

RITA MEDICAL SYSTEMS INC  
Form 10-Q  
November 07, 2006  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended September 30, 2006

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 000-30959

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**RITA MEDICAL SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction of  
incorporation or organization)

46421 Landing Parkway  
Fremont, CA 94538

94-3199149  
(I.R.S. Employer  
Identification No.)

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(Address of principal executive offices, including zip code)

510-771-0400

(Registrant's telephone number, including area code)

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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 past 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 a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer  Accelerated Filer  Non-Accelerated Filer

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

As of October 31, 2006, there were 43,248,964 shares of the Registrant's common stock outstanding.

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**Table of Contents****PART 1. FINANCIAL INFORMATION****Item 1. Financial Statements****RITA MEDICAL SYSTEMS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except per share data)**

	September 30, 2006 (unaudited)	December 31, 2005
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 6,434	\$ 5,522
Accounts and note receivable, net of allowance for doubtful accounts of \$958 at September 30, 2006 and \$1,077 at December 31, 2005	7,442	7,264
Inventories	5,703	5,380
Prepaid and other current assets	1,149	941
<b>Total current assets</b>	<b>20,728</b>	<b>19,107</b>
Long term note receivable, net of collection allowance of \$31 at December 31, 2005		58
Property and equipment, net	1,724	1,959
Goodwill	91,339	91,339
Intangible assets, net	21,878	23,502
Other assets	420	502
<b>Total assets</b>	<b>\$ 136,089</b>	<b>\$ 136,467</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,185	\$ 2,091
Accrued liabilities	3,989	3,306
Current portion of long term debt		113
<b>Total current liabilities</b>	<b>6,174</b>	<b>5,510</b>
Long term debt, net of current portion	9,700	9,700
Other long term liabilities	72	62
<b>Total liabilities</b>	<b>15,946</b>	<b>15,272</b>
Commitments and contingencies (Note 14)		
Stockholders' equity :		
Common stock, \$0.001 par value:		
Authorized: 150,000 shares at September 30, 2006 and at December 31, 2005		
Issued and outstanding: 43,241 shares at September 30, 2006 (unaudited) and 42,676 shares at December 31, 2005	43	43
Additional paid-in capital	223,789	220,403
Accumulated deficit	(103,689)	(99,251)
<b>Total stockholders' equity</b>	<b>120,143</b>	<b>121,195</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 136,089</b>	<b>\$ 136,467</b>

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The accompanying notes are an integral part of these condensed consolidated financial statements.

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share data, unaudited)

	Three months ended		Nine months ended	
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
Sales	\$ 12,905	\$ 11,191	\$ 38,224	\$ 34,351
Cost of goods sold	4,613	4,522	14,328	13,950
<b>Gross profit</b>	<b>8,292</b>	<b>6,669</b>	<b>23,896</b>	<b>20,401</b>
Operating expenses:				
Research and development	1,363	894	4,049	2,932
Selling, general and administrative	7,758	6,299	23,779	20,482
Restructuring charges				60
<b>Total operating expenses</b>	<b>9,121</b>	<b>7,193</b>	<b>27,828</b>	<b>23,474</b>
<b>Loss from operations</b>	<b>(829)</b>	<b>(524)</b>	<b>(3,932)</b>	<b>(3,073)</b>
Interest expense	(179)	(206)	(526)	(704)
Interest income and other expense, net	80	25	20	(3)
<b>Net loss</b>	<b>\$ (928)</b>	<b>\$ (705)</b>	<b>\$ (4,438)</b>	<b>\$ (3,780)</b>
<b>Net loss per common share, basic and diluted</b>	<b>\$ (0.02)</b>	<b>\$ (0.02)</b>	<b>\$ (0.10)</b>	<b>\$ (0.09)</b>
Shares used in computing net loss per common share, basic and diluted	43,227	41,794	43,143	41,601

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(In thousands, unaudited)**

	<b>Nine months ended September 30,</b>	
	<b>2006</b>	<b>2005</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (4,438)	\$ (3,780)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation, amortization and loss on disposal of assets	2,602	2,939
Amortization of stock-based compensation	2,174	85
Allowance for doubtful accounts	(69)	30
Provision for obsolete inventories	503	317
<b>Changes in operating assets and liabilities:</b>		
Accounts and note receivable	(139)	(455)
Inventories	(826)	(677)
Prepaid and other assets	31	(431)
Accounts payable and accrued liabilities	1,006	(1,418)
Deferred revenue	31	(11)
<b>Net cash provided by/(used in) operating activities</b>	<b>875</b>	<b>(3,401)</b>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(743)	(913)
Purchase of marketable securities		(81)
Sales and maturities of marketable securities		963
Cash used in acquisition of product license	(500)	(250)
Note receivable, other assets and other long term liabilities	181	(93)
<b>Net cash used in investing activities</b>	<b>(1,062)</b>	<b>(374)</b>
<b>Cash flows from financing activities:</b>		
Proceed from issuance of convertible debt		9,700
Principal payments on debt	(113)	(16,609)
Proceeds from issuance of common stock, net of issuance costs	1,212	873
<b>Net cash provided by/(used in) financing activities</b>	<b>1,099</b>	<b>(6,036)</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>912</b>	<b>(9,811)</b>
Cash and cash equivalents at beginning of period	5,522	12,978
<b>Cash and cash equivalents at end of period</b>	<b>\$ 6,434</b>	<b>\$ 3,167</b>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Accrued liability in conjunction with acquisition of product license	\$	\$ 500
Equity issued in conjunction with acquisition of product license	\$	\$ 404

The accompanying notes are an integral part of these condensed consolidated financial statements.

