remeasured at fair value through earnings at each reporting period. During 2012, 2011 and 2010, \$179, \$23 and (\$165), respectively, of income (expense) was recorded as a result of the remeasurement of the fair value of these stock options. As of December 31, 2012 and 2011, respectively, fully vested stock options to acquire 38 and 34 shares of common stock held by non-employee consultants remained unexercised and a liability of \$78 and \$208 was included in accrued liabilities in the Consolidated Balance Sheets as of December 31, 2012 and 2011, respectively.

**15. SEGMENT AND GEOGRAPHIC INFORMATION**

The Company considers reporting segments in accordance with FASB ASC 280, Segment Reporting. The Company develops, manufactures, and sells devices designed primarily for the surgical ablation of cardiac tissue for the treatment of atrial fibrillation and systems designed for the exclusion of the left atrial appendage. These devices are developed and marketed to a broad base of medical centers in the United States and internationally. Management considers all such sales to be part of a single reportable segment.

Geographic revenue was as follows:

<b>Revenue:</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>
United States	\$ 52,616	\$ 48,931	\$ 47,518
International	17,631	15,471	11,488
<b>Total</b>	<b>\$ 70,247</b>	<b>\$ 64,402</b>	<b>\$ 59,006</b>

Revenue by product type was as follows:

<b>Revenue:</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>
Open-heart	\$ 32,880	\$ 29,202	\$ 29,024
Minimally Invasive	12,733	14,166	16,110
AtriClip	7,003	5,563	2,384
Total United States	52,616	48,931	47,518
International	17,631	15,471	11,488
<b>Total</b>	<b>\$ 70,247</b>	<b>\$ 64,402</b>	<b>\$ 59,006</b>

The majority of the Company's long-lived assets are located in the United States.

**Table of Contents****ATRICURE, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(In Thousands, Except Per Share Amounts)****16. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)****(Dollars in thousands, except per share data)**

	March 31,		For the Three Months Ended				December 31,	
	2012	2011	June 30, 2012	2011	September 30, 2012	2011	2012	2011
Operating Results:								
Revenue	\$ 17,476	\$ 15,637	\$ 18,268	\$ 16,780	\$ 16,139	\$ 15,222	\$ 18,364	\$ 16,763
Gross profit	12,752	11,893	12,711	12,278	11,549	11,085	13,002	11,740
Loss from operations	(1,496)	(1,074)	(1,320)	(771)	(2,529)	(1,191)	(1,852)	(1,695)
Net loss	(1,620)	(1,273)	(1,326)	(946)	(2,567)	(1,156)	(2,020)	(2,080)
Net loss per share (basic and diluted)	\$ (0.10)	\$ (0.08)	\$ (0.08)	\$ (0.06)	\$ (0.16)	\$ (0.07)	\$ (0.12)	\$ (0.13)

Amounts may not sum to consolidated totals for the full year due to rounding. Basic and diluted net loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly per share amounts will not necessarily equal the total for the year.

**17. SUBSEQUENT EVENT**

In January 2013 the Company completed a public offering of common stock under its July 2011 shelf registration. The Company sold 4.0 million shares of common stock, par value \$0.001 per share, at a price of \$7.25 per share to generate proceeds of \$27.1 million after expenses. Offering costs were recorded in additional paid in capital to offset proceeds.

**Table of Contents**

## SCHEDULE

## SCHEDULE II

## VALUATION AND QUALIFYING ACCOUNTS

## VALUATION AND QUALIFYING ACCOUNTS

	Beginning Balance	Additions	Deductions	Ending Balance
<b>Allowance for doubtful accounts receivable</b>				
Year ended December 31, 2012	\$ 37	\$ 75	\$ 63	\$ 49
Year ended December 31, 2011	9	29	1	37
Year ended December 31, 2010	24	8	23	9
<b>Reserve for sales returns and allowances</b>				
Year ended December 31, 2012	\$ 40	\$ 262	\$ 197	\$ 105
Year ended December 31, 2011	53	52	65	40
Year ended December 31, 2010	3	55	3	53
<b>Allowance for inventory valuation</b>				
Year ended December 31, 2012	\$ 206	\$ 381	\$ 320	\$ 267
Year ended December 31, 2011	32	311	137	206
Year ended December 31, 2010	183	47	198	32
<b>Valuation allowance for deferred tax assets</b>				
Year ended December 31, 2012	\$ 29,316	\$ 2,369	\$	\$ 31,685
Year ended December 31, 2011	27,312	2,004		29,316
Year ended December 31, 2010	26,194	1,118		27,312



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**Table of Contents**

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

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

We have evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13(a)-15(e) and 15(d)-15(e) of the Securities Exchange Act of 1934 (the Exchange Act), as of the end of the period covered by this report. Our management, including the Chief Executive Officer and Chief Financial Officer, supervised and participated in the evaluation. Based on the evaluation, we concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's forms and rules, and the material information relating to the Company is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Control systems, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that control objectives are met. Because of inherent limitations in all control systems, no evaluation of controls can provide assurance that all control issues and instances of fraud, if any, within a company will be detected. Additionally, controls can be circumvented by individuals, by collusion of two or more people or by management override. Over time, controls can become inadequate because of changes in conditions or the degree of compliance may deteriorate. Further, the design of any system of controls is based in part upon assumptions about the likelihood of future events. There can be no assurance that any design will succeed in achieving its stated goals under all future conditions. Because of the inherent limitations in any cost-effective control system, misstatements due to errors or fraud may occur and not be detected.

**Changes in Internal Control over Financial Reporting**

There were no changes in the Company's internal control over financial reporting that occurred during the quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Management's Annual Report on Internal Control Over Financial Reporting**

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control over financial reporting includes policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements. The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2012. No matter how well designed, because of inherent limitations in all control systems, internal control over financial reporting may not prevent or detect misstatements should they occur. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the

**Table of Contents**

control procedures may deteriorate. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework*. Based on such assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2012. Deloitte & Touche LLP, the Company's independent registered public accounting firm has audited the consolidated financial statements included in this Annual Report on Form 10-K and, as part of its audit, has issued an attestation report on the effectiveness of the Company's internal control over financial reporting. The attestation report can be found on the following page as part of this Item 9A.

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**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

AtriCure, Inc. and subsidiaries

West Chester, Ohio

We have audited the internal control over financial reporting of AtriCure, Inc. and subsidiaries (the Company) as of December 31, 2012, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended December 31, 2012 of the Company and our report dated March 8, 2013 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ Deloitte & Touche LLP

Cincinnati, Ohio

March 8, 2013

**Table of Contents****ITEM 9B. OTHER INFORMATION**

None.

**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 2013 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of 2012 (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 following table summarizes information about our equity compensation plans as of December 31, 2012.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights <sup>(1)</sup> (a)	Weighted-average exercise price of outstanding options, warrants and rights <sup>(2)</sup> (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 <sup>(3)</sup>	3,675,352	\$ 8.81	432,052
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>3,675,352</b>	<b>\$ 8.81</b>	<b>432,052</b>

(1) Represents outstanding stock options, restricted stock and performance shares as of December 31, 2012.

(2) The weighted average exercise price is calculated without taking into account restricted stock and performance shares that will become issuable, without any cash consideration or other payment, as vesting requirements and/or performance goals are achieved.

(3) Amounts include awards under our 2001 Stock Option Plan and 2005 Equity Incentive Plan but exclude shares purchased under our 2008 Employee Stock Purchase Plan.

The remaining 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 in this Form 10-K or incorporated by reference in this Form 10-K:

<b>Exhibit No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on April 20, 2005).
3.2	Second Amended and Restated Bylaws (incorporated by reference to our Registration Statement on Form S-1 (Registration No. 333-124197) filed on April 20, 2005).
4.1	Specimen common stock certificate (incorporated by reference to Amendment No. 2 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on July 7, 2005).
4.2	Warrant to purchase AtriCure, Inc. common stock issued to Silicon Valley Bank on May 1, 2009 (incorporated by reference to our Quarterly Report on Form 10-Q, filed on August 10, 2009).
4.3	Form of Senior Indenture dated as of July 1, 2011 between AtriCure, Inc. and U.S. Bank National Association, as Trustee incorporated by reference to our Registration Statement on Form S-3 (Registration No. 333-175288), filed on July 1, 2011.
4.4	Form of Subordinated Indenture dated as of July 1, 2011 between AtriCure, Inc. and U.S. Bank National Association, as Trustee incorporated by reference to our Registration Statement on Form S-3 (Registration No. 333-175288), filed on July 1, 2011.
10.1 <sup>#</sup>	2001 Stock Option Plan (incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on June 14, 2005).
10.2 <sup>#</sup>	Agreement, dated as of July 18, 2006, by and between AtriCure, Inc. and the Cleveland Clinic (incorporated by reference to our Current Report on Form 8-K, filed on July 20, 2006).
10.3 <sup>#</sup>	Amendment No. 1, dated as of December 1, 2008, to Agreement dated as of July 18, 2006 by and between AtriCure, Inc. and the Cleveland Clinic (incorporated by reference to our Annual Report on Form 10-K filed on March 16, 2009).
10.4 <sup>#</sup>	Amendment No. 2, effective as of December 28, 2009, to Agreement dated as of July 18, 2006 by and between AtriCure, Inc. and the Cleveland Clinic (incorporated by reference to our Annual Report on Form 10-K filed on March 30, 2010).
10.5 <sup>#</sup>	Employment Agreement, dated as of October 1, 2011, between AtriCure, Inc. and Patricia Kennedy (incorporated by reference to our Quarterly Report on Form 10-Q, filed on November 4, 2011).
10.6 <sup>#</sup>	Employment Agreement, dated as of January 16, 2012, between AtriCure, Inc. and Andrew L. Lux (incorporated by reference to our Current Report on Form 8-K, filed on January 17, 2012).
10.7 <sup>#</sup>	Employment Agreement, dated as of November 1, 2012, between AtriCure, Inc. and Michael H. Carrel (incorporated by reference to our Current Report on Form 8-K, filed on November 1, 2012).
10.8 <sup>#</sup>	Agreement between AtriCure, Inc. and David J. Drachman dated effective as of August 2, 2012 (incorporated by reference to our Quarterly Report on Form 10-Q filed on August 3, 2012).

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.9#	Agreement between AtriCure, Inc. and Julie A. Piton dated effective as of April 30, 2012 (incorporated by reference to our Current Report on Form 8-K filed on May 2, 2012).
10.10#	2005 Equity Incentive Plan, as amended on September 19, 2007 (incorporated by reference to Exhibit 10.1 to the Registrant's Form S-8 Registration Statement (File No. 333-152014) filed on June 30, 2008), and as amended on March 6, 2013 (filed herewith).
10.11#	2008 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Form S-8 Registration Statement (File No. 333-152013) filed on June 30, 2008).
10.12#	Form of Performance Share Agreement (incorporated by reference to our Current Report on Form 8-K, filed on October 31, 2008).
10.13#	Amended Form of Performance Share Agreement (incorporated by reference to our Current Report on Form 8-K, filed on March 30, 2009).
10.14#	Form of Change in Control Agreement between AtriCure and AtriCure Executive Officers.
10.15	Settlement Agreement as of February 2, 2010 by and among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, the Company and the Relator (incorporated by reference to our Current Report on Form 8-K, filed on February 5, 2010).
10.16	Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and AtriCure, Inc. (incorporated by reference to our Current Report on Form 8-K, filed on February 5, 2010).
10.17	Amended and Restated Loan and Security Agreement, dated as of September 13, 2010, between Silicon Valley Bank and AtriCure, Inc. (incorporated by reference to our Current Report on Form 8-K, filed on September 17, 2010).
10.18	Export-Import Bank Loan and Security Agreement, dated as of September 13, 2010, between Silicon Valley Bank and AtriCure, Inc. (incorporated by reference to our Current Report on Form 8-K, filed on September 17, 2010).
10.19	First Loan Modification Agreement, dated as of March 15, 2011, between Silicon Valley Bank and AtriCure, Inc. (incorporated by reference to our Current Report on Form 8-K, filed on March 16, 2011).
10.20	Export-Import Bank First Loan Modification Agreement, dated as of March 15, 2011, between Silicon Valley Bank and AtriCure, Inc. (incorporated by reference to our Current Report on Form 8-K, filed on March 16, 2011).
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10.23	Third Loan Modification Agreement, dated as of May 31, 2012, between Silicon Valley Bank and AtriCure, Inc. (incorporated by reference to our Current Report on Form 8-K, filed on June 4, 2012).
10.24	Fourth Loan Modification Agreement, dated as of September 26, 2012, between Silicon Valley Bank and AtriCure, Inc. (incorporated by reference to our Current Report on Form 8-K, filed on September 28, 2012).

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.25	Joinder and Fifth Loan Modification Agreement, dated as of January 30, 2013, between Silicon Valley Bank and AtriCure, Inc. (incorporated by reference to our Current Report on Form 8-K, filed on January 31, 2013).
10.26	Export-Import Bank Joinder and Third Loan Modification Agreement, dated as of January 30, 2013, between Silicon Valley Bank and AtriCure, Inc. (incorporated by reference to our Current Report on Form 8-K, filed on January 31, 2013).
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.
31.2	Rule 13a-14(a) Certification of Chief Financial 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.
32.2	Certification pursuant to 18 U.S.C. Section 1350 by the Chief Financial Officer, as adopted, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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# Compensatory plan or arrangement.

\* XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.



**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: March 8, 2013

/s/ Michael H. Carrel  
**Michael H. Carrel**

**President and Chief Executive Officer**

**(Principal Executive Officer)**

Date: March 8, 2013

/s/ M. Andrew Wade  
**M. Andrew Wade**

**Vice President and Chief Financial Officer**

**(Principal Accounting and Financial Officer)**

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael H. Carrel, 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 March 8, 2013.

<b>Signature</b>	<b>Title(s)</b>
/s/ Richard M. Johnston	<b>Richard M. Johnston</b>
<b>Richard M. Johnston</b>	<i>Chairman of the Board</i>
/s/ Michael H. Carrel	<b>Michael H. Carrel</b>
<b>Michael H. Carrel</b>	<i>Director, President and Chief Executive Officer</i>
	<i>(Principal Executive Officer)</i>
/s/ M. Andrew Wade	<b>M. Andrew Wade</b>
<b>M. Andrew Wade</b>	<i>Vice President and Chief Financial Officer</i>
	<i>(Principal Accounting and Financial Officer)</i>
/s/ Mark A. Collar	<b>Mark A. Collar</b>

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**Mark A. Collar**

*Director*

/s/ Donald C. Harrison

**Donald C. Harrison**

**Donald C. Harrison**

*Director*

/s/ Michael D. Hooven

**Michael D. Hooven**

**Michael D. Hooven**

*Director*

/s/ Elizabeth D. Krell

**Elizabeth D. Krell**

**Elizabeth D. Krell**

*Director*

**Table of Contents**

<b>Signature</b>	<b>Title(s)</b>
/s/ Mark R. Lanning	<b>Mark R. Lanning</b>
<b>Mark R. Lanning</b>	<i>Director</i>
/s/ Karen P. Robards	<b>Karen P. Robards</b>
<b>Karen P. Robards</b>	<i>Director</i>

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to our Registration Statement on Form S-1 (Registration No. 333-124197) filed on April 20, 2005)).
3.2	Second Amended and Restated Bylaws (incorporated by reference to our Registration Statement on Form S-1 (Registration No. 333-124197) filed on April 20, 2005).
4.1	Specimen common stock certificate (incorporated by reference to Amendment No. 2 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on July 7, 2005).
4.2	Warrant to purchase AtriCure, Inc. common stock issued to Silicon Valley Bank on May 1, 2009 (incorporated by reference to our Quarterly Report on Form 10-Q, filed on August 10, 2009).
4.3	Form of Senior Indenture dated as of July 1, 2011 between AtriCure, Inc. and U.S. Bank National Association, as Trustee incorporated by reference to our Registration Statement on Form S-3 (Registration No. 333-175288), filed on July 1, 2011.
4.4	Form of Subordinated Indenture dated as of July 1, 2011 between AtriCure, Inc. and U.S. Bank National Association, as Trustee incorporated by reference to our Registration Statement on Form S-3 (Registration No. 333-175288), filed on July 1, 2011.
10.1 <sup>#</sup>	2001 Stock Option Plan (incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on June 14, 2005).
10.2 <sup>#</sup>	Agreement, dated as of July 18, 2006, by and between AtriCure, Inc. and the Cleveland Clinic (incorporated by reference to our Current Report on Form 8-K, filed on July 20, 2006).
10.3 <sup>#</sup>	Amendment No. 1, dated as of December 1, 2008, to Agreement dated as of July 18, 2006 by and between AtriCure, Inc. and the Cleveland Clinic (incorporated by reference to our Annual Report on Form 10-K filed on March 16, 2009).
10.4 <sup>#</sup>	Amendment No. 2, effective as of December 28, 2009, to Agreement dated as of July 18, 2006 by and between AtriCure, Inc. and the Cleveland Clinic (incorporated by reference to our Annual report on Form 10-K filed on March 16, 2009).
10.5 <sup>#</sup>	Employment Agreement, dated as of October 1, 2011, between AtriCure, Inc. and Patricia Kennedy (incorporated by reference to our Quarterly Report on Form 10-Q, filed on November 4, 2011).
10.6 <sup>#</sup>	Employment Agreement, dated as of January 16, 2012, between AtriCure, Inc. and Andrew L. Lux (incorporated by reference to our Current Report on Form 8-K, filed on January 17, 2012).
10.7 <sup>#</sup>	Employment Agreement, dated as of November 1, 2012, between AtriCure, Inc. and Michael H. Carrel (incorporated by reference to our Current Report on Form 8-K, filed on November 1, 2012).
10.8 <sup>#</sup>	Agreement between AtriCure, Inc. and David J. Drachman dated effective as of August 2, 2012 (incorporated by reference to our Quarterly Report on Form 10-Q filed on August 3, 2012).
10.9 <sup>#</sup>	Agreement between AtriCure, Inc. and Julie A. Piton dated effective as of April 30, 2012 (incorporated by reference to our Current Report on Form 8-K filed on May 2, 2012).
10.10 <sup>#</sup>	2005 Equity Incentive Plan, as amended on September 19, 2007 (incorporated by reference to Exhibit 10.1 to the Registrant's Form S-8 Registration Statement (File No. 333-152014) filed on June 30, 2008), and as amended on March 6, 2013 (filed herewith).

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.11#	2008 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Form S-8 Registration Statement (File No. 333-152013) filed on June 30, 2008).
10.12#	Form of Performance Share Agreement (incorporated by reference to our Current Report on Form 8-K, filed on October 31, 2008).
10.13#	Amended Form of Performance Share Agreement (incorporated by reference to our Current Report on Form 8-K, filed on March 30, 2009).
10.14#	Form of Change in Control Agreement between AtriCure and AtriCure Executive Officers.
10.15	Settlement Agreement as of February 2, 2010 by and among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, the Company and the Relator (incorporated by reference to our Current Report on Form 8-K, filed on February 5, 2010).
10.16	Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and AtriCure, Inc. (incorporated by reference to our Current Report on Form 8-K, filed on February 5, 2010).
10.17	Amended and Restated Loan and Security Agreement, dated as of September 13, 2010, between Silicon Valley Bank and AtriCure, Inc. (incorporated by reference to our Current Report on Form 8-K, filed on September 17, 2010).
10.18	Export-Import Bank Loan and Security Agreement, dated as of September 13, 2010, between Silicon Valley Bank and AtriCure, Inc. (incorporated by reference to our Current Report on Form 8-K, filed on September 17, 2010).
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