
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2005

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 000-51470



AtriCure, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

34-1940305
(I.R.S. Employer
Identification No.)

6033 Schumacher Park Drive
West Chester, OH 45069
(Address of principal executive offices)

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

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2) YES NO

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at October 31, 2005
Common Stock, \$.001 par value	12,066,005

[Table of Contents](#)

Table of Contents

	<u>Page</u>
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	
Condensed Balance Sheets as of September 30, 2005 and December 31, 2004	3
Condensed Statements of Operations for the Three and Nine Months Ended September 30, 2005 and 2004	4
Condensed Statements of Cash Flows for the Nine Months Ended September 30, 2005 and 2004	5
Notes to Condensed Financial Statements	6
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3. Quantitative and Qualitative Disclosures About Market Risks	41
Item 4. Controls and Procedures	41
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	41
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	42
Item 4. Submission of Matters to a Vote of Security Holders	42
Item 6. Exhibits	43
Signatures	44
Certifications	

[Table of Contents](#)

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ATRICURE, INC.
CONDENSED BALANCE SHEETS

	(Unaudited) September 30, 2005	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	\$ 38,335,926	\$ 5,175,177
Accounts receivable, less allowance for doubtful accounts of \$81,900 and \$56,779 as of September 30, 2005 and December 31, 2004, respectively	3,769,495	3,520,621
Inventory	2,424,719	1,087,408
Prepaid expenses	1,084,617	112,740
Deferred tax asset	48,000	—
Total current assets	45,662,757	9,895,946
Property and equipment, net	3,551,038	2,410,051
Deferred offering costs	—	412,005
Intangible assets	1,040,278	—
Goodwill	3,840,837	—
Other assets	215,327	12,618
Total assets	\$ 54,310,237	\$ 12,730,620
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable (a)	\$ 2,191,349	\$ 733,444
Commissions/bonus payable	1,174,233	791,639
Accrued vacation	398,589	175,698
Income taxes payable	398,583	—
Accrued liabilities	1,534,555	1,604,992
Current maturities of capital lease obligation	24,579	—
Current maturities of long-term debt	299,006	—
Total current liabilities	6,020,894	3,305,773
Capital lease obligation	44,178	—
Long-term debt	1,201,540	—
Deferred tax liability	48,000	—
Redeemable preferred stock:		
Preferred stock, \$0.001 par value; designated Series A, 2,182,521 shares authorized, issued and outstanding as of December 31, 2004	—	7,979,396
Preferred stock, \$0.001 par value; designated Series B, 4,059,720 shares authorized; 3,829,499 issued and outstanding as of December 31, 2004	—	28,776,745
Total redeemable preferred stock	—	36,756,141
Shareholders' equity (deficit):		
Common stock, \$0.001 par value, 90,000,000 and 10,526,315 shares authorized as of September 30, 2005 and December 31, 2004, respectively; 12,060,414 and 1,880,169 issued and outstanding as of September 30, 2005 and December 31, 2004, respectively	12,060	1,880
Additional paid-in capital	85,980,827	3,281,447
Unearned compensation	(669,383)	(981,612)
Accumulated deficit	(38,327,879)	(29,633,009)
Total shareholders' equity (deficit)	46,995,625	(27,331,294)
Total liabilities and shareholders' equity	\$ 54,310,237	\$ 12,730,620
<i>(a) Includes the following liabilities resulting from transactions with Enable Medical Corporation prior to the acquisition as of August 10, 2005 (See Notes 3 & 8):</i>		
Accounts payable	\$ —	\$ 434,869

ATRICURE, INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Revenues	\$ 7,169,748	\$ 4,499,894	\$22,397,927	\$13,426,770
Cost of revenues (a)	2,015,458	1,161,784	5,913,099	3,637,127
Gross profit	5,154,290	3,338,110	16,484,828	9,789,643
Operating expenses:				
Research and development expenses (a)	2,612,977	1,166,798	6,320,371	2,918,378
Selling, general and administrative expenses	6,308,516	3,881,154	16,670,850	9,971,480
Total operating expenses	8,921,493	5,047,952	22,991,221	12,889,858
Loss from operations	(3,767,203)	(1,709,842)	(6,506,393)	(3,100,215)
Preferred stock interest expense	(379,669)	(976,292)	(2,332,254)	(2,928,876)
Other interest income (expense), net	106,943	24,442	122,552	80,025
Other income	84,868	—	84,868	—
Loss before income taxes	(3,955,061)	(2,661,692)	(8,631,227)	(5,949,066)
Income tax expense	(9,375)	(284)	(42,225)	(16,972)
Net loss available to common shareholders	\$(3,964,436)	\$(2,661,976)	\$(8,673,452)	\$(5,966,038)
Basic and diluted loss per share	\$ (0.49)	\$ (1.46)	\$ (2.18)	\$ (3.29)
Weighted average shares outstanding:				
Basic and diluted	8,151,220	1,822,696	3,981,354	1,811,460

(a) Includes the following expenses resulting from transactions with Enable Medical Corporation prior to the acquisition as of August 10, 2005 (See Notes 3 & 8):

Cost of revenues	\$ 943,313	\$ 1,094,785	\$ 4,259,269	\$ 3,614,074
Research and development expenses	\$ 139,365	\$ 340,964	\$ 1,201,583	\$ 837,018

ATRICURE, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2005	2004
Cash flows from operating activities:		
Net loss	\$ (8,673,452)	\$ (5,966,038)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,006,566	664,744
Amortization of intangible asset	29,722	—
Amortization of deferred financing costs	24,462	—
Stock compensation	497,898	705,594
Preferred stock interest	2,332,254	2,928,876
Changes in assets and liabilities:		
Accounts receivable	1,188,002	(1,399,937)
Inventory	(483,136)	(392,345)
Prepaid expenses	(949,167)	109,460
Other assets	412,420	(7,132)
Accounts payable	975,896	428,092
Commissions payable	161,478	192,387
Accrued liabilities	(135,198)	361,683
Net cash used in operating activities	<u>(3,612,255)</u>	<u>(2,374,616)</u>
Cash flows from investing activities:		
Purchases of property & equipment	(1,486,948)	(1,263,578)
Cash paid for acquisition, net	(6,420,681)	—
Net cash used in investing activities	<u>(7,907,629)</u>	<u>(1,263,578)</u>
Cash flow from financing activities:		
Proceeds from long-term debt borrowings	1,500,000	—
Payments on long-term debt	(11,981)	—
Payments on capital lease obligations	(5,386)	—
Proceeds from stock offering	43,176,994	—
Proceeds from stock option exercise and warrants	21,006	79,952
Net cash provided by financing activities	<u>44,680,633</u>	<u>79,952</u>
Net increase (decrease) in cash and cash equivalents	33,160,749	(3,558,242)
Cash and cash equivalents - beginning of period	5,175,177	10,399,338
Cash and cash equivalents - end of period	<u>\$38,335,926</u>	<u>\$ 6,841,096</u>
Supplemental cash flow information:		
Cash paid for income taxes	\$ —	\$ —
Cash paid for interest	\$ 27,847	\$ —
Warrants issued in connection with line of credit	\$ 216,083	\$ —
Preferred stock conversion	\$39,109,808	\$ —

ATRICURE, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of the Business—AtriCure, Inc. (the “Company”) was incorporated in the State of Delaware on October 31, 2000, as a spin-off of Enable Medical Corporation, to focus on the surgical treatment of atrial fibrillation. Atrial fibrillation (“AF”) is a rapid, irregular quivering of the upper chambers of the heart. The Company sells its medical devices to hospitals and medical clinics both in the United States of America and internationally. International sales were approximately \$0.6 million and \$0.2 million for the three months ended September 30, 2005 and 2004, respectively, and \$2.1 million and \$1.0 for the nine months ended September 30, 2005, and 2004, respectively.

Basis of Presentation— The accompanying interim financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission. The accompanying interim financial statements are unaudited, but in the opinion of management, contain all the normal, recurring adjustments considered necessary to present fairly the financial position, results of operations and cash flows for the periods presented in conformity with generally accepted accounting principles applicable to interim periods. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) have been omitted or condensed. The Company believes the disclosures herein are adequate to make the information presented not misleading. Results of operations are not necessarily indicative of the results expected for the full fiscal year or for any future period.

The accompanying condensed financial statements should be read in conjunction with the audited financial statements of the Company included in the Company’s prospectus filed with the Securities and Exchange Commission.

Certain amounts in the accompanying financial statements and notes thereto have been reclassified to conform to the current year presentation.

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

Revenue Recognition—Revenues are generated primarily from the sale of the Company’s Bipolar Ablation System. Revenue is recognized when title to the goods and risk of loss transfer to customers and there are no remaining obligations that will affect the customer’s final acceptance of the sale. The Company’s standard sales terms define the transfer of title and risk of loss to occur upon shipment to the respective customer. The Company maintains no post-shipment obligations to the recipients of the products. No installation, calibration or testing of this equipment is performed by the Company subsequent to shipment to the customer in order to render it operational. Product revenue includes shipping revenue of approximately \$31,000 and \$25,000 for the three months ended September 30, 2005 and 2004, respectively, and \$99,000 and \$62,000 for the nine months ended September 30, 2005 and 2004, respectively. Cost of freight is included in cost of goods sold. Commission income is recognized as the related sales are made. The Company sells its products through a direct and indirect sales force. Sales terms are consistent for both end-users and distributors, with terms generally not exceeding 120 days. Customers and distributors generally have no right of return.

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

[Table of Contents](#)

Inventory—Inventories are stated at the lower of cost or market using the first-in, first-out (“FIFO”) cost method and consist of the following:

	September 30, 2005	December 31, 2004
Raw material	\$ 333,079	\$ —
Work in process	654,418	—
Finished goods	1,437,222	1,087,408
Total inventory	\$ 2,424,719	\$ 1,087,408

Property and Equipment—Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed on the straight-line method for financial reporting purposes over the estimated useful lives of the assets, which range from three to five years. The Company, using its best estimates based on reasonable and supportable assumptions and projections, reviews for impairment of property and equipment in accordance with Statement of Financial Accounting Standards (“SFAS”) No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets.” The Company did not recognize any impairment of property and equipment for the three and nine month periods ended September 30, 2005 and 2004.

Included in Property and Equipment are generators and cryo-units that are loaned at no cost to medical providers to use the Company’s product. These generators and cryo-units are depreciated over three years. The three year life reflects the fact that the generators and cryo-units are run by internal computers and are programmed with software to regulate the power to the handpieces. As they are most similar to a computer, and the tolerance for imprecision is extremely low due to the nature of the work they perform, the Company anticipates that the estimated useful life cycle of these generators will be approximately three years. Such depreciation is included in cost of sales. The total of such depreciation was approximately \$202,000 and \$148,000 for the three months ended September 30, 2005 and 2004, respectively, and \$561,000 and \$379,000 for the nine months ended September 30, 2005 and 2004, respectively.

Total accumulated depreciation was approximately \$2,654,000 and \$1,647,000 as of September 30, 2005 and December 31, 2004, respectively.

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

Other income—The Company receives research grants, which are recognized as funds are expended and not as awarded by awarding agencies.

Earnings (Loss) Per Share—Basic net loss per share is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the period. Since the Company has experienced losses for all periods presented, net loss per share excludes the effect of 1,293,490 and 1,001,992 options outstanding at September 30, 2005 and 2004, respectively, because such options are anti-dilutive. Therefore the number of shares calculated for basic net loss per share is also used for the diluted net loss per share calculation. All share and per share amounts reflect the 1-for-3.8 reverse stock split that was effected on July 27, 2005.

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

Stock-Based Employee Compensation—The Company accounts for its stock-based awards to employees using the intrinsic value method in accordance with Accounting Principles Board (“APB”) No. 25, “Accounting for Stock Issued to Employees,” and its related interpretations. The Company has adopted the pro forma disclosure requirements of SFAS No. 123, “Accounting for Stock-Based Compensation.” Accordingly, compensation expense has been recognized in the financial statements for stock-based awards to employees based on the intrinsic value, if any, of the options issued.

During the three and nine months ended September 30, 2005 and 2004, the Company incurred a charge for stock compensation for employees for options issued with exercise prices below market value. The Company recorded a charge of approximately \$67,000 and \$48,000 for these options for the three months ended September 30, 2005 and 2004, respectively and \$192,000 and \$171,000 for the nine months ended September 30, 2005 and 2004, respectively, which represents the portion pertaining to the three and nine months ending September 30, 2005 and 2004 based on the options’ vesting requirements.

Table of Contents

SFAS No. 123 requires the disclosure of pro forma net income or loss as if the Company had adopted the fair value method. Under SFAS No. 123, the fair value of stock-based awards to employees is calculated through the use of the option pricing models, even though such models were developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which significantly differ from the Company's stock option awards. These models also require subjective assumptions, including expected time to exercise, which greatly affect the calculated values. If the computed fair values of the stock-based awards had been amortized to expense over the vesting period of the awards, the effect would have been as follows:

(Dollars in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net loss available to common shareholders	\$(3,964)	\$(2,662)	\$(8,673)	\$(5,966)
Add: Stock-based employee compensation expense included in net loss available to shareholders, net of related tax effect	67	48	192	171
Deduct: Stock-based employee compensation expense if the fair market method had been applied, net of related tax effects	(120)	(89)	(272)	(272)
Pro forma net loss available to common shareholders if the fair market method had been applied	<u>\$(4,017)</u>	<u>\$(2,703)</u>	<u>\$(8,753)</u>	<u>\$(6,067)</u>
Net loss per common share:				
Diluted-as reported	\$ (0.49)	\$ (1.46)	\$ (2.18)	\$ (3.29)
Diluted-pro forma	\$ (0.49)	\$ (1.48)	\$ (2.20)	\$ (3.35)

In calculating the compensation costs under SFAS No. 123, the fair value of the options is estimated on the grant date using the Black-Scholes option pricing model considering the following weighted average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Risk free interest rates	1.00% to 3.86%	1.00 to 2.89%	1.00% to 3.86%	1.00 to 2.89%
Expected lives (years)	4	4	4	4
Volatility	0.00% to 57.00%	0.00%	0.00% to 57.00%	0.00%

Based on the assumptions noted above, the weighted average fair value of the options granted for the nine months ended September 30, 2005 and 2004 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Weighted average fair value of options granted	\$ 6.96	\$ 6.75	\$ 4.97	\$ 5.77

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

Concentrations of Credit Risk—The Company establishes an allowance for doubtful accounts based upon factors surrounding the credit risk of specific customers, historical trends and other information.

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

Deferred Offering Costs—The Company had deferred expenses, primarily legal fees, incurred in connection with its filing of a registration statement to sell common shares. These costs reduced the proceeds of the common stock offering (see Note 3).

Stock-Based Compensation—The Company has issued nonstatutory common stock options to consultants to purchase shares of common stock. Such options vest over a service period ranging from immediately to four years. The fair value, which is subject to adjustment at each vesting date based upon the fair value of the Company's common stock, was determined using the Black-Scholes valuation model with the following weighted average assumptions: contractual life of ten years; volatility ranging from 0% to 57%; risk-free interest rate ranging from 1.00% to 3.75% and no dividends during the expected term. The values attributable to these options have been amortized over the service period on a graded vesting method and the vested portion of these options was re-measured at each vesting date.

Stock compensation expense with respect to non-employee awards totaled approximately \$86,000 and \$117,000 for the three months ended September 30, 2005 and 2004, respectively and \$305,000 and \$534,000 for the nine months ended September 30, 2005 and 2004, respectively.

2. ACQUISITION

On August 10, 2005, the Company acquired all of the outstanding shares of Enable Medical Corporation ("Enable"). The results of operations for Enable have been included in the Company's Condensed Statements of Operations since that date. Enable is a related party and is the manufacturer of the single-use disposable handpieces (refer to Note 8). As a result of the acquisition, the Company expects to gain better control over manufacturing and supply chain activities, as well as enhance its engineering capabilities and improve the Company's margins.

[Table of Contents](#)

The Company paid approximately \$6.4 million to acquire Enable, net of \$0.8 million cash acquired. The aggregate purchase price was \$7.0 million, of which \$0.5 million was paid in February 2005 and the remaining \$6.5 million was paid in August 2005. The Company also incurred legal and professional expenses associated with the acquisition of approximately \$0.2 million. The purchase price reflects the expected growth potential of Enable and its profitability. As a result of this, the purchase price was in excess of the fair market value of the assets acquired, and the Company recorded goodwill of approximately \$3.8 million during the quarter.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed on August 10, 2005. The allocation of the excess purchase price was based upon preliminary estimates and assumptions. Accordingly, the allocations are subject to revision when the Company receives final information, including appraisals and analyses, which the Company expects to be finalized no later than one year of the purchase date.

	August 10, 2005
Current assets	\$2,361,762
Property and equipment	660,612
Goodwill	3,840,837
Intangible assets	1,070,000
Other assets	11,502
Assets acquired	7,944,713
Current liabilities	1,461,940
Capital lease obligation	62,092
Liabilities assumed	1,524,032
Net assets acquired	\$6,420,681

Intangible assets are currently estimated to be approximately \$1.1 million and consist of proprietary manufacturing technology, which is being amortized over 5 years. Amortization expense was approximately \$30,000 for the three and nine months ended September 30, 2005. The proprietary manufacturing technology was valued based on Enable's unique ability to manufacture the products to meet the Company's close tolerance specifications for surgical products. Enable has developed an expertise in plating, mold, adhesive, and assembly technology that has permitted it to be the sole supplier to the Company. The Company has utilized the income approach in conjunction with the excess earnings approach to value the cash flow attributable to the proprietary manufacturing technology. The Company has identified the product line revenues and the relevant costs and expenses and deducted the required returns on other contributing assets from the free cash flows, deriving the residual cash flows generated from the proprietary manufacturing technology assets, to which a discount rate was applied to determine a present value.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Revenues	\$ 7,203,193	\$ 4,612,712	\$22,604,568	\$13,883,565
Net loss available to common shareholders	\$(3,847,164)	\$(2,353,835)	\$(7,986,639)	\$(4,837,520)
Basic and diluted loss per share	\$ (0.47)	\$ (1.29)	\$ (2.01)	\$ (2.67)

3. INITIAL PUBLIC OFFERING

On August 10, 2005, the Company consummated an initial public offering of 4.6 million shares of its common stock at \$12.00 per share, which included the underwriters' exercise of their over-allotment option on August 9, 2005 to purchase 600,000 shares of the Company's common stock, of which 450,000 shares were sold by selling shareholders and 150,000 shares were sold by the Company. The Company did not receive any proceeds from the sale of the 450,000 shares of common stock that were sold by selling shareholders. These share amounts reflect a 1-for-3.8 reverse split of the capital stock that was affected on July 27, 2005. In connection with the offering, all of the 6,012,020 outstanding shares of preferred stock were converted into 6,012,020 shares of common stock. Proceeds to the Company from the offering, after deducting underwriting discounts, commissions and offering expenses, were approximately \$43.2 million. Offering expenses were approximately \$3.1 million.

4. COMPREHENSIVE LOSS

The Company has no items that qualify as an element of comprehensive loss as defined by SFAS No. 130, "Reporting Comprehensive Income;" therefore, comprehensive loss is the same as net loss.

5. FINANCING ARRANGEMENTS

In March 2005, the Company entered into an agreement for a credit facility with Lighthouse Capital Partners V, L.P. up to \$5,000,000, to be drawn down by the earlier of an initial public offering of common stock or September 1, 2005. This credit facility is secured by substantially all of the Company's assets, excluding intellectual property. The interest rate for any amounts drawn down is the prime rate plus 1.75%. Under the terms of the agreement, the Company is required to pay monthly installments of interest only through August 2005 and monthly installments of principal and interest thereafter, in addition to a fee due at maturity on September 1, 2009 equal to 15% of the aggregate amount borrowed under the credit facility, with prepayment in whole allowed at any time without penalty.

[Table of Contents](#)

As of September 30, 2005, there was approximately \$1.5 million outstanding under this facility. In addition, the agreement required the Company to issue to the lender 55,208 warrants to purchase an equal number of shares of common stock at an exercise price of \$11.29 per share. The warrants shall expire the earlier of March 8, 2012 or 1 year after the closing of the initial public offering.

In addition, the Company granted Lighthouse a first perfected lien upon all of its tangible and intangible assets, including accounts receivable, inventory, equipment, furniture and fixtures, but excluding intellectual property.

6. PURCHASE OBLIGATIONS

In June 2005, the Company entered into a 19-month development agreement with Stellartech Research Corporation whereby Stellartech agreed to develop enhancements to the current ASU technology and granted the Company a license to use Stellartech's technology in the field of cardiac arrhythmia treatment. The Company agreed to pay Stellartech on an hourly basis, based on the types of services being performed. In addition, materials and components, out-of-pocket expenses and outside services will be billed to the Company at cost plus a specified percentage. The Company may terminate this agreement upon 30 days' notice. Under the terms of this agreement, the Company has certain indemnification obligations to Stellartech for its performance of services under the agreement, except for Stellartech's breach, fraud, negligence or misconduct and infringement relating to intellectual property owned by Stellartech, for each of which it indemnifies the Company.

In June 2005, the Company also entered into a manufacturing agreement with Stellartech whereby the Company agreed to purchase, and Stellartech agreed to supply the first 400 Ablation Sensing Units, or ASUs, that the Company requires. For a period of two years after the delivery of the first 400 ASUs purchased from Stellartech by the Company since January 2004, the Company must purchase, from Stellartech, at least 75% of the Company's ASU requirements. The Company may, however, extinguish its obligation to purchase 75% of its ASU requirements from Stellartech by paying to Stellartech either a certain percentage of the gross margin Stellartech would have received if it had manufactured the ASUs or a specified dollar amount. At September 30, 2005, the Company has a total obligation of approximately \$662,000 under this agreement. This agreement has an initial three-year term and renews for successive one-year periods, unless terminated. This manufacturing agreement may be terminated by Stellartech for any reason upon six months' notice to the Company. The Company may terminate the agreement in the event the development agreement is terminated prior to expiration or after the Company has fulfilled the purchase requirements under the agreement. Under the terms of this agreement, the Company has certain indemnification obligations, including with respect to claims relating to intellectual property infringement, design defects and manufacturing defects. Any supply interruption or failure to obtain the Company's ASU would limit the Company's ability to sell its system and could have a material adverse effect on its business, financial condition and results of operations.

In July 2005, the Company entered into a development and license agreement with UST Inc., whereby UST agreed to design and develop a high intensity focused ultrasound, or HIFU, system to create certain types of lesions and granted the Company an exclusive, worldwide license to related technology. The Company agreed to pay UST an initial development fee of \$375,000 and an additional development fee of \$966,000, payable in fourteen monthly installments. If UST has not completed its development services within fourteen months, the Company will be required to pay UST the direct costs incurred by it for the following six months in connection with continuing to render development services. The Company is also required to pay UST royalties of 4% of the net sales of the HIFU system, up to a maximum amount of \$15 million in royalties. In addition, the Company is required to make certain license and maintenance payments to UST for the sublicenses granted to it under the terms of this agreement. The Company may terminate this agreement at any time by giving notice to UST. UST may terminate this agreement if the Company fails to timely commercialize the HIFU system or if the Company fails to timely pursue FDA approval or clearance of the HIFU system. Under the terms of this agreement, the Company has certain indemnification obligations to UST for its breach of this agreement.

7. REDEEMABLE PREFERRED STOCK

In 2001, the Company issued 2,182,521 shares of Series A Preferred Stock at \$2.39 per share. In exchange for the Series A Preferred Stock, the Company received \$4,025,000 in cash and converted a \$1,150,000 promissory note that was issued in January 2001 and the related accrued interest of \$49,958. The proceeds were reduced by \$131,426 in direct expenses associated with the offering. Amortization of the direct issuance expenses was \$1,958 and \$5,787 for the three months ended September 30, 2005 and 2004, respectively, and \$12,053 and \$20,398 for the nine months ended September 30, 2005 and 2004, respectively.

In 2002, the Company issued 3,829,499 shares of Series B Preferred Stock at \$5.43 per share. In exchange for the Series B Preferred Stock, the Company received \$17,274,500 in cash and converted a \$3,500,000 note and the related accrued interest of \$35,000. The proceeds were reduced by \$96,704 in direct expenses associated with the initial public offering. Amortization of the direct issuance expenses was \$1,418 and \$4,190 for the three months ended September 30, 2005 and 2004, respectively, and \$9,358 and \$15,615 for the nine months ended September 30, 2005 and 2004, respectively.

Each share of Series A and B Preferred Stock was convertible by the holders into common stock of the Company at any time after the date of issuance. The number of shares of common stock that would be received upon conversion would have been determined by dividing \$2.39 by the Series A conversion price and \$5.43 by the Series B conversion price (original issue price subject to adjustments as specified in the Company's Certificate of Incorporation) in effect at the time of conversion. In addition, upon conversion, the holder of each share of Series A or B Preferred Stock would have received cash in an amount equal to all dividends declared but unpaid and any and all other amounts owing with respect to the Series A or B Preferred Stock. Upon the closing of the Company's initial public offering, all of the 6,012,020 outstanding shares of preferred stock were converted into 6,012,020 shares of common stock, as discussed above in Note 3.

The holders of at least two-thirds of the then issued and outstanding shares of Series A or a majority of the then issued and outstanding shares of Series B Preferred Stock may have caused the Company, beginning on June 6, 2007, and on each of the first and second anniversaries thereof, to redeem from the holders of the Series A or B Preferred Stock at a price equal to the original Series A or B Preferred Stock purchase price plus all declared or accrued but unpaid dividends and an amount equal to 15% per annum (by simple interest calculation) of the original Series A or B per share purchase price from the date of May 25, 2001 (Series A) and June 6, 2002 (Series B), through and until the redemption date. The 15% rate was payable only if the Series A or B Preferred Stock was redeemed. Since the Series A and B Preferred Stock were converted prior to redemption, no amount was due for the 15% rate. Pursuant to their terms, the Series A and B Preferred Stock converted into shares of common stock on a one-for-one basis upon completion of the initial public offering since the Company received gross proceeds of at least \$35,000,000. The preferred stock was converted to common stock on the initial public offering date and the carrying amount of the preferred stock was reclassified to common stock. There was no gain or loss recognized, and the amounts accrued in prior periods for the 15% return were not reversed.

Increases in the cumulative Series A preferred stock, included in the accompanying financial statements, for the 15% rate was \$76,197 and \$195,935 for the three months ended September 30, 2005 and 2004, respectively, and \$468,069 and \$587,805 for the nine months ended September 30, 2005 and 2004, respectively. Increases in the Series B preferred stock, included in the accompanying financial statements, for the 15% rate was \$303,472 and \$780,357 for the three months ended September 30, 2005 and 2004, respectively, and \$1,864,185 and \$2,341,068 for the nine months ended September 30, 2005 and 2004, respectively.

8. RELATED PARTY

Prior to the acquisition, Enable was a related party with whom the Company transacted business.

In November 2000, the Company entered into a rental and administrative services agreement with Enable, whereby the Company obtains access and use of facility, personnel, and systems from Enable. This agreement expired in January 2003. In January 2002 (amended in 2003), the Company entered into a master development, manufacturing, and supply agreement with Enable. Pursuant to the terms of the development, manufacturing, and supply agreement with Enable, the Company was required to pay Enable a monthly fee of at least \$96,000 for certain product development services during the period from February 1, 2003 to January 31, 2004. After January 31, 2004 there is no specified monthly fee requirement. The agreement expired in January 2005, but was extended to December 2005 in February 2005. The agreement was subsequently cancelled as of August 10, 2005 in connection with the acquisition.

9. RECENT ACCOUNTING PRONOUNCEMENTS

In November 2004, the FASB issued FAS No. 151, "Inventory Costs." This Statement amends the guidance in ARB No. 43, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight handling costs and wasted material (spoilage). The provisions of this Statement will be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company has not yet determined the impact that adopting SFAS No. 151 will have on its financial position and results of operations.

In December 2004, The Financial Accounting Standards Board ("FASB") issued a revision to SFAS 123, "Share-Based Payment" ("SFAS 123(R)"). The revision requires all entities to recognize compensation expense in an amount equal to the fair value of share-based payments granted to employees. SFAS 123(R) eliminates the alternative method of accounting for employee share-based payments previously available under APB No. 25 ("APB 25"). In April 2005, the SEC delayed the effective date of SFAS 123(R) to fiscal years beginning after June 15, 2005. As a result, SFAS 123(R) will be effective for the Company beginning in the first quarter of fiscal 2006. The Company has not completed its evaluation of the impact that adopting SFAS 123(R) will have on its financial statements.

In March 2005, the FASB issued FASB Interpretation No. 47, "Accounting for Conditional Asset Retirement Obligations" ("FIN 47"). This Interpretation clarifies that an entity is required to recognize a liability for the fair value of a conditional asset retirement obligation when incurred if the liability's fair value can be reasonably estimated. The provisions of this Interpretation shall be effective for calendar-year companies no later than the end of fiscal years ending after December 31, 2005. The Company is currently evaluating the impact of the adoption of FIN 47 on its financial position and results of operations.

In May 2005, the FASB issued SFAS 154, "Accounting Changes and Error Corrections – A Replacement of Accounting Principles Board (APB) Opinion No. 20 and SFAS 3." SFAS 154 requires retrospective application to prior periods' financial statements for a change in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. Additionally, retrospective application is not required when explicit transition requirements specific to newly adopted accounting principles exist. Retrospective application requires the cumulative effect of the change on periods prior to those presented to be reflected in the carrying amounts of assets and liabilities as of the beginning of the first period presented and the offsetting adjustments to be recorded to opening retained earnings. SFAS 154 retains the guidance contained in APB No. 20 for reporting both the correction of an error in previously issued financial statements and a change in accounting estimate. SFAS 154 will become effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company is required to adopt the provisions of SFAS 154, as applicable, beginning in the first quarter of fiscal 2006.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the accompanying condensed financial statements and notes thereto contained in Item 1 of Part I of this Form 10-Q, and our audited financial statements and notes thereto as of and for the year ended December 31, 2004 included in our Prospectus filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on August 8, 2005, to provide an understanding of our results of operations, financial condition, and cash flows.

Forward-Looking Statements

This Form 10-Q, including the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," 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 quarterly report on Form 10-Q. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this Form 10-Q 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-Q. 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.

Overview

We develop, manufacture and sell innovative surgical devices designed to create precise lesions, or scars, in soft tissues. Our primary product line is the AtriCure bipolar ablation system, which accounted for 96% of our revenues for the nine months ended September 30, 2005 and 99% of our revenues for the nine months ended September 30, 2004. The AtriCure bipolar ablation system consists of a compact power generator known as an ablation sensing unit, or ASU, and several uniquely designed disposable handpieces that connect to the ASU. We also market the bipolar pen and the Wolf dissector, which are separate from, but complement, our system. Medical journals have described the adoption by leading cardiothoracic surgeons of the AtriCure bipolar ablation system as a standard treatment alternative during open-heart surgical procedures to safely, rapidly and reliably create lesions in cardiac tissue to block the abnormal electrical impulses that cause atrial fibrillation, or AF, a rapid, irregular quivering of the upper chambers of the heart.

Cardiothoracic surgeons have used the AtriCure bipolar ablation system to treat AF in over 18,000 patients since its general commercial release in the United States in January 2003. We believe that our system is currently a market leader in the treatment of AF during open-heart surgical procedures, and that surgeons have commenced use of our system as a sole-therapy minimally invasive treatment for AF, which is performed on patients who are not undergoing a separate open-heart procedure. We anticipate that substantially all of our sales for the foreseeable future will relate to the AtriCure bipolar ablation system for the treatment of AF.

From our inception in November 2000 through the first half of 2002, our operations consisted primarily of development-stage activities, including the development of the AtriCure bipolar ablation system, raising capital, obtaining product clearances, conducting product testing and evaluations, and recruiting personnel. After limited sales of our system in 2002, we commenced the general commercial release of our system in January 2003, generating total revenues of approximately \$1.8 million for 2002, \$9.8 million for 2003, \$19.2 million for 2004 and approximately \$22.4 million for the nine months ended September 30, 2005. We had a net loss available to common shareholders (after accrual of interest on our redeemable preferred stock) of approximately \$9.0 million for 2002, \$7.1 million for 2003, \$9.5 million for 2004 and approximately \$8.7 million for the nine months ended September 30, 2005.

Table of Contents

We currently sell the AtriCure bipolar ablation system to customers in the United States through our direct sales force and, to a lesser extent, through independent manufacturers' representatives. We also sell our system outside of the United States, primarily in Asia, Europe, South America, Canada and the Middle East, through distributors who pay us in U.S. dollars. To date, our sales outside of the United States have been limited, constituting approximately 7.4% of our total revenues for 2004 and approximately 9.4% of our total revenues for the nine months ended September 30, 2005, and we expect international sales to remain limited for the foreseeable future. We have expanded our sales and training force in the United States from 26 employees as of December 31, 2004 to 46 employees as of September 30, 2005, and we expect to continue to grow our sales and training staff over time.

Our future growth will depend on our ability to generate sales of the AtriCure bipolar ablation system through increasing acceptance by the medical community of our system as a standard treatment alternative for the surgical treatment of AF. Acceptance of our system is dependent upon, among other factors, awareness and education of the medical community about the surgical treatment of AF, in general, and the existence and effectiveness of the AtriCure bipolar ablation system, in particular.

In 2001, the FDA cleared the AtriCure bipolar ablation system for the ablation and coagulation of soft tissues during certain non-cardiac-related surgical procedures, but our system has not been cleared or approved in the United States for the ablation of cardiac tissue or for the treatment of AF. In addition, in July 2005 we received FDA clearance for our single-use disposable AtriCure bipolar pen for cardiac tissue ablation. We do not believe that our AtriCure bipolar ablation system is currently being used for its FDA-cleared indications and, accordingly, substantially all of our revenues are currently generated through the non-FDA-approved, or off-label, use of our system for the treatment of AF. While the FDA does not prevent doctors from using a product on an off-label basis, we cannot legally market a product for an off-label use. Because the AtriCure bipolar ablation system is currently our only significant product, the sustainability of our current operations, as well as our future viability, is dependent upon the continuation of sales of our system. We believe that sole-therapy minimally invasive treatment for AF represents the largest growth opportunity for us. If this market fails to develop, or the AtriCure bipolar ablation system is not widely adopted for use in this market, we may not achieve greater revenues or become profitable. In order to establish the sole-therapy minimally invasive AF treatment market, the current referral practices of doctors must change.

In June 2005, the FDA denied 510(k) clearance (the 510(k) notification is one type of process in which a medical device company can obtain FDA clearance before it may market a medical device in the United States based on substantial equivalence to an already marketed device) for use of our system to ablate cardiac tissue, because the FDA determined that our system is not substantially equivalent to an already cleared device. This means that we would now be required to gain FDA approval to market the device through the submission of a pre-market approval application, or PMA, a lengthier process, in order to gain FDA authorization of our system for the cardiac indication. While we may appeal the FDA's decision, that clearance would not eliminate the need to seek FDA approval through a separate PMA for the use of our system to treat AF. After conducting necessary clinical trials, we intend to seek FDA approval as early as 2008 or 2009 for the use of our system to treat AF, which we view as our market opportunity. If lack of FDA clearance or approval of our system for the treatment of AF were to prevent sales of our system, not only would we no longer receive revenues from the sale of our system, but we also would require significant financing to conduct clinical trials and to sustain our operations until such time as sales could resume. We cannot assure you that we can obtain these FDA approvals, that we would have, or could raise, sufficient financial resources to sustain our operations pending FDA approval, or that, if and when the required approvals are obtained, there will be a market for the AtriCure bipolar ablation system.

Our costs and expenses consist of cost of revenues, research and development expenses and selling, general and administrative expenses. Cost of revenues consists principally of the cost of purchasing and manufacturing our products. Research and development expenses consist principally of expenses incurred with respect to internal and external research and development activities and the conduct of clinical trials. With the FDA's authorization, we have begun the RESTORE-SR clinical trial relating to the use of the AtriCure bipolar ablation system to treat AF during open-heart surgery. We have also obtained FDA approval to conduct the RESTORE-SR II clinical study to evaluate the feasibility of using our system as a sole-therapy minimally invasive treatment for AF. This prospective, non-randomized feasibility trial is expected to enroll 25 patients at 5 leading US centers. Selling, general and administrative expenses consist principally of costs associated with our sales and administrative functions, accounting and legal fees and educational grants to medical institutions.

We expect our operating expenses to continue to increase in the future in absolute dollar terms and as a percentage of revenue as a result of increased sales and marketing expenses incurred to foster our revenue growth, continued

[Table of Contents](#)

research and development, increased general and administrative expenses to keep pace with our overall growth, the costs of being a public company and costs associated with seeking FDA approval of our system for use in the surgical treatment of AF.

During the remainder of 2005, we expect continued growth in our organization to support our expanding business. Managing that growth in a cost-effective manner will be important to achieving long-term profitability.

Recent Developments

Initial Public Offering

On August 10, 2005, we consummated an initial public offering of 4.6 million shares of our common stock at \$12.00 per share, which included the underwriters' exercise of their over-allotment option, on August 9, 2005, to purchase 600,000 shares of our common stock of which 450,000 shares were sold by selling shareholders and 150,000 shares were sold by us. We did not receive any proceeds from the sale of the 450,000 shares of common stock that were sold by selling shareholders. These share amounts reflect a 1-for-3.8 reverse split of our capital stock that was effected on July 27, 2005. In connection with the offering, all of the 6,012,020 outstanding shares of preferred stock were converted into 6,012,020 shares of common stock. Proceeds to us from the offering, after deducting underwriting discounts, commissions and offering expenses, were \$43.2 million. Offering expenses were approximately \$3.1 million.

Acquisition of Enable Medical Corporation

On August 10, 2005 we acquired Enable Medical Corporation, the manufacturer of our single-use disposal handpieces. The results of operations formerly conducted by Enable have been included in our Condensed Statements of Operations since that date. As a result of the acquisition, we expect to gain better control over manufacturing and supply chain activities, as well as enhance our engineering capabilities and improve our margins.

We paid approximately \$6.4 million to acquire Enable, net of \$0.8 million cash acquired. The aggregate purchase price was \$7.0 million, of which \$0.5 million was paid in February 2005 and the remaining \$6.5 million was paid in August 2005. We also incurred legal and professional expenses associated with the acquisition of approximately \$0.2 million. The purchase price reflects the expected growth potential of Enable and its profitability. As a result of this, the purchase price was in excess of the fair market value of the assets acquired, and we recorded goodwill of approximately \$3.8 million during the quarter.

Results of Operations

Three months ended September 30, 2005 compared to the three months ended September 30, 2004

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

	Three Months Ended September 30,			
	2005		2004	
	Amount	% of Revenue	Amount	% of Revenue
Revenues	\$ 7,170	100%	\$ 4,500	100%
Cost of revenues	2,016	28%	1,162	26%
Gross profit	5,154	72%	3,338	74%
Expenses:				
Research and development expenses	2,613	36%	1,167	26%
Selling, general and administrative expenses	6,308	88%	3,881	86%
Total operating expenses	8,921	124%	5,048	112%
Loss from operations	(3,767)	-52%	(1,710)	-38%
Preferred stock interest expense	(380)	-5%	(976)	-22%
Other interest income, net	107	1%	24	1%
Other income	85	1%	—	0%
Loss before taxes	(3,955)	-55%	(2,662)	-59%
Income tax expense	(9)	0%	—	0%
Net loss available to common shareholders	\$(3,964)	-55%	\$(2,662)	-59%

Revenues. Revenues are primarily derived from sales of our bipolar ablation system. Total revenues increased approximately \$2.7 million, from approximately \$4.5 million for the three months ended September 30, 2004, to approximately \$7.2 million for the three months ended September 30, 2005. The increase was primarily attributable to an increase in the volume of units sold domestically and internationally of our bipolar ablation system and the addition of our recently launched bipolar pen. The increase in units sold of our previously existing product line contributed approximately \$2.3 million of the total increase in sales, while the addition of the new bipolar pen product contributed approximately \$0.3 million to the increase in revenues. While our average domestic and international selling prices increased by approximately 4% and 12%, respectively, from the third quarter 2004 to third quarter 2005, the significant increase in volume of lower priced international sales as a percentage of total sales resulted in a relatively flat overall average selling price.

Cost of revenues. Cost of revenues increased approximately \$0.8 million, from approximately \$1.2 million for the three months ended September 30, 2004 to approximately \$2.0 million for the three months ended September 30, 2005, reflecting the approximately 62% increase in total units sold for the three months ended September 30, 2005 as compared to the three months ended September 30, 2004. As a percentage of revenues, cost of revenues increased from 26% for the three months ended September 30, 2004 to 28% for the three months ended September 30, 2005. The primary factors contributing to the increased percentage were one-time costs associated with hiring senior manufacturing personnel, as well as the amortization of intangible assets associated with our acquisition of Enable.

[Table of Contents](#)

Research and development expenses. Research and development expenses increased approximately \$1.4 million, from approximately \$1.2 million for the three months ended September 30, 2004 to approximately \$2.6 million for the three months ended September 30, 2005. The increase was primarily attributable to the addition of 28 full-time research and development personnel, of which 13 were former Enable employees, the expansion of our research and development activities to increase our product offerings and the expansion of our clinical trials. Our product development activities include projects to extend and improve the existing system, develop our new endoscopic ablation system, create new enabling devices such as new dissection, guidance and ablation tools, and research for new technologies. As a percentage of total revenues, research and development expenses increased from 26% for the three months ended September 30, 2004 to 36% for the three months ended September 30, 2005. We anticipate a continued increase in overall research and development spending as a percentage of revenues for the remainder of 2005.

Selling, general and administrative expenses. Selling, general and administrative expenses increased approximately \$2.4 million, from approximately \$3.9 million for the three months ended September 30, 2004 to approximately \$6.3 million for the three months ended September 30, 2005. The increase was primarily attributable to an increase in headcount-related charges of approximately \$1.5 million, an increase in educational grants to medical institutions and training expenditures of approximately \$0.4 million, and an increase in general corporate expenditures of approximately \$0.5 million. The increase in headcount-related charges is primarily attributable to the acquisition of Enable and the addition of sales personnel who call on doctors to discuss the general attributes of our system, and respond in a non-promotional manner to unsolicited requests for information from doctors on the use of our system in the treatment of AF. As a percentage of total revenues, selling, general and administrative expenses increased from 86% for the three months ended September 30, 2004 to 88% for the three months ended September 30, 2005.

Preferred stock interest expense. Preferred stock interest expense decreased approximately \$0.6 million, from approximately \$1.0 million for the three months ended September 30, 2004 to approximately \$0.4 million for the three months ended September 30, 2005. The decrease was attributable to the conversion of all shares of preferred stock into common stock upon the closing of our initial public offering on August 10, 2005.

Other interest income, net. Other interest income, net increased significantly from approximately \$24,000 for the three months ended September 30, 2004 to approximately \$107,000 for the three months ended September 30, 2005, due to the increased cash and cash equivalents resulting from the proceeds of our August 2005 initial public offering. The current period increase was partially offset by the interest expense incurred as a result of our long-term debt.

Other income. Other income was approximately \$85,000 for the three months ended September 30, 2005. Other income consists of research grants that were recognized as a result of the Enable acquisition.

Nine months ended September 30, 2005 compared to the nine months ended September 30, 2004

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

	Nine Months Ended September 30,			
	2005		2004	
	Amount	% of Revenue	Amount	% of Revenue
Revenues	\$22,398	100%	\$13,427	100%
Cost of revenues	5,913	26%	3,637	27%
Gross profit	16,485	74%	9,790	73%
Expenses:				
Research and development expenses	6,320	28%	2,918	22%
Selling, general and administrative expenses	16,671	75%	9,972	74%
Total operating expenses	22,991	103%	12,890	96%
Loss from operations	(6,506)	-29%	(3,100)	-23%
Preferred stock interest expense	(2,332)	-11%	(2,929)	-22%
Other interest income, net	122	1%	80	1%
Other income	85	0%	—	0%
Loss before taxes	(8,631)	-39%	(5,949)	-44%
Income tax expense	(42)	0%	(17)	0%
Net loss available to common shareholders	\$ (8,673)	-39%	\$ (5,966)	-44%

Revenues. Total revenues increased approximately \$9.0 million, from approximately \$13.4 million for the nine months ended September 30, 2004 to approximately \$22.4 million for the nine months ended September 30, 2005. The increase was primarily attributable to an increase in the volume of units sold domestically and internationally and the addition of our recently launched bipolar pen. The increase in units sold of our previously existing product line contributed approximately \$8.6 million of the total increase in sales, while the addition of the new pen product contributed approximately \$0.3 million to the increase in revenues. While our average domestic selling price increased approximately 6% for the nine months ended September 30, 2005 over the nine months ended September 30, 2004, the significant increase in the volume of lower priced international sales as a percentage of total sales resulted in a marginal decline in our overall average selling price for the nine months ended September 30, 2005 over the nine months ended September 30, 2004. This marginal decline in our selling price partially offset the overall revenue increase by approximately \$0.5 million.

[Table of Contents](#)

Cost of revenues. Cost of revenues increased approximately \$2.3 million, from approximately \$3.6 million for the nine months ended September 30, 2004 to approximately \$5.9 million for the nine months ended September 30, 2005 due to the approximately 72% increase in total units sold in the nine months ended September 30, 2005 as compared to the nine months ended September 30, 2004. As a percentage of revenues, cost of revenues declined from 27% for the nine months ended September 30, 2004 to 26% for the nine months ended September 30, 2005. The primary factor contributing to the decrease was lower cost per unit as a result of the increase in units purchased.

Research and development expenses. Research and development expenses increased approximately \$3.4 million, from approximately \$2.9 million for the three months ended September 30, 2004 to approximately \$6.3 million for the nine months ended September 30, 2005. The increase was primarily attributable to the addition of 28 full-time research and development personnel, of which 13 were former Enable employees, the expansion of our research and development activities to increase our product offerings and the expansion of our clinical trials. Our product development activities include projects to extend and improve the existing system, develop the new endoscopic ablation system, create new enabling devices such as new dissection, guidance and ablation tools, and research for new technologies. As a percentage of total revenues, research and development expenses increased from 22% for the nine months ended September 30, 2004 to 28% for the nine months ended September 30, 2005, due to increased spending on new product initiatives. We anticipate a continued increase in overall research and development spending as a percentage of revenues in the remainder of 2005.

Selling, general and administrative expenses. Selling, general and administrative expenses increased approximately \$6.7 million, from approximately \$10.0 million for the nine months ended September 30, 2004 to approximately \$16.7 million for the nine months ended September 30, 2005. The increase was primarily attributable to an increase in headcount-related charges of approximately \$4.9 million, an increase in educational grants to medical institutions and training expenditures of approximately \$1.0 million, and an increase in general corporate expenditures of approximately \$1.1 million. These increases were partially offset by lower temporary employee and consultant charges of approximately \$0.3 million. Headcount-related charges were primarily attributable to the rapid expansion of our sales force to meet our growing market and the acquisition of Enable. As a percentage of total revenues, selling, general and administrative expenses increased from 74% for the nine months ended September 30, 2004 to 75% for the nine months ended September 30, 2005.

Preferred stock interest expense. Preferred stock interest expense decreased approximately \$0.6 million, from approximately \$2.9 million for the nine months ended September 30, 2004 to approximately \$2.3 million for the nine months ended September 30, 2005. The decrease was attributable to the conversion of all shares of preferred stock into common stock upon the closing of our initial public offering on August 10, 2005.

Other interest income, net. Other interest income, net increased approximately \$42,000, from approximately \$80,000 for the nine months ended September 30, 2004 to approximately \$122,000 for the nine months ended September 30, 2005, due to increased cash and cash equivalents as a result of the August 2005 initial public offering. The current period increase was partially offset by the interest expense incurred as a result of our long-term debt.

Other income. Other income was approximately \$85,000 for the nine months ended September 30, 2005. Other income consists of research grants that were recognized as a result of the Enable acquisition.

Liquidity and Capital Resources

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

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

As of September 30, 2005, we had cash and cash equivalents of approximately \$38.3 million and short-term and long-term debt of approximately \$1.5 million, resulting in a net cash position of approximately \$36.8 million. We had working capital of approximately \$39.6 million and an accumulated deficit of approximately \$38.3 million as of September 30, 2005.

Cash flows used in operating activities. Net cash used in operations was approximately \$3.6 million for the nine months ended September 30, 2005 and \$2.4 million for the nine months ended September 30, 2004. For the nine months ended September 30, 2005, the increase in net cash used in operating activities was attributable primarily to the net losses after adjustments for non-cash depreciation and amortization, stock compensation and preferred stock interest and partially offset by a decrease in working capital requirements. For the nine months ended September 30, 2004, net cash used in operating activities was attributable primarily to the net losses after adjustments for non-cash depreciation, stock compensation and preferred stock interest and increases in working capital requirements.

Cash flows used in investing activities. Net cash used in investing activities was approximately \$7.9 million for the nine months ended September 30, 2005 and \$1.3 million for the nine months ended September 30, 2004. For each of these periods, cash used in investing activities reflected purchases of property and equipment and, for the nine months ended September 30, 2005, the net purchase price paid for the acquisition of Enable of approximately \$6.4 million.

Cash flows provided by financing activities. Cash flows provided by financing activities were approximately \$44.7 million for the nine months ended September 30, 2005 and approximately \$80,000 for the nine months ended September 30, 2004. For the nine months ended September 30, 2005, net cash provided by financing activities was attributable to the proceeds from the issuance of common stock related to our initial public offering, borrowings under our Lighthouse credit facility, and the issuance of common stock related to stock option exercises. For the nine months ended September 2004, net cash provided by financing activities was attributable to the issuance of common stock related to stock option exercises.

Credit facility. We entered into a \$5.0 million credit facility on March 8, 2005 with Lighthouse Capital Partners V, L.P. for working capital requirements. Outstanding borrowings under the facility bear interest at the prime rate plus 1.75% and our ability to draw down funds under this facility terminated upon our initial public offering. Under the terms of the facility, we are required to pay any monthly installments of interest only through August 2005 and monthly installments of principal and interest thereafter, in addition to a fee due at maturity on September 1, 2009 equal to 15% of the aggregate amount borrowed under the credit facility, with prepayment in whole allowed at any time without penalty. As of September 30, 2005, there was approximately \$1.5 million outstanding under this facility.

[Table of Contents](#)

In connection with entering this facility, we granted Lighthouse a warrant to purchase 55,208 shares of our common stock, or shares into which such series of stock is converted, at a price of \$11.29 per share. In valuing this warrant, we relied upon recognized option pricing models. The valuations used closed-form models, such as the Black-Scholes-Merton model and the Bjerksund and Stensland approximation model, as well as the lattice form binomial models. The time to expiration of the warrant ranges between 1.0 year and 7.0 years, and we assumed values for volatility and expected dividend yield equal to 35.0% and 0%, respectively. The risk-free discount rate used ranged between 3.23% and 4.22%. Utilizing these inputs in the option-pricing models for the warrant, a value for the warrant of \$3.91 per underlying share was determined, which has been recorded as deferred financing costs and will be amortized over the term of the credit facility.

In addition, we granted Lighthouse a first perfected lien on all our tangible and intangible assets, including accounts receivable, inventory, equipment, furniture and fixtures, but excluding intellectual property.

Uses of liquidity and capital resources. Our future capital requirements depend on a number of factors, including possible acquisitions and joint ventures, the rate of market acceptance of our current and future products, the resources we devote to developing and supporting our products, future expenses to expand and support our sales and marketing efforts, costs relating to changes in regulatory policies or laws that affect our operations and costs of filing, prosecuting, defending and enforcing our intellectual property rights. We expect to increase capital expenditures consistent with our anticipated growth in research and development, manufacturing, infrastructure and personnel. In addition, we acquired Enable contemporaneously with the closing of our initial public offering for aggregate payments by us of \$7.0 million.

We believe that net proceeds from our initial public offering, together with our current cash and cash equivalents, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months.

Contractual Obligations

Except as described below, during the three months ended September 30, 2005, there were no material changes outside the ordinary course of our business to our contractual obligations and commitments, which were discussed in the table appearing under "Management's Discussion and Analysis of Financial Condition and Results of Operations - Uses of liquidity and capital resources" in our Prospectus filed on August 8, 2005.

In July 2005, we entered into a development and license agreement with UST Inc., whereby UST agreed to design and develop a high intensity focused ultrasound, or HIFU, system to create certain types of lesions and granted us an exclusive, worldwide license to related technology. We believe that HIFU may be a valuable alternative source of energy for making certain kinds of lesions. We agreed to pay UST an initial development fee of \$375,000 and an additional development fee of \$966,000, payable in fourteen monthly installments. If UST has not completed its development services within fourteen months, we will be required to pay UST the direct costs incurred by it for the following six months in connection with continuing to render development services. We are also required to pay UST royalties of 4% of the net sales of the HIFU system, up to a maximum amount of \$15 million in royalties. In addition, we are required to make certain license and maintenance payments to UST for the sublicenses granted to us under the terms of this agreement. We may terminate this agreement at any time by giving notice to UST. UST may terminate this agreement if we fail to timely commercialize the HIFU system or if we fail to timely pursue FDA approval or clearance of the HIFU system. Under the terms of this agreement, we have certain indemnification obligations to UST for our breach of this agreement.

Off-balance-sheet arrangements

As of September 30, 2005 we do not have any off-balance-sheet arrangements.

Critical Accounting Policies and Estimates

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

[Table of Contents](#)

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

Stock-based compensation. We account for employee stock options using the intrinsic value method in accordance with Accounting Principles Board (“APB”) No. 25, Accounting for Stock Issued to Employees, Financial Accounting Standards (“FASB”) Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation, and related interpretations. We have adopted the disclosure-only provisions of Statement of Financial Accounting Standards (“SFAS”) No. 123, Accounting for Stock Based Compensation, as amended.

The information regarding net loss as required by SFAS No. 123, presented in Note 1 to our financial statements, has been determined as if we had accounted for our employee stock options under the fair value method. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the irregular impact of future years’ vesting.

Revenue recognition. Revenues are generated primarily from the sale of the AtriCure bipolar ablation system. Pursuant to our standard sales terms, revenue is recognized when title to the goods and risk of loss transfer to customers and there are no remaining obligations that will affect the customer’s final acceptance of the sale. Our standard sales terms define the transfer of title and risk of loss to occur upon shipment to the respective customer. We maintain no post-shipment obligations to the recipients of the products. No installation, calibration or testing of this equipment is performed by us subsequent to shipment to the customer in order to render it operational. Product revenues includes shipping revenues of approximately \$31,000 and \$25,000 for the three months ended September 30, 2005 and 2004, respectively and \$99,000 and \$62,000 for the nine months ended September 30, 2005 and 2004, respectively. Cost of freight is included in cost of goods sold. Commission income is recognized from sales of certain cryotherapy products as sales are made on which the commission is earned. We sell our products through a direct and indirect sales force. Sales terms are consistent for both end-users and distributors, with terms generally not exceeding 120 days. Customers and distributors generally have no right of return.

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

Inventory. Inventories are stated at the lower of cost or market using the first-in, first-out, or FIFO, cost method and consist of raw materials, work in process and finished goods.

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

Recent Accounting Pronouncements

In November 2004, the FASB issued FAS No. 151 entitled “Inventory Costs.” This Statement amends the guidance in ARB No. 43, “Inventory Pricing,” to clarify the accounting for abnormal amounts of idle facility expense, freight handling costs and wasted material (spoilage). The provisions of this Statement will be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company has not yet determined the impact that adopting SFAS No. 151 will have on its financial position and results of operations.

In December 2004, The Financial Accounting Standards Board (“FASB”) issued a revision to Statement of Financial Accounting Standards 123, “Share-Based Payment (“SFAS 123(R)”). The revision requires all entities to recognize compensation expense in an amount equal to the fair value of share-based payments granted to employees. SFAS 123(R) eliminates the alternative method of accounting for employee share-based payments previously

[Table of Contents](#)

available under Accounting Principles Board Opinion No. 25 (“APB 25”). In April 2005, the Securities and Exchange Commission delayed the effective date of SFAS 123(R) to fiscal years beginning after June 15, 2005. As a result, SFAS 123(R) will be effective for the Company beginning in the first quarter of fiscal 2006. We have not completed our evaluation of the impact that adopting SFAS 123(R) will have on the financial statements.

In March 2005, the FASB issued FASB Interpretation No. 47 (“FIN 47”), “Accounting for Conditional Asset Retirement Obligations.” This Interpretation clarifies that an entity is required to recognize a liability for the fair value of a conditional asset retirement obligation when incurred if the liability’s fair value can be reasonably estimated. The provisions of this Interpretation shall be effective for calendar-year companies no later than the end of fiscal years ending after December 31, 2005. The Company is currently evaluating the impact of the adoption of FIN 47 on its financial position and results of operations.

In May 2005, the FASB issued SFAS 154, “Accounting Changes and Error Corrections – A Replacement of Accounting Principles Board (APB) Opinion No. 20 and SFAS 3.” SFAS 154 requires retrospective application to prior periods’ financial statements for a change in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. Additionally, retrospective application is not required when explicit transition requirements specific to newly adopted accounting principles exist. Retrospective application requires the cumulative effect of the change on periods prior to those presented to be reflected in the carrying amounts of assets and liabilities as of the beginning of the first period presented and the offsetting adjustments to be recorded to opening retained earnings. SFAS 154 retains the guidance contained in APB No. 20 for reporting both the correction of an error in previously issued financial statements and a change in accounting estimate. SFAS 154 will become effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We are required to adopt the provisions of SFAS 154, as applicable, beginning in the first quarter of fiscal 2006.

Risk Factors

Risks Relating To Our Business

We expect to derive substantially all of our future revenues from sales of the AtriCure bipolar ablation system. If the AtriCure bipolar ablation system fails to gain or loses market acceptance for the treatment of AF, we may not generate sufficient revenues to continue our operations.

Currently, our primary product line is the AtriCure bipolar ablation system, which we commercially introduced in 2002 in the United States and in 2003 outside of the United States. We expect that sales of the AtriCure bipolar ablation system will account for substantially all of our revenues for the foreseeable future and that our future revenues will depend on the acceptance by the medical community of the AtriCure bipolar ablation system as a standard treatment alternative for the surgical treatment of AF during open-heart surgical procedures and as a sole-therapy minimally invasive treatment for AF.

Acceptance of our system for the treatment of AF is dependent upon, among other factors, the level of screening for AF and the awareness and education of the medical community about the surgical treatment of AF, in general, and the existence, effectiveness and safety of the AtriCure bipolar ablation system, in particular. Our system and the procedures involved with the treatment of AF using our system are relatively new. We cannot assure you that doctors will continue to use the AtriCure bipolar ablation system or that demand for the surgical treatment of AF will not decline or will increase as quickly as we expect.

We may not be able to maintain or increase market acceptance of the AtriCure bipolar ablation system for a number of additional reasons, including:

- our inability to promote our system for use on cardiac tissue or for the treatment of AF until we obtain additional FDA approvals or clearances;
- our inability to train doctors in the use of our system for the ablation of cardiac tissue or for the treatment of AF until we obtain additional FDA approvals or clearances;

[Table of Contents](#)

- our inability to establish or sustain acceptance of our system within the medical community;
- liability risks for doctors and hospitals associated with the off-label use of our system and the use of new technologies or procedures;
- findings or perceptions relating to the safety or effectiveness of our system or the safety or effectiveness of the surgical treatment of AF;
- medical device reports to the FDA and foreign regulatory authorities, which are required in the event our products malfunction or cause or contribute to a death, serious injury or other adverse event;
- publicity concerning our system, competing products or the surgical treatment of AF;
- the cost of our system;
- the availability of alternative treatments or procedures that may be, or may be perceived as, more effective, safer, faster, easier to use or less costly than our system; and
- policies of healthcare payors with respect to coverage and reimbursement.

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

Use of the AtriCure bipolar ablation system as a sole-therapy minimally invasive treatment for AF, which is not currently an established market, represents our major growth opportunity. If this market does not develop or our system is not widely adopted for use in this market, it may adversely impact our ability to grow our revenues.

We believe that sole-therapy minimally invasive treatment for AF, which is not currently an established market, will ultimately represent the largest segment of the market for the surgical treatment of AF. If this market fails to develop, or if our system is not widely adopted for use in this market, it may adversely impact our ability to grow our revenues. In order to establish the sole-therapy minimally invasive AF treatment market, doctors treating patients with AF who would not otherwise require an open-heart surgical procedure must change their current practice of referring patients to cardiologists and electrophysiologists and instead refer these patients to cardiothoracic surgeons for surgical AF treatment. Doctors may decide not to change their referral patterns for a variety of reasons including, for example, that limited clinical data is available relating to the safety and effectiveness of our system, that only a limited number of procedures have been performed using our system, that clinical testing of our system is in the feasibility stage, that doctors who refer their patients to cardiothoracic surgeons may risk losing their patients and that doctors may prefer to treat patients using drugs or catheter-based ablation. If doctors do not refer their patients to cardiothoracic surgeons for surgical AF treatment, we will not be able to establish a market for the use of our system for the sole-therapy minimally invasive treatment of AF, and our future growth and revenues will suffer.

The failure to educate or train a sufficient number of doctors in the use of the AtriCure bipolar ablation system could reduce the market acceptance of our system and reduce our revenues.

It is critical to the success of our sales efforts to ensure that there are a sufficient number of doctors familiar with, trained on and proficient in the use of our system. While we educate and train doctors as to the skills involved in the proper use of our system and technology, we cannot educate or train them to use our system for the ablation of cardiac tissue or the surgical treatment of AF unless and until we obtain additional FDA approvals or clearances. Currently, doctors learn to use our system for the treatment of AF through independent training programs provided

[Table of Contents](#)

by hospitals and universities and through independent peer-to-peer training among doctors. We provide research and educational grants to institutions, some of which are used to fund programs to teach the procedures involved in the surgical treatment of AF, including the use of our system for such treatment. However, while we make doctors generally aware of these programs, these institutions determine the faculty and the content of the programs. We also rely on doctors to independently inform their colleagues about these programs. We cannot assure you that a sufficient number of doctors will become aware of training programs or that doctors will dedicate the time, funds and energy necessary for adequate training in the use of our system.

Unless we obtain additional FDA approvals or clearances, we will not be able to promote the AtriCure bipolar ablation system to ablate cardiac tissue or to treat AF and our ability to maintain and grow our business could be harmed.

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

We have not received FDA clearance or approval to promote our system for the ablation of cardiac tissue or for the use of our system in the treatment of AF. In December 2004, we submitted a 510(k) notification to obtain clearance for use of our system for the ablation of cardiac tissue, which had previously been sought by us and denied in 2002 and 2003. In June 2005, the FDA denied 510(k) clearance, finding that our system was not substantially equivalent to the already cleared predicate devices relied on in our 510(k) notice. The FDA also noted in its letter that our system has been reclassified as a Class III device. This means that we would now be required to obtain a full PMA, rather than a 510(k), in order to gain FDA authorization of our system for the ablation of cardiac tissue. We may appeal the FDA's decision, but we cannot assure you that the FDA would agree to reverse its decision. If that appeal is not successful, we would not intend to pursue a PMA for the ablation of cardiac tissue using our system. Whether or not the FDA provides clearance for the use of the AtriCure bipolar ablation system to ablate cardiac tissue, we will need to obtain separate approvals from the FDA for use of the AtriCure bipolar ablation system in the treatment of AF as part of an open-heart procedure and as a sole-therapy minimally invasive procedure through the submission of separate PMAs to the FDA.

Unless and until we obtain FDA clearance or approval for the use of our system for the ablation of cardiac tissue or for the treatment of AF, we and others acting on our behalf may not promote our system for such uses, make any claim that our system is safe and effective for such uses, or proactively discuss or provide information on the use of our system in connection with such uses. These limitations put us at a disadvantage relative to our competitors who have received clearance or approval to market their products for the ablation of cardiac tissue.

We cannot assure you that future clearances or approvals of the AtriCure bipolar ablation system will be granted or that current or future clearances or approvals of the AtriCure bipolar ablation system will not be withdrawn. Failure to obtain a clearance or approval or loss of an existing clearance or approval, could hurt our ability to maintain and grow our business.

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

In order to obtain FDA approvals to promote the AtriCure bipolar ablation system for AF treatment, we will need to demonstrate in clinical trials that our system is safe and effective for such use. In order to conduct clinical trials, it is necessary to receive an investigational device exemption, or IDE, from the FDA. While we have obtained the required IDE from the FDA for the conduct of clinical trials for the use of our system as a treatment for AF during open-heart surgical procedures, the FDA or institutional review boards, or IRBs, that also oversee the trials for the

[Table of Contents](#)

purpose of protecting the study subjects can halt clinical trials at any time for safety reasons or because we or any of our clinical investigators do not follow the FDA's requirements for conducting clinical trials. In addition, the FDA may modify its requirements with respect to various aspects of our clinical study, in which case our ongoing clinical trial may not be achievable. Moreover, future clinical trials of our system to treat AF as a sole-therapy minimally invasive procedure will likely proceed in phases beginning with a feasibility trial. The FDA has granted us an IDE to conduct a feasibility study relating to the use of the AtriCure bipolar system for the sole-therapy minimally invasive treatment of AF, but there is no guarantee that the FDA will grant us approval to conduct clinical trials. If we are unable to receive approval to conduct clinical trials or the trials are halted by the FDA or others, we would not be able to promote the AtriCure bipolar ablation system for use in the treatment of AF in the United States.

While we have begun the RESTORE-SR trial, a clinical trial to support the submission of our PMA seeking FDA approval to use the AtriCure bipolar ablation system for the treatment of AF during elective open-heart procedures, enrollment in the trial has been slower than expected. As of September 30, 2005, we had enrolled approximately 15.9% of the treatment patients and approximately 9.2% of the total patients that are required to be enrolled in this study. We cannot assure you that this clinical trial will be completed in a timely manner or successfully or that the results obtained will be acceptable to the FDA.

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

Further, we cannot make comparative claims regarding the use of the AtriCure bipolar ablation system against any alternative treatments without conducting comparative clinical studies, which would be expensive and time consuming. We do not have any current plans to conduct such comparative clinical studies to evaluate the AtriCure bipolar ablation system against any alternative method of treatment.

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

If the results obtained from our clinical trials, any other clinical studies, or clinical or commercial experience indicate that our system is not safe or effective, or not as safe or effective as other treatment options, the FDA may not approve our system for the treatment of AF, adoption of the use of our system for the treatment of AF may suffer and our business would be harmed.

We 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 the AtriCure bipolar ablation system in the treatment of AF, which is considered an off-label use of our system because the sole indication for which our system has received FDA clearance or approval is the ablation and coagulation of soft tissues during certain non-cardiac-related surgical procedures. Under the Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products, including our system, for off-label uses. This means that we may not make claims about the safety or effectiveness of the AtriCure bipolar ablation system for the ablation of cardiac tissue or the treatment of AF and may not proactively discuss or provide information on the use of our system for the treatment of AF, except in certain limited scientific and other settings.

Due to these legal constraints, our sales and marketing efforts focus only on the general technical attributes and benefits of the AtriCure bipolar ablation system and not on the use of our system for AF treatment or other cardiac uses. At the same time, we provide certain support for the use of the AtriCure bipolar ablation system in the treatment of AF that we believe is non-promotional and therefore permitted. In particular, since our system is only being used by doctors for the treatment of AF, we train our sales force on the use of our system by cardiothoracic surgeons to treat AF, and off-label sales are included in our sales force compensation structure. Sales personnel call on cardiothoracic surgeons, electrophysiologists, and other doctors to discuss the general attributes of our system

[Table of Contents](#)

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

There is a material risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of these activities constitute the promotion of our system for a non-FDA-approved use in violation of the law. We also face the risk that FDA or other regulatory authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities.

Government investigations concerning the promotion of off-label uses and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and would likely be required to change substantially our sales, promotion, grant and educational activities. For example, in November 2004, we received a letter from the FDA relating to certain cardiac-related information on our website in connection with the AtriCure bipolar ablation system, which we subsequently removed. There is also a possibility that we could be enjoined from making sales of the AtriCure bipolar ablation system for any non-FDA-approved use, which effectively would bar all sales of our system until we receive FDA clearances or approval, if ever. In addition, as a result of enforcement actions against us or our senior officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid.

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

The use of products we sell may result in a variety of serious complications, including damage to the heart, internal bleeding, death, or other adverse events, potentially leading to product liability claims. Serious complications, including death, have been encountered in connection with the surgical treatment of AF, including in connection with a limited number of sole-therapy minimally invasive procedures in which our system was used. Although our manufacturing processes and those of our suppliers are required to comply with the FDA's quality system regulations, or QSR, covering the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products, if products we sell are defectively designed, manufactured or labeled, contain inadequate warnings, contain defective components or are misused, we may become subject to costly litigation by our customers or their patients.

We carry product liability insurance that is limited in scope and amount and may not be adequate to fully protect us against product liability claims. We could be required to pay damages that exceed our insurance coverage. Any product liability claim, with or without merit, could result in an increase in our product liability insurance rates or our inability to secure coverage on reasonable terms, if at all. Even in the absence of a claim, our insurance rates may rise in the future. Any product liability claim, even a meritless or unsuccessful one, would be time consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, withdrawal of clinical trial volunteers, injury to our reputation and loss of revenues. Any of these events could negatively affect our earnings and financial condition.

Our current inability to educate or train doctors in the use of the AtriCure bipolar ablation system for the treatment of AF, due to legal prohibitions on off-label promotion of medical devices, could result in injuries to patients or other adverse events that lead to litigation against us, which could be costly to our business.

Our sales team educates doctors in the technology and general application of the AtriCure bipolar ablation system, but we cannot currently educate or train doctors to use our system for the ablation of cardiac tissue or for the surgical treatment of AF.

[Table of Contents](#)

Hospitals and universities offer independent educational programs for the treatment of AF utilizing the AtriCure bipolar ablation system, and there is independent doctor-to-doctor training to use our system for the treatment of AF. We do not require that doctors who use the AtriCure bipolar ablation system have any specific training in the use of our system. We cannot assure you that doctors utilizing our system are using it correctly. Because we rely on training by hospitals and universities and doctor-to-doctor training, we do not control the quality of the training received by the doctors who use our system. Not requiring training on the use of our system may expose us to greater risk of product liability for injuries occurring during procedures utilizing the AtriCure bipolar ablation system. If demand for the AtriCure bipolar ablation system grows, the increased number of procedures performed using our system may potentially lead to more injuries and an increased risk of product liability. In addition, the off-label use of our system by the doctors may expose us to greater risks relating to product liability claims.

Serious complications arising out of surgical procedures for the treatment of AF, including surgical AF treatments involving our system, could harm our business in a variety of important ways.

Serious complications, including death, have been encountered in connection with the surgical treatment of AF, including in connection with a limited number of sole-therapy minimally invasive procedures in which our system was used. The rate of serious complications associated with surgical AF treatments in general, or surgical AF treatments involving the use of our system in particular, may be greater than the rate of serious complications associated with alternative therapies for the treatment of AF or AF itself.

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

- our system may fail to gain or may lose market acceptance;
- the market for the sole-therapy minimally invasive treatment of AF may fail to develop;
- the medical community may fail to adopt our system for the sole-therapy minimally invasive treatment of AF;
- the FDA or foreign regulatory authorities may revoke the clearances or approvals they have granted for the use of our system for the ablation of soft tissue;
- the FDA or foreign regulatory authorities may refuse, delay or revoke clearances, approvals or clinical trials of our system for the ablation of cardiac tissue or the treatment of AF;
- the FDA or other domestic or foreign regulatory or enforcement authorities may be more likely than otherwise to pursue an action against us for promoting our products for off-label uses; and
- we may be subject to product liability claims.

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

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

The medical device industry, including the market for the treatment of AF, is highly competitive, subject to rapid technological change and significantly affected by new product introductions and promotional activities of other participants. We cannot assure you that the AtriCure bipolar ablation system will compete effectively against drugs, catheter-based ablation, implantable devices such as pacemakers or defibrillators, other bipolar ablation systems or other surgical AF treatments, which may be more well-established among doctors and hospitals. Many companies are promoting devices for the treatment of AF, and we anticipate that new or existing competitors may develop

[Table of Contents](#)

competing products, procedures or clinical solutions. There are few barriers to prevent new entrants or existing competitors from developing products to compete directly with ours. Some companies also compete with us to attract qualified scientific and technical personnel as well as funding. Our primary competitors include Guidant Corp., Medtronic, Inc., St. Jude Medical Inc., Boston Scientific Corporation, Edwards Lifesciences Corporation and CryoCath Technologies Inc. These companies are larger than AtriCure or enjoy competitive advantages, including:

- broader product offerings;
- established and more comprehensive distribution networks;
- less expensive products and procedures that take less time to perform;
- greater resources, including financial resources and more extensive experience in product development, manufacturing, regulatory clearance and approval, promotion, distribution and selling and patent litigation; and
- established relationships with hospitals, healthcare providers and payors.

Some competitors have FDA clearance for the use of their products to ablate cardiac tissue or FDA approval for the use of their products to ablate cardiac tissue during open-heart surgery. Our competitors are currently conducting clinical trials for the use of their products in the treatment of AF, which if successful, may impact the future sales of the AtriCure bipolar ablation system. Furthermore, demand for the AtriCure bipolar ablation system could be diminished by equivalent or superior products and technologies being offered by competitors, including products utilizing bipolar technology which could prove to be more effective, faster, safer or less costly than the AtriCure bipolar ablation system. The introduction of new products, procedures or clinical solutions by competitors may result in price reductions, reduced margins or loss of market share and may render our products obsolete, which could adversely affect our net revenues and future profitability.

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

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our patent applications may not issue as patents at all or in a form that will be advantageous to us. Our issued patents and those that may issue in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. Although we have taken steps to protect our intellectual property and proprietary technology, we cannot assure you that third parties will not be able to design around our patents or, if they do infringe upon our technology, that we will be successful in or have sufficient resources to pursue a claim of infringement against those third parties. We believe that third parties may have developed or are developing products that could infringe upon our patent rights. Any pursuit of an infringement claim by us may involve substantial expense or diversion of management attention. In addition, although we have entered into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, investigators and advisors, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

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

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

Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Any patent dispute, even a meritless or unsuccessful one, would be time consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, the disruption of development and marketing efforts, injury to our reputation and loss of revenues. Any of these events could negatively affect our earnings and financial condition.

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

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

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

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

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

Insurance carriers have been raising premiums charged for medical malpractice insurance due, at least in part, to increased risks associated with off-label procedures, including higher damage awards for successful 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 revenues may fall as doctors or hospitals decide against purchasing the AtriCure bipolar ablation system due to the cost or unavailability of insurance coverage.

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

We have a limited operating history and have incurred net losses each year since our inception, including net losses available to common shareholders of \$9.0 million in 2002, \$7.1 million in 2003 and \$9.5 million in 2004. As of September 30, 2005, we had an accumulated deficit of approximately \$38.3 million.

[Table of Contents](#)

Our net losses available to common shareholders have resulted principally from costs and expenses relating to sales and promotional efforts, research and development, seeking regulatory clearances and approvals, and general operating expenses. We expect to continue to make substantial expenditures and to incur additional operating losses in the future as we expand our sales, manufacturing, marketing and product development activities, increase our administrative staff and further develop and commercialize our products, including completing clinical trials and seeking regulatory clearances and approvals for the AtriCure bipolar ablation system. If sales of our system do not continue to grow as we anticipate, we will not be able to achieve profitability. Our expansion efforts may prove more expensive than we currently anticipate, and we may not succeed in increasing our revenues sufficiently to offset these higher expenses. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and shareholders' deficit and we may never become profitable.

Our federal tax net operating loss carryforwards will be limited or lost, resulting in greater income tax expense because we experienced an ownership change of more than 50 percentage points upon the initial public offering of our common stock.

In connection with our initial public offering in August 2005, we experienced an ownership change as defined by the Internal Revenue Code of 1986 that will limit the availability of our net operating loss carryforwards to offset any future taxable income, which may increase our future income tax expense. Our inability to use these net operating loss carryforwards to reduce taxable income is based on an ownership change of more than 50 percentage points under rules contained in the United States Internal Revenue Code. We had federal income tax net operating loss carryforwards of approximately \$16.3 million at December 31, 2004 that, if not utilized to reduce our taxable income, will begin to expire in 2021.

Our capital needs after the next 12 months are uncertain and we may need to raise additional funds in the future and such funds may not be available on acceptable terms, if at all.

We believe that our current cash, cash equivalents and short-term investments, will be sufficient to meet our projected capital requirements for at least the next 12 months. Our capital requirements will depend on many factors, including:

- the revenues generated by sales of our products;
- the costs associated with expanding our manufacturing and marketing activities, as well as sales and distribution efforts;
- the rate of progress and cost of our research and development activities;
- the costs of obtaining and maintaining FDA and other regulatory clearances and approvals of, and intellectual property protection for, our products and products in development;
- the effects of competing technological and market developments; and
- the number and timing of acquisitions and other strategic transactions.

As a result of these factors, we may need to raise additional funds, and we cannot be certain that such funds will be available to us on acceptable terms, if at all. Furthermore, if we issue equity securities to raise additional funds, our existing shareholders may experience dilution, and if we issue equity or debt securities, such securities may have rights, preferences and privileges senior to those of our existing shareholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our future products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise funds on acceptable terms, we may not be able to expand our operations, develop new products, take advantage of future opportunities or respond to competitive pressures or unanticipated customer requirements.

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

The growth that we have experienced and that we may experience in the future requires us to rapidly expand our sales personnel and manufacturing operations. Our United States sales and training force increased from 10 employees on January 1, 2003 to 46 employees as of September 30, 2005, and we expect to continue to grow. As a result of the closing of the initial public offering, we purchased Enable, the manufacturer of our single-use disposable handpieces. As of September 30, 2005, we have a total of 151 employees. Rapid expansion in personnel could result in unanticipated costs and disruptions to our operations. Organizational growth could strain our existing managerial, operational, financial and other resources. We will need to expand our current, or implement new, financial and operating systems, which may be costly and time-consuming.

For us to maintain and expand our business successfully, we must manufacture commercial quantities of our system's components, as well as components for other existing and future products, in compliance with regulatory requirements, including the FDA's Quality System Regulation, or QSR, at an acceptable cost and on a timely basis. Our anticipated growth may strain our ability to manufacture an increasingly large variety and supply of our products. Manufacturing facilities often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. If we cannot scale and manage our business or our manufacturing operations appropriately, maintain control over expenses or otherwise adapt to future growth, our growth may be impaired and our future revenue and operating results will suffer.

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

We currently rely on single and limited source third-party vendors for the manufacture of many of the components used in the AtriCure bipolar ablation system. For example, we rely on one vendor to manufacture our ablation sensing unit, or ASU, and we have not been able to identify any alternate supplier to manufacture our ASU, or our single-use disposable handpieces, bipolar pen or Wolf dissector if we become unable to do so. In addition, in some cases there are relatively few, or no, alternative sources of supply for certain other components that are critical to the AtriCure bipolar ablation system. We also distribute a cryotherapy, or extreme cold, ablation device that doctors have used to make specialized lesions in the heart for the treatment of AF in addition to the lesions made by the AtriCure bipolar ablation system, and our inability to offer this device to potential users of our system could negatively affect sales of our system.

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

- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- we may have difficulty locating and qualifying alternative suppliers;
- switching components may require product redesign and new submissions to the FDA which could significantly delay production or, if the FDA refuses to approve the changes, completely eliminate our ability to manufacture or sell our system;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products those suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

Identifying and qualifying additional or replacement suppliers for any of the components used in the AtriCure bipolar ablation system, if required, may not be accomplished quickly or at all and could involve significant additional costs. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products, and could therefore have a material adverse effect on our business, financial condition and results of operations.

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

To mitigate the risk of supply interruptions, we may determine to maintain excess inventory of the products or components supplied to us by third parties. Managing our inventory levels is important to our cash position and results of operations. As we expand, managing our inventory levels becomes more difficult. An excessive amount of inventory reduces our cash available for operations and may result in excess or obsolete materials. Inadequate inventory levels may make it difficult for us to meet customer product demand, resulting in decreased revenues. An inability to forecast future revenues or estimated life cycles of products may result in inventory-related charges that would negatively affect our gross margins and results of operations.

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

Our manufacturing facility and the manufacturing facility of any of our third-party component manufacturers, critical suppliers or third-party sterilization facility are required to comply with the FDA's quality systems regulations, or QSR, which sets forth minimum standards for the procedures, execution and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our systems. The FDA may enforce its QSR, among other ways, through periodic unannounced inspections. If our manufacturing facility or the manufacturing facility of any of our third-party component manufacturers, critical suppliers or third-party sterilization facility, fails a QSR inspection, our and their operations could be disrupted, and manufacturing interrupted. Failure to take adequate and timely corrective action in response to an adverse QSR inspection could force a shutdown of our manufacturing operations or a recall of our products. Adverse QSR inspections could delay FDA approval of our system and could have an adverse effect on our production, sales and profitability. We and any of our third party vendors may also encounter other problems during manufacturing including failure to follow specific protocols and procedures, equipment malfunction and environmental factors, any of which could delay or impede our ability to meet demand. The manufacture of our product also subjects us to risks that could harm our business, including problems relating to the sterilization of our products or facilities and errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products. Any interruption or delay in the manufacturer of the product or any of its components could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products, and could therefore have a material adverse effect on our business, financial condition and results of operations.

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

Our products are classified by the FDA as medical devices and as such are subject to extensive regulation in the United States by the FDA and numerous other federal, state and foreign governmental authorities. FDA regulations, guidance, notices and other issuances specific to medical devices are broad and regulate, among other things:

- product design, development, manufacturing and labeling;
- product testing, including electrical testing, transportation testing and sterility testing;
- pre-clinical laboratory and animal testing;
- clinical trials in humans;
- product safety, effectiveness and quality;

[Table of Contents](#)

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

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

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

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing or delaying our pending requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

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

We are also subject to medical device reporting regulations that require us to file reports with the FDA if our products reasonably are the cause of or contribute to an adverse event, death, serious injury or in the event of product malfunction. As of October 31, 2005, we have submitted a total of ten medical device reports to the FDA involving the AtriCure bipolar ablation system. There have been other incidents that have occurred during open-heart and sole-therapy minimally invasive procedures using our system that we have not, and believe were not required to be, reported to the FDA, including two patient deaths. If the FDA disagrees with us, however, and determines that we should have submitted reports for these adverse events, we could be subject to significant regulatory fines or other penalties. In addition, the number of medical device reports we make, or the magnitude of the problems reported, could cause the FDA or us to terminate or modify our clinical trials or recall or cease the sale of our products, and could hurt commercial acceptance of our product in the market.

Modifications to the AtriCure bipolar ablation system may require new clearances or approvals or require us to cease promoting or recall the modified products until such clearance or approvals are obtained.

Any modification to a 510(k)-cleared device that would constitute a change in its intended use, design or manufacture, could require a new 510(k) clearance or, possibly, submission and FDA approval of a PMA. The FDA requires every medical device company to make the determination as to whether a new 510(k) is to be filed in the first instance, but the FDA may review any medical device company's decision. We have previously made modifications to the AtriCure bipolar ablation system but do not believe such modifications require us to submit an additional 510(k) clearance. The FDA may not agree with our decisions regarding whether new clearances or approvals are required. If the FDA disagrees with us and requires us to submit a new 510(k) or PMA for then-existing modifications, we may be required to cease promoting or to recall the modified product until we obtain clearance or approval. In addition, we could be subject to significant regulatory fines or other penalties. Furthermore, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Delays in receipt or failure to receive clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects.

We will spend considerable time and money complying with federal, state and foreign regulations in addition to FDA regulations, and, if we are unable to fully comply with such regulations, we could face substantial penalties.

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

- state food and drug laws, including laws regulating the manufacture, promotion and distribution of medical devices;
- state consumer protection, fraud and business practice laws;
- the federal Anti-Kickback Statute, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid Programs;
- the federal False Claims Act, which prohibits submitting a false claim or causing of the submission of a false claim to the government;
- Medicare laws and regulations that prescribe the requirements for coverage and payment, including the amount of such payment, and laws prohibiting false claims for reimbursement under Medicare and Medicaid;
- 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;

[Table of Contents](#)

- state laws that prohibit the practice of medicine by non-doctors and by doctors not licensed in a particular state, and fee-splitting arrangements between doctors and non-doctors, as well as state law equivalents to the Anti-Kickback Statute and the Stark Law, which may not be limited to government-reimbursed items;
- Federal and State healthcare fraud and abuse laws or laws protecting the privacy of patient medical information, including the Health Insurance Portability and Accountability Act, or HIPAA;
- the Federal Trade Commission Act and similar laws regulating advertising and consumer protection; and
- similar and other regulations outside the United States.

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

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

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

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

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

[Table of Contents](#)

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

Adverse changes in payors' policies toward coverage and reimbursement for surgical AF treatment would harm our ability to promote and sell the AtriCure bipolar ablation system.

Third-party payors are increasingly exerting pressure on medical device companies to reduce their prices. Even to the extent that the treatment of AF using the AtriCure bipolar ablation system is reimbursed by private payors and governmental payors, adverse changes in payors' policies toward coverage and reimbursement for surgical AF treatment would also harm our ability to promote and sell the AtriCure bipolar ablation system. Payors continue to review their policies and can, without notice, deny coverage for treatments that include the use of our product. 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 the AtriCure bipolar ablation system. Alternatively, government or private payors may deem the treatment of AF utilizing the AtriCure bipolar ablation system experimental or not medically necessary and, as such, not provide coverage.

Adverse changes in coverage and reimbursement for surgical AF treatment could harm our business and reduce our revenues.

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

Our success depends upon our system's acceptance by the medical community as safe and effective in the treatment of AF. Serious complications, including death, have been encountered in connection with the surgical treatment of AF, including in connection with a limited number of sole-therapy minimally invasive procedures in which our system was used. Important factors upon which the efficacy of our system will be measured include long-term data on the number of patients that continue to experience AF following treatment with our system and the number of patients that have serious complications resulting from AF treatment using our system. Our clinical trials may produce limited data regarding the efficacy of our system for the treatment of AF, or may identify unexpected safety issues. We cannot provide any assurance that the data collected during our clinical trials will be compelling to the medical community or to the FDA, because it may not be scientifically meaningful and may not demonstrate that the AtriCure bipolar ablation system is an attractive procedure when compared against data from alternative procedures and products. In addition, the long-term effects of the AtriCure bipolar ablation system procedure are not known.

The results of short-term clinical experience of the AtriCure bipolar ablation system do not necessarily predict long-term clinical benefit. If the long-term clinical trial results are not as positive as the short-term results or the long-term results do not otherwise meet doctors' expectations, the FDA may not approve our system for the treatment of AF, the AtriCure bipolar ablation system may not become widely adopted, and doctors may recommend alternative treatments for their patients. Another significant factor is acute safety data on complications that occur during the treatment of AF during open-heart surgical procedures and as a sole-therapy minimally invasive treatment.

If the results obtained from our RESTORE-SR trial or any other clinical studies or clinical or commercial experience indicate that the AtriCure bipolar ablation system is not safe or effective, or not as safe or effective as other treatment options or than current short-term data would suggest, the FDA may not approve our system for the treatment of AF, adoption of the use of our system for the treatment of AF may suffer and our business would be harmed.

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

[Table of Contents](#)

procedures performed by doctors who are technically proficient. Consequently, both short- and long-term results reported in these studies may be significantly more favorable than typical results of practicing doctors, which could negatively impact rates of adoption of the AtriCure bipolar ablation system.

We sell the AtriCure bipolar ablation system outside of the United States and are subject to various risks relating to international operations, which could harm our international revenues and profitability.

During the nine months ended September 30, 2005, approximately 9.4% of our total revenues were attributable to sales in markets outside of the United States. We currently depend on third-party distributors to sell the AtriCure bipolar ablation system outside of the United States, and if these distributors underperform, we may be unable to increase or maintain our level of international revenue. Over the long term, we intend to grow our business outside of the United States, and to do so we will need to attract additional distributors or hire direct sales personnel to expand the territories in which we sell the AtriCure bipolar ablation system. Distributors may not commit the necessary resources to promote and sell our system to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, we may not realize expected long-term international revenue growth.

Doing business outside of the United States exposes us to risks distinct from those we face in our domestic operations. For example, our operations outside of the United States are subject to different regulatory laws and requirements in each jurisdiction where we operate or have sales. Our or our distributors' failure to comply with current or future foreign regulatory requirements, or the assertion by foreign authorities that we or they have failed to comply, could result in adverse consequences, including enforcement actions, fines and penalties, recalls, cessation of sales, civil and criminal prosecution, and the consequences could be disproportionate to the relative contribution of our international operations to our results of operations. Moreover, if political or economic conditions deteriorate in these countries, our ability to conduct our international operations could be limited and the costs could be increased, which could negatively affect our operating results. Engaging in business outside of the United States inherently involves a number of other difficulties and risks, including:

- export restrictions and controls relating to technology;
- pricing pressure that we may experience internationally;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs and other trade barriers;
- the need to hire additional personnel to promote our system outside of the United States;
- international terrorism and anti-American sentiment;
- fluctuations in exchange rates for future sales denominated in non-United States currency; and
- difficulties in obtaining and enforcing intellectual property rights.

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

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

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

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

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and technologies. Accordingly, we may in the future pursue the acquisition of, or joint ventures relating to, complementary businesses, products or technologies instead of developing them ourselves. We have no current commitments with respect to any acquisition or investment. We do not know if we will be able to successfully complete any acquisitions or joint ventures, or future acquisitions or joint ventures, or whether we will be able to successfully integrate any acquired business, product or technology or retain any key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we are unable to integrate any acquired businesses, products or technologies effectively, our business will suffer. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses.

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

We are highly dependent on the skills and experience of our President and Chief Executive Officer, David J. Drachman, our Chief Technology Officer, Michael D. Hooven, and other employees. We do not have any insurance in the event of the death or disability of our key personnel other than Mr. Drachman and Mr. Hooven. We do not currently have any employment agreements with any of our officers 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 the AtriCure bipolar ablation system and our operations and the limited pool of people with relevant experience in the medical device field, the loss of service of one or more of these individuals could significantly affect our ability to operate and manage our business. In particular, the departure of our Chief Technology Officer may impair our ability to develop new, advanced technologies. 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 the AtriCure bipolar ablation system and further develop products, while managing anticipated growth by implementing effective planning, manufacturing and operating processes. Managing this growth will require us to attract and retain additional management and technical personnel. Our offices are located in West Chester, Ohio where it is difficult to attract and retain employees with experience in the medical device industry. We rely on direct sales employees and manufacturer's representatives to sell the AtriCure bipolar ablation system in the United States. We plan to expand our sales team and failure to adequately train our employees in the use and benefits of our products will prevent us from achieving our market share and revenue growth goals. In addition, we have key relationships with doctors that involve procedure and tool development, market development and clinical development. If any of these doctors end their relationship with us, our business would be negatively

[Table of Contents](#)

impacted. We cannot assure you that we will be able to attract and retain the personnel and doctor relationships necessary to grow and expand our business and operations. If we fail to identify, attract, retain and motivate these highly skilled personnel and doctors, we may be unable to continue our development and sales activities.

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

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

Risks Relating To Our Common Stock

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

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

- doctor and patient acceptance of the surgical treatment of AF using our system;
- adverse regulatory developments with respect to our products, such as recalls, new regulatory requirements, changes in regulatory requirements or guidance and timing of regulatory clearances and approvals for new products;
- coverage and reimbursement determinations for our products and the related procedures;
- the timing of orders received; delays or interruptions in manufacturing or shipping of our products;
- pricing of our products;
- media reports and publications and announcements about products or new innovations that could compete with our products or about the medical device product segment in general;
- market conditions or trends related to the medical device and healthcare industries or the market in general;
- additions to or departures of our key personnel;
- disputes, litigation or other developments relating to proprietary rights, including patents, and our ability to obtain patent protection for our technologies;

[Table of Contents](#)

- changes in financial estimates, investors' perceptions or recommendations by securities analysts;
- variations in our quarterly financial and operating results; and
- changes in accounting principles.

These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. If our quarterly 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 comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

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

We have approximately 12.1 million shares of common stock outstanding as of October 31, 2005. The 4,600,000 shares sold in our initial public offering are freely tradable without restriction under the federal securities laws unless purchased by our affiliates. The remaining shares of common stock outstanding are available for public sale subject in some cases to volume and other limitations. Substantially all of these remaining shares are subject to the lock-up agreements with certain underwriters.

If our common shareholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock could fall. The holders of approximately 6,012,020 shares of our common stock and the holders of warrants to purchase 250,368 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. Furthermore, if we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registration rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

In addition, we may need to raise capital in the future to fund our operations. If we raise funds by issuing equity securities, our stock price may decline and our existing shareholders may experience significant dilution. Furthermore, we may enter into financing transactions at prices that represent a substantial discount to market price. A negative reaction by investors and securities analysts to any sale of our equity securities could result in a decline in the trading price of our common stock.

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

As of September 30, 2005, our executive officers, directors and principal shareholders, and entities affiliated with them, beneficially owned in the aggregate greater than 50% of our common stock following our offering. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling shareholders. These shareholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our shareholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

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

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

- authorizing the issuance without further approval of “blank check” preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of shareholders to elect director candidates;
- limiting the ability to remove directors;
- limiting the ability of shareholders to call special meetings of shareholders;
- prohibiting shareholder action by written consent, thereby requiring all shareholder actions to be taken at a meeting of shareholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by shareholders at shareholder meetings.

In addition, Section 203 of the Delaware General Corporation Law limits business combination transactions with 15% shareholders 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 shareholders. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace the current management team. If a change of control or change in management is delayed or prevented, you may lose an opportunity to realize a premium on your shares of common stock or the market price of our common stock could decline.

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

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. Furthermore, we may in the future become subject to 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 will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. These requirements may place a strain on our systems and resources. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight will be required. This may divert management’s attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and we cannot assure you that we will be able to do so in a timely fashion.

Item 3. Quantitative and Qualitative Disclosures About Market Risks

We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions.

For the nine months ended September 30, 2005, none of our sales were denominated in currencies other than U.S. dollars. Although all of our sales and purchases are currently denominated in U.S. dollars, future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products outside the United States. We invest our excess cash primarily in U.S. government securities, corporate bonds and commercial paper. Accordingly, we believe that, while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

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

As required by SEC Rule 13a-15(b), an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this report was carried out under the supervision and with the participation of our management, including our chief executive officer and chief financial officer. Based on that evaluation, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are effective at the reasonable assurance level to ensure that material information relating to us, is made known to them, particularly during the period in which this report was prepared, in order to allow timely decisions regarding required disclosure.

Internal Control Over Financial Reporting

Our management, with the participation of our chief executive officer and chief financial officer, also conducted an evaluation of our internal control over financial reporting to determine whether any changes occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, there was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not a party to any pending or threatened litigation, except as described in the following sentences. A competitor filed a suit on August 3, 2005 that seeks an injunction to prevent us from continuing to employ its former employee (who commenced employment with us two days earlier) as a sales representative and that makes related claims against the employee and us, including requests for damages in an unspecified amount. While we cannot provide any assurances as to the ultimate outcome of this suit, given the information currently known by us, we do not currently expect the outcome of this suit to have a material adverse effect upon us. We may from time to time become a party to additional legal proceedings.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) Unregistered Sales of Equity Securities

During the quarter ending September 30, 2005, we granted options to purchase an aggregate of 179,107 shares of our common stock at an exercise price ranging from \$12.00 to \$13.89 per share.

The grants of the options were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act, or Regulation D and the other rules and regulations promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions not involving a public offering or transactions under compensatory benefit plans. The recipients of such options were our employees, directors or bona fide consultants and received the securities pursuant to our 2001 Stock Option Plan or 2005 Equity Incentive Plan. Each of the recipients of securities in these transactions had adequate access, through employment, business or other business relationships, to information about us.

(b) Initial Public Offering and Use of Proceeds from the Sale of Registered Securities

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

During the quarter ended September 30, 2005, we spent \$6.4 million of the proceeds from the offering toward the acquisition of Enable Medical Corporation, approximately \$375,000 toward our obligations under a development and license agreement, approximately \$2.6 million on research and development activities related to product development, clinical trials and regulatory approvals and approximately \$6.3 million on selling, general and administrative purposes. Pending use of the remaining net proceeds of the offering, we intend to invest such proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments.

We have not yet determined the amount or timing of the expenditures for each of the categories listed above and these expenditures may vary significantly depending on a variety of factors, including the timing of additional regulatory approvals and new product introductions. As a result, we will retain broad discretion in the allocation and use of the net proceeds of the offering.

(c) Repurchases of Equity Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

On July 15, 2005, our stockholders acted by written consent to approve and adopt our 2005 Equity Incentive Plan, a certificate of amendment of our certificate of incorporation effecting a 1-for-3.8 reverse stock split of our outstanding capital stock and certain other changes, our amended and restated certificate of incorporation that became effective upon the closing of our initial public offering, and our second amended and restated by-laws that became effective upon the closing of our initial public offering.

Stockholders holding an aggregate of 20,819,459 shares of our capital stock, 7,035,753 shares of our Series A convertible preferred stock and 12,828,706 shares of our Series B convertible preferred stock approved each of the above matters and stockholders holding approximately 9,240,250 shares of our capital stock, 1,257,826 shares of our Series A convertible preferred stock and 1,723,391 shares of our Series B convertible preferred stock did not vote with respect to the above matters.

The above action was effected pursuant to an action by written consent of our stockholders in compliance with Section 228 of the Delaware Corporation Law.

[Table of Contents](#)

Item 6. Exhibits

(a) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
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

(b) Reports on Form 8-K.

On August 16, 2005, we filed with the SEC a Current Report on Form 8-K reporting the consummation of our acquisition of Enable Medical Corporation.

On September 9, 2005, we furnished the SEC with a Current Report on Form 8-K reporting the public dissemination of a press release announcing our financial results for the quarter ended June 30, 2005.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AtriCure, Inc.
(REGISTRANT)

Date: November 15, 2005

/s/ David J. Drachman

David J. Drachman
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 15, 2005

/s/ Thomas J. Etergino

Thomas J. Etergino
Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David J. Drachman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AtriCure, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others, particularly during the period in which this report is being prepared;
 - b. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2005

By: /s/ David J. Drachman

David J. Drachman
President and Chief Executive Officer and Director
(Principal Executive Officer)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Thomas J. Etergino, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AtriCure, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others, particularly during the period in which this report is being prepared;
 - b. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2005

By: /s/ Thomas J. Etergino

Thomas J. Etergino
Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of AtriCure, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David J. Drachman, President and Chief Executive Officer and Director of the Company, certify, pursuant to Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 15, 2005

By: /s/ David J. Drachman

David J. Drachman
President and Chief Executive Officer and Director
AtriCure, Inc.

A signed original of this written statement or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement has been provided to AtriCure, Inc. and will be retained by AtriCure, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-Q or as a separate disclosure document.

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of AtriCure, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas J. Etergino, Vice President and Chief Financial Officer of the Company, certify, pursuant to Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 15, 2005

By: /s/ Thomas J. Etergino

Thomas J. Etergino
Vice President and Chief Financial Officer
AtriCure, Inc.

A signed original of this written statement or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement has been provided to AtriCure, Inc. and will be retained by AtriCure, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-Q or as a separate disclosure document.