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**RITA MEDICAL SYSTEMS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. Basis of presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared by RITA Medical Systems, Inc. (the Company) in accordance with accounting principles generally accepted in the United States of America for interim financial information. These principles are consistent in all material respects with those applied in the Company's financial statements contained in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2005, and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X promulgated by the Securities and Exchange Commission. The balance sheet data as of December 31, 2005 was derived from audited financial statements and does not include all disclosures contained in the 2005 annual report to stockholders. Interim financial statements do not include all of the information and footnotes required by generally accepted accounting principles in the United States of America for complete financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all adjustments (all of which are of a normal recurring nature, including the elimination of intercompany accounts) necessary to present fairly the financial position, results of operations and cash flows of the Company for the periods indicated. Interim results of operations are not necessarily indicative of the results to be expected for the full year or any other interim periods. These unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and footnotes thereto contained in the Company's annual report on Form 10-K for the year ended December 31, 2005.

**2. Liquidity**

As of September 30, 2006, the Company's total assets were \$136.1 million, total liabilities were \$15.9 million and working capital was \$14.6 million. The Company's balance of cash and cash equivalents on September 30, 2006 was \$6.4 million. In August 2008, the Company will be required to make \$9.7 million in debt payments, presuming no conversion of its outstanding convertible debt into equity prior to the maturity date of the issue.

On January 31, 2006, the Company entered into a Credit Agreement with CapitalSource Finance LLC (CapitalSource), which provides for a revolving credit facility in the principal amount of up to \$7 million. Estimated availability under the revolving credit facility was approximately \$5 million as of September 30, 2006. To date, there have been no borrowings under the revolving credit facility.

Current and anticipated demand for the Company's products, including the production process for those products, affects the need for capital. Changes in these or other factors could have a material impact on capital requirements and may require the Company to raise additional capital. While the Company believes that its existing cash resources will be sufficient to fund its operating needs for the next twelve months, additional financing may be required for the Company's currently envisioned long-term needs. If the Company needs to raise additional financing, it will seek to issue additional equity or debt securities, utilize its existing credit facility, obtain an additional credit facility or renegotiate debt repayment terms. There can be no assurance that any additional financing will be available on terms acceptable to the Company, or at all. In addition, future equity financings could result in dilution to stockholders, and future debt financings could result in certain financial and operational restrictions. Failure to obtain sufficient funds on acceptable terms when needed, to make timely debt payments, or to achieve the Company's growth or profitability objectives may require the Company to curtail operations, perhaps to a significant extent.

**3. Accounting for stock-based compensation**

**Stock-Based Benefit Plans**

**2005 Stock and Incentive Plan:** The Company implemented the 2005 Stock and Incentive Plan (2005 Plan) subsequent to stockholder approval at the Company's annual stockholder meeting in June 2005. This plan was implemented to replace the Company's 2000 Stock Plan, to expand the types of equity awards permitted under the equity compensation plans and to take tax deductions for certain equity compensation paid to executive officers under Section 162(m) of the Internal Revenue Code of 1986, as amended. The Company reserved for issuance a maximum of 5,591,390 shares of the Company's common stock under the 2005 Plan. In 2006, the Board of Directors approved an amendment of the 2005 Plan to increase the number of shares of common stock issuable under the 2005 Plan as calculated at that time by an additional 500,000 shares to a total of 5,876,746 shares. This amendment was subsequently approved by the Company's stockholders in June 2006. The types of awards that may be granted under the 2005 Plan include restricted stock grants, restricted stock units, stock appreciation rights, stock purchase rights, and other similar types of awards as well as cash awards. Up to 400,000 shares of common stock may be granted under the 2005 Plan as restricted stock grants, stock purchase rights and restricted stock units or any similar type of award that does not require the participant to pay the Company an amount equal to the fair





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market value of the common stock as of the award grant date. The maximum number of shares subject to awards that may be granted to any one participant under the 2005 Plan during any single fiscal year of the Company is 1,000,000 shares and the maximum value of any cash award granted under the 2005 Plan is \$500,000. The 2005 Plan will expire in 2015 unless it is terminated earlier pursuant to its terms. The average vesting period of options granted under this plan has been four years. Most of the options granted under this plan utilize cliff vesting, under which a portion of the underlying shares vest at the six month anniversary of the date of grant, with ratable monthly vesting thereafter. Options granted under this plan may also provide for ratable monthly vesting without a cliff provision. On September 30, 2006, there were 910,009 options available for grant under the 2005 Plan.

**2000 Director's Stock Option Plan:** Under the 2000 Director's Stock Option Plan, one million shares of common stock have been reserved for issuance to non-employee directors. Option grants have been and will continue to be made at the fair market value of the common stock on the date of the grant. Options granted under this plan become exercisable, generally vest on a cumulative basis and generally expire ten years from the date of grant. The average vesting period of options granted under this plan has been approximately two years. On September 30, 2006, there were 420,568 options available for grant under the 2000 Director's Stock Option Plan.

**2000 Stock Plan:** Prior to its termination subsequent to the Company's adoption of the 2005 Plan, the 2000 Stock Plan provided for the grant of incentive stock options to employees and non-statutory stock options and stock purchase rights to employees, directors and consultants. A total of 2,000,000 common shares were originally available for issuance under this plan at its inception in 2000. Increases to the shares available for issuance occurred on the first day of each fiscal year through 2005 in the amount of the lesser of 1,000,000 shares, 7% of the Company's outstanding common stock on the last day of the preceding fiscal year or a lower number as determined by the board of directors. Incentive stock options granted under this plan had an exercise price of at least 100% of the fair market value of the common stock on the date of the grant, and at least 110% of the fair market value of the common stock if the options were awarded to an employee who held more than 10% of the total voting power of all classes of the Company's stock. Options granted under this plan become exercisable and vest on a cumulative basis at the discretion of the board of directors and generally expire ten years from the date of grant. The average vesting period of options granted under this plan was approximately four years. The Company's Board of Directors has determined that no future grants will be made under this plan.

**1998 Incentive Stock Plan:** The 1998 Incentive Stock Plan was assumed by the Company in connection with its merger with Horizon Medical Products, Inc. ( Horizon ). Options granted under this plan became fully vested immediately prior to the merger, and will generally expire ten years from the original date of grant. The Company's Board of Directors has determined that no future grants will be made under this plan.

**1994 Incentive Stock Plan:** Under the 1994 Incentive Stock Plan, options were granted to employees and non-employees at prices determined by the Board of Directors to be not lower than 85% of the fair market value of the common stock for non-statutory stock options or 100% of the fair market value of the common stock for incentive stock options. For individuals who at the time of grant owned stock representing more than 10% of the voting power of all classes of outstanding stock, options were granted at prices not lower than 110% of the fair value of the common stock for both non-statutory and incentive stock options. Options granted under this plan become exercisable and vest on a cumulative basis at the discretion of the board of directors and generally expire ten years from the date of grant. The average vesting period of options granted under this plan was approximately four years. The Company's Board of Directors has determined that no future grants will be made under this plan.

**2000 Employee Stock Purchase Plan:** The Company's 2000 Employee Stock Purchase Plan was adopted in 2000. A total of 650,000 common shares were initially reserved for issuance under this plan. An additional 650,000 shares were reserved in 2005. In 2006, the Board of Directors decided not to increase the number of common shares reserved under the plan. Future increases may occur on the first day of each year until 2010, in amounts equal to the lesser of 650,000 shares, 4% of the Company's outstanding common stock on the last day of the preceding year, or such lesser number that the Board of Directors determines. This plan permits employees to purchase common shares at a price equal to the lower of 85% of the fair market value of the common stock at the beginning of each offering period or the end of each offering period. Employee purchases are nonetheless limited to 15% of eligible cash compensation, and other restrictions regarding the amount of annual purchases also apply.

**Warrants**

In December 2001, the Company issued a warrant to BEKL Corporation under the terms of a clinical data and patent license agreement. The warrant is exercisable for 25,000 shares of the Company's common stock at a price of \$6.10 per share and expires in December 2006. Its aggregate fair value of approximately \$110,000 was charged to operations in 2001. Fair value was determined using the Black-Scholes valuation model.

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On July 29, 2004, the Company completed its merger with Horizon. Under the terms of the merger agreement, the Company assumed warrants exercisable in 125,000 shares of Horizon common stock, which were converted into warrants exercisable for 52,650 shares of the Company's common stock at an average price of \$2.11 per share. Their aggregate fair value of approximately \$201,000 was recorded as part of the purchase price of Horizon acquisition using fair values determined under the Black-Scholes valuation model. In 2005, warrants to purchase 21,060 shares of common stock were exercised in a net issuance exchange for 9,521 shares of the Company's common stock. In 2006, warrants to purchase another 21,060 shares of common stock were exercised in a net issuance exchange for 12,098 shares of the Company's common stock. The remaining warrant to purchase 10,530 shares of common stock will expire in 2011.

As part of the Stock and Warrant Purchase Agreements dated November 24, 2004, the Company issued warrants to purchase an aggregate of 3,272,724 shares of its common stock. The warrants have an initial exercise price of \$4.00 per share and expire on November 24, 2009. The warrants provide for adjustment of the number and kind of securities purchasable upon exercise of the warrants, as well as for adjustment of the per share exercise price, upon the occurrence of certain specified events. These specified events include, without limitation, the payment by the Company of a dividend or a distribution on its common stock in shares of common stock, the consolidation or merger of the Company with another entity in which the Company is not the surviving entity, and the recapitalization, reclassification or reorganization of the capital stock of the Company. The warrants also contain a standard anti-dilution adjustment provision which provides for an adjustment in the per share exercise price in the event that the Company issues and sells shares of its common stock for per share consideration that is less than the exercise price then in effect, subject to customary limitations and exclusions, but in no event will the per share exercise price for the warrant be adjusted to less than \$3.23.

**Adoption of SFAS 123 (R)**

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, (SFAS 123(R)) which establishes standards for the accounting of transactions in which an entity exchanges its equity instruments for goods or services, primarily focusing on accounting for transactions where an entity obtains employee services in share-based payment transactions. SFAS 123(R) requires a public entity to measure the cost of employee services received in exchange for an award of equity instruments, including stock options, based on the grant-date fair value of the award and to recognize it as compensation expense over the period the employee is required to provide service in exchange for the award, usually the vesting period. SFAS 123(R) supersedes the Company's previous accounting under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25) for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 (SAB 107) relating to SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

The Company adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company's fiscal year 2006. The Company's Consolidated Financial Statements as of and for the three and nine months ended September 30, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, the Company's Consolidated Financial Statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R).

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

Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized in the Company's Consolidated Statement of Operations for the three and nine month periods ended September 30, 2006 included compensation expense for share-based payment awards granted prior to, but not yet vested as of December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). As stock-based compensation expense recognized in the Consolidated Statement of Operations for the first nine months of fiscal 2006 has been based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. For the three and nine month periods ended September 30, 2006, the Company applied estimated average forfeiture rates of approximately 11.1% for non-officer grants



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and 3.2% for officer grants, based on historical forfeiture experience. The estimated pricing term of option grants for the three nine and month periods ended September 30, 2006 was 5.0 years for non-officer grants and 5.6 years for officer grants. In the Company's pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred.

SFAS 123(R) requires the cash flows resulting from the tax benefits resulting from tax deductions in excess of the compensation cost recognized for those options to be classified as financing cash flows. Due to the Company's loss position, there were no such tax benefits during the three and nine month periods ended September 30, 2006 and September 30, 2005. Prior to the adoption of SFAS 123(R), those benefits would have been reported as operating cash flows had the Company received any tax benefits related to stock option exercises.

The fair value of stock-based awards to employees and directors is calculated using the Black-Scholes option pricing model, even though this model was developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which differ significantly from the Company's stock options. The Black-Scholes model also requires subjective assumptions, including future stock price volatility and expected time to exercise, which greatly affect the calculated values. The expected term of options granted is derived from historical data on employee exercises and post-vesting employment termination behavior. The risk-free rate selected to value any particular grant is based on the U.S Treasury rate that corresponds to the pricing term of the grant effective as of the date of the grant. The expected volatility is based on the historical volatility of the Company's stock price. These factors could change in the future, affecting the determination of stock-based compensation expense in future periods.

**Valuation and Expense Information under SFAS 123(R)**

The weighted-average fair value of stock-based compensation is based on the single option valuation approach. Forfeitures are estimated and it is assumed no dividends will be declared. The estimated fair value of stock-based compensation awards to employees is amortized using the straight-line method over the vesting period of the options. The Company's fair value calculations for stock-based compensation awards to employees for the three and nine month periods ended September 30, 2006 were based on the following assumptions:

	<b>Three Months Ended September 30, 2006</b>	<b>Nine Months Ended September 30, 2006</b>
Risk-free interest rate	4.6% -4.9%	4.3% -5.1%
Expected life (years)	5.0 -5.6	5.0 -5.6
Expected volatility	58%	58% -63%
Expected dividends	None	None

The corresponding assumptions for the 2000 Employee Stock Purchase Plan were as follows:

	<b>Three Months Ended September 30, 2006</b>	<b>Nine Months Ended September 30, 2006</b>
Risk-free interest rate	3.7% - 5.3%	3.7% - 5.3%
Expected life (years)	0.5	0.5
Expected volatility	29% - 32%	29% - 60%
Expected dividends	None	None

The following table summarizes stock-based compensation expense related to stock options and employee stock purchase plan purchases under SFAS 123(R) for the three and nine month periods ended September 30, 2006. The table further includes stock-based compensation expense related to shares issued to the Company's directors as a portion of their retainer for the three months ended September 30, 2006. (in thousands):

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	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Stock-based compensation expense included in:		
Cost of sales	\$ 35	\$ 108
Research and development	129	341
Selling, general and administrative	531	1,725
<b>Total stock-based compensation expense</b>	<b>\$ 695</b>	<b>\$ 2,174</b>

For the three and nine month periods ended September 30, 2006, the amounts of stock-based compensation expense related to stock options were approximately \$660,000 and \$2,093,000, respectively. For the three and nine month periods ended September 30, 2006, the amounts of stock-based compensation expense related to employee stock purchase plan purchases were approximately \$12,000 and \$58,000, respectively. For both the three month and nine month periods ended September 30, 2006, the amount of stock-based compensation related to shares issued to the Company's directors as a portion of their retainer was approximately \$23,000.

The Company's net loss for the three and nine month periods ended September 30, 2006 was \$928,000 and \$4,438,000, respectively. The Company's net loss for the three months ended September 30, 2006 was \$672,000 greater than it would have been if the Company had continued to account for share-based compensation under APB Opinion No. 25. The Company's net loss per common share, basic and diluted, for the three months ended September 30, 2006 was \$0.02. The Company's net loss per common share, basic and diluted, for the three months ended September 30, 2006 was \$0.01 greater than it would have been if the Company had continued to account for share-based compensation under APB Opinion No. 25. The Company's net loss for the nine months ended September 30, 2006 was \$2,151,000 greater than it would have been if the Company had continued to account for share-based compensation under APB Opinion No. 25. The Company's net loss per common share, basic and diluted, for the nine months ended September 30, 2006 was \$0.10. The Company's net loss per common share, basic and diluted, for the nine months ended September 30, 2006 was \$0.05 greater than it would have been if the Company had continued to account for share-based compensation under APB Opinion No. 25.

A summary of option activity under the Company's stock equity plans during the nine months ended September 30, 2006 is as follows:

Options	Number of Shares (in Thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in Thousands)
Outstanding at December 31, 2005	7,527	\$ 2.85		
Granted	1,319	3.68		
Exercised	(484)	2.09		
Cancelled	(571)	4.43		
<b>Outstanding at September 30, 2006</b>	<b>7,791</b>	<b>\$ 2.92</b>	<b>7.28</b>	<b>\$ 4,901</b>
Vested or expected to vest at September 30, 2006	7,196	\$ 2.87	7.12	\$ 4,893
<b>Exercisable at September 30, 2006</b>	<b>4,798</b>	<b>\$ 2.53</b>	<b>6.35</b>	<b>\$ 4,743</b>

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The following table summarizes significant ranges of outstanding and exercisable options as of September 30, 2006:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number outstanding	Weighted Average Exercise Price
0.50 - 1.07	1,794	5.39	\$ 1.06	1,794	\$ 1.06
1.19 - 1.94	123	5.83	1.63	123	1.63
2.02 - 2.52	1,049	5.54	2.41	890	2.39
2.57 - 3.07	754	7.99	2.90	519	2.90
3.09 - 3.42	1,463	8.47	3.26	560	3.23
3.43 - 3.92	1,407	8.97	3.72	329	3.69
3.94 - 6.75	1,103	8.21	4.26	485	4.45
8.02 - 34.73	98	4.28	12.51	98	12.51
	7,791	7.28	\$ 2.92	4,798	\$ 2.53

The per share weighted average fair value of options granted during the three months ended September 30, 2006 and September 30, 2005 was \$1.77 and \$2.22, respectively. The per share weighted average fair value of options granted during the nine months ended September 30, 2006 and September 30, 2005 was \$2.11 and \$2.09, respectively.

The total intrinsic value of options exercised during the three months ended September 30, 2006 and September 30, 2005 was approximately \$8,000 and \$368,000, respectively. The total intrinsic value of options exercised during the nine months ended September 30, 2006 and September 30, 2005 was approximately \$737,000 and \$535,000, respectively.

As of September 30, 2006, total unrecognized forfeiture adjusted compensation costs related to nonvested stock options was approximately \$5.4 million, which is expected to be recognized as an expense over a weighted average period of approximately 2.6 years.

*Pro Forma Information Under SFAS 123 for Periods Prior to Fiscal 2006*

Prior to fiscal 2006, the weighted-average fair value of stock-based compensation to employees was based on the single option valuation approach. Forfeitures were recognized as they occurred and it was assumed no dividends would be declared. The estimated fair value of stock-based compensation awards to employees was amortized using the straight-line method over the vesting period of the options. The weighted-average fair value calculations were based on the following assumptions for the Company's stock option plans and employee stock purchase plan (ESPP):

	Three months ended September 30, 2005		Nine months ended September 30, 2005	
	Option Plans	ESPP	Option Plans	ESPP
Volatility	78%	60%	78%	60%
Risk-free interest rate	3.83%	2.77%	3.83%	2.22%
Expected Life	5 years	0.5 years	5 years	0.5 years
Expected Dividends	None	None	None	None

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Pro forma results for the three and nine month periods ended September 30, 2005 are as follows (in thousands, except per share amounts):

	Three months ended September 30, 2005	Nine months ended September 30, 2005
Net loss, as reported	\$ (705)	\$ (3,780)
Add: Stock-based employee compensation expense included in reported net loss	51	85
Deduct: Total stock-based employee compensation determined under the fair value based method for all awards	(619)	(1,624)
Net loss, pro-forma	\$ (1,273)	\$ (5,319)
Basic and diluted net loss per common share:		
As reported	\$ (0.02)	\$ (0.09)
Pro-forma	\$ (0.03)	\$ (0.13)

**4. Net loss per share**

Basic earnings per share figures are calculated based on the weighted-average number of common shares outstanding during the period. Diluted earnings per share further includes the effect of potentially dilutive securities consisting of stock options, warrants and stock issuable upon conversion of convertible notes into shares of the Company's common stock provided that the inclusion of such securities is not antidilutive. The Company has reported net losses and therefore has excluded such potentially dilutive securities from its calculation of diluted earnings per share. The following numbers of shares represented by outstanding stock options, warrants and stock issuable upon conversion of convertible notes (prior to application of the treasury stock method) were excluded from the computation of diluted net loss per share as of September 30, 2006 and 2005 as their effect was antidilutive (in thousands):

	September 30, 2006	September 30, 2005
Effect of potentially dilutive securities		
Options	7,791	7,432
Warrants	3,308	3,350
Stock issuable upon conversion of convertible notes	2,407	2,407
Weighted average shares used in basic and diluted net loss per common share	13,506	13,189

**5. Inventories**

The components of the Company's inventories at September 30, 2006 (unaudited) and December 31, 2005, respectively, were as follows (in thousands):

	September 30, 2006	December 31, 2005
Raw materials	\$ 2,192	\$ 2,354
Work-in-process	778	703
Finished goods	2,733	2,323
	\$ 5,703	\$ 5,380





**Table of Contents****6. Property and equipment and related depreciation**

The components of the Company's property and equipment and related accumulated depreciation at September 30, 2006 (unaudited) and December 31, 2005, respectively, were as follows (in thousands):

	September 30, 2006	December 31, 2005
Computer equipment and software	\$ 1,589	\$ 1,538
Furniture and fixtures	347	347
Leasehold improvements	631	1,394
Machinery and equipment	3,391	3,259
	5,958	6,538
Less: accumulated depreciation and amortization	(4,234)	(4,579)
	\$ 1,724	\$ 1,959

Depreciation expense was approximately \$306,000 and \$319,000 for the three month periods ended September 30, 2006 and 2005, respectively. Depreciation expense was approximately \$984,000 and \$817,000 for the nine month periods ended September 30, 2006 and 2005, respectively.

**7. Intangible assets and related amortization**

The Company's intangible assets and related accumulated amortization at September 30, 2006 (unaudited) and December 31, 2005, respectively, were as follows (in thousands):

	September 30, 2006			December 31, 2005		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Capitalized patent defense litigation costs	\$ 2,755	\$ (1,018)	\$ 1,737	\$ 2,755	\$ (836)	\$ 1,919
Capitalized patent license agreements	3,804	(1,242)	2,562	3,804	(932)	2,872
Loan closing costs	127	(49)	78	127	(18)	109
Patent and loan related intangibles	6,686	(2,309)	4,377	6,686	(1,786)	4,900
Intangible assets recorded at merger with Horizon:						
Customer relationships	16,600	(2,398)	14,202	16,600	(1,568)	15,032
Product technology	2,490	(177)	2,313	2,490		2,490
Trademarks	1,080	(94)	986	1,080		1,080
Acquisition related intangibles	20,170	(2,669)	17,501	20,170	(1,568)	18,602
	\$ 26,856	\$ (4,978)	\$ 21,878	\$ 26,856	\$ (3,354)	\$ 23,502

The capitalized patent defense litigation costs relate to the Company's suit against RadioTherapeutics, a division of Boston Scientific Corporation. This suit was settled in April 2003 and no additional costs have been capitalized since that date.

The capitalized patent license agreements include a license acquired during 2005 from EMCision Limited Incorporated ( EMCision ), the settlement of the Company's suit against RadioTherapeutics and suits brought against the Company by Boston Scientific Corporation and several related parties. In May 2005, the Company capitalized \$1.2 million related to cash payments of \$250,000, an additional liability to pay \$500,000 and issuance of 150,000 shares of its common stock valued at \$403,500 to EMCision to acquire patent license agreement to sell the HABIB 4X resection device. All payments associated with acquisition of the EMCision patent license have been made. Also, in April 2003, the Company

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capitalized \$2,650,000 in payments made to acquire patent license agreements from Boston Scientific and the other opposing litigants.

Loan closing costs of \$127,000 associated with the Company's August 5, 2005 private placement of convertible debt have been capitalized as an intangible asset.

During the fourth quarter of 2005, the Company performed an analysis of its intangible assets in accordance with SFAS No. 144 and recorded an impairment charge of \$5.5 million as a result of this analysis primarily due to revised revenue projections of certain of the Company's specialty access products.

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The following table presents details of the amortization expense of intangible assets as reported in the Consolidated Statements of Operations (in thousands, unaudited):

	Three months ended September 30,		Nine months ended September 30,	
	2006	2005	2006	2005
Cost of goods sold	\$ 162	\$ 246	\$ 486	\$ 700
Research and development	61	61	182	182
Selling, general and administrative	308	395	924	1,192
Interest expense	11	9	32	48
	\$ 542	\$ 711	\$ 1,624	\$ 2,122

The weighted average remaining life for the intangible assets was approximately 11.3 years at September 30, 2006. Estimated amortization expense of the intangible assets for the three months ended December 31, 2006 and each of the four years ended December 31, 2007 through 2010 and thereafter is as follows (in thousands):

Fiscal year ending December 31,	Estimated Intangible Asset Amortization Expense
2006 (remaining three months)	\$ 541
2007	2,166
2008	2,148
2009	2,036
2010	1,914
Thereafter	13,073
Total	\$ 21,878

**8. Goodwill**

The Company's merger with Horizon in fiscal year 2004 resulted in goodwill of \$91.3 million, which is the excess of purchase price over the fair value of assets acquired. There were no changes to goodwill during the nine month period ended September 30, 2006. Based on the results of its annual impairment tests performed during November of 2005 and 2004 in accordance with SFAS No. 142, the Company determined that no impairment on the carrying value of its goodwill existed as of its annual impairment test date of October 31, 2005 and 2004. As of those dates, the Company's market capitalization exceeded its net book value and therefore no further analysis was required.

During the fourth quarter of 2005, due to revised revenue projections of certain of the Company's specialty access products, the Company performed an analysis of its intangible assets in accordance with SFAS No. 144 and recorded an impairment charge of \$5.5 million as a result of this analysis. This was considered a possible indicator of impairment of goodwill, and the Company re-performed its goodwill impairment test as of December 31, 2005. As of December 31, 2005, the Company's market capitalization exceeded its net book value and therefore no further analysis was required.

Although the Company's market capitalization was higher than its net book value at October 31, 2005, December 31, 2005, September 30, 2006 and October 31, 2006, the Company's market capitalization has dropped below its net book value in the past and could do so in the future. If the Company's market capitalization drops below its net book value and/or there are indicators of impairment either at its next impairment test date of October 31, 2007 or at interim basis, the Company may be required to perform an additional impairment assessment regarding its goodwill, which includes the analysis of discounted future cash flows which management believes to be an important factor in determination of the Company's sole reporting unit. This analysis takes into consideration certain assumptions on revenue growth and operating expenses. Since these financials assumptions are subject to variability, the impairment evaluation could result in a charge to earnings.



**Table of Contents****9. Accrued liabilities**

The components of the Company's accrued liabilities as of September 30, 2006 (unaudited) and December 31, 2005 were as follows (in thousands):

	September 30, 2006	December 31, 2005
Payroll and related expenses	\$ 1,058	\$ 911
Accrued vacation	472	357
Accrued legal and audit expenses	408	250
Accrued property, sales, franchise and income taxes	423	306
Accrued patent license cost		500
Accrued royalties	510	422
Accrued interest	189	14
Insurance note payable, short term	532	293
Deferred revenue	31	
Other accrued liabilities	366	253
	\$ 3,989	\$ 3,306

**10. Debt**

On August 5, 2005, the Company completed a private placement of subordinated Senior Convertible Notes (the "New Notes") with an aggregate principal amount of \$9.7 million. The New Notes were issued pursuant to a Securities Purchase Agreement (the "Purchase Agreement") among the Company and Atlas Master Fund, Ltd., which is not related to the Company. No warrants or other securities were issued in conjunction with the Purchase Agreement and the Company incurred no financing costs other than normal and customary legal and other professional expenses. The New Notes are convertible into shares of the Company's common stock at an initial conversion price of \$4.03 per share of common stock which was greater than the per share fair market value of our common stock on the date of issuance of the New Notes. The conversion price is subject to adjustment in certain circumstances including common stock splits or other standard anti-dilution provisions. Until conversion or maturity, the New Notes bear interest at the rate of 6.5% per annum, payable semiannually in cash. Absent conversion, the New Notes mature on August 5, 2008 (the "Maturity Date"). If on the Maturity Date the closing price of the common stock has been at or above 102% of the then current conversion price for at least 10 consecutive business days immediately preceding the Maturity Date, then any remaining principal outstanding under the New Notes shall automatically be converted into common stock, subject to certain conditions. The issuance of the New Notes was deemed to be exempt from registration under the Securities Act of 1933 in reliance upon Section 4(2) thereof as transactions by an issuer not involving any public offering.

As of the issuance date of the New Notes, the Company owed \$8.3 million plus accrued interest to holders of the Senior Subordinated Convertible Notes (the "Senior Notes") and \$1.4 million plus accrued interest to the holder of the Junior Promissory Note (the "Junior Note"). Pursuant to the terms of the New Notes, the Company was required to repay the Senior Notes and the Junior Note within 21 days of the issuance of the New Notes, or August 26, 2005. The Senior Notes were repaid on August 9, 2005 and the Junior Note was repaid on August 11, 2005.

None of the Company's note agreements are collateralized. The principal covenants of the note agreements relate to events of default which include, but are not limited to, failure to pay an obligation when due, breach of any covenant which remains uncured for 15 days, bankruptcy and a change of control. Generally, upon an event of default, the holders of a majority of the aggregate principal amount of the notes outstanding may declare the unpaid principal and interest on the notes immediately due and payable. As of September 30, 2006 and as of the date of filing of this quarterly report on Form 10-Q, the Company was in compliance with the covenants of the note agreements.

**11. Credit Facility**

On January 31, 2006, the Company entered into a Credit Agreement with CapitalSource Finance LLC ("CapitalSource"). The Credit Agreement provides for a revolving credit facility in the principal amount of up to \$7 million.

The amount of principal available for the Company to borrow at any time is limited to the aggregate of (i) varying percentages of the amount of the Company's eligible receivables and (ii) varying percentages of the amount of the Company's eligible finished goods inventory. The applicable

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percentages are determined based on the level of the Company's EBITDA (as defined in the Credit Agreement) for the prior quarter and its inventory turns ratio. In addition, the amount otherwise available to borrow based on the aforementioned criteria is required to be reduced by a required liquidity reserve of \$1,000,000 to \$1,500,000 depending on the level of the Company's EBITDA (as defined in the Credit Agreement) for the prior quarter. The principal available for the Company to borrow at September 30, 2006 was approximately \$5 million.

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The obligations under the Credit Agreement are secured by a security interest in substantially all of the tangible and intangible assets of the Company and its subsidiaries. The Credit Agreement provides for the use of a lockbox for the collection of the Company's receivables if advances under the Credit Agreement are outstanding. Borrowings under the revolving credit facility bear interest at a floating rate equal to Citibank, N.A.'s prime rate (the Prime Rate) plus 1.25%, provided, however, that the Prime Rate shall not be less than 7.25%. Interest on advances is payable on the first day of each calendar month. The full amount borrowed under the revolving credit facility will mature on the earlier of (i) January 31, 2009 or (ii) 30 days before the maturity date of the debt in the Senior Subordination Agreement, dated as of January 31, 2006, by and among Atlas Master Fund, Ltd. (Atlas), CapitalSource and the Company (the Subordination Agreement). Pursuant to the terms of the Subordination Agreement, the claims, demands, rights and remedies of Atlas were subordinated to the claims, rights and remedies of CapitalSource.

The Credit Agreement also includes requirements to maintain financial covenants in order to be eligible to borrow including (i) a minimum level quarterly EBITDA (as defined in the Credit Agreement) of \$325,000 during 2006, \$150,000 during 2007, and \$62,500 during 2008, and (ii) cash balances of no less than \$1,000,000 to \$2,500,000 depending on the level of EBITDA (as defined in the Credit Agreement) for the prior quarter.

The Credit Agreement contains affirmative covenants that require the Company to promise, among other things, to deliver financial statements and other financial information to CapitalSource, to maintain its insurance policies, to allow inspection of its operations, to provide a customary right of first refusal to CapitalSource in the event that a third party proposes a debt financing, to pay its taxes and to maintain its inventory. The Credit Agreement also contains negative covenants that will limit the ability of the Company to, among other things, incur additional indebtedness, create any liens on any of its collateral, make certain investments, pay dividends, enter into certain transactions with affiliates, amend its charter documents, transfer its assets or make payments on permitted subordinated debt. The Credit Agreement contains customary events of default, including, but not limited to: (a) non-payment of amounts due; (b) material breach of representations, warranties or covenants under the Credit Agreement or the documents pertaining thereto; (c) insolvency; (d) receivership or bankruptcy; (e) certain changes in control; (f) loss of collateral; (g) withdrawal of United States Food and Drug Administration approval of products; (h) recall of products; or (i) other material adverse changes. Upon the occurrence of an event of default, the amounts due outstanding under the revolving credit facility may be accelerated and may become immediately due and payable. In addition, upon the occurrence of an event of default, CapitalSource shall, among other things, have the right to (a) apply any property of the Company and its subsidiaries held by CapitalSource to reduce the obligations; (b) foreclose on liens; (c) take possession of or sell any collateral or pledged securities; and (d) reduce the amount of capital available under the revolving credit facility.

The Company paid a commitment fee of \$140,000, plus legal out-of-pocket costs incurred by CapitalSource of approximately \$83,000, in connection with the Credit Agreement. The Company must also pay a collateral management fee equal to 0.05% of the average outstanding principal amount of the revolving credit facility each month and must pay a monthly unused line fee equal to 0.04% per month of the difference derived by subtracting (i) the daily average amount of the balances under the revolving credit facility outstanding during the preceding month, from (ii) \$7,000,000. Payments of the monthly unused line fee have totaled approximately \$22,000 for the nine months ended September 30, 2006. Additionally, the Company is obligated to pay a termination fee of up to \$210,000 if it terminates the Credit Agreement prior to its expiration. The Company has not yet made any borrowings under the revolving credit facility.

**12. Restructuring**

The Company accounts for restructuring in accordance with SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. In the six month period ended June 30, 2005, in connection with the merger of RITA and Horizon, the Company recorded a restructuring charge of \$60,000 related to the termination of employees to eliminate certain duplicative activities, primarily in the sales, accounting and operations areas. The total of such charges since July 29, 2004, the day the Horizon merger was completed, totaled \$1,369,000. The Company charged \$1,309,000 to expense in 2004 and \$60,000 to expense in 2005 and completed the cash payments related to the workforce reduction in January 2006.

**13. Segment information**

The Company separates its portfolio of medical oncology products into two groups, specifically, localized therapy products and specialty access catheter products. Localized therapy products consist of the radiofrequency ablation (RFA) products sold by RITA prior to the merger, the Company's Habib 4X resection device and the Company's LC Bead embolization product, which is distributed under a license agreement completed in April 2006. Specialty access catheter (SAC) products are the products sold by Horizon prior to the merger or those developed after the merger using Horizon's technology.



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Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the Company's chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker is its President and Chief Executive Officer. The Company's chief operating decision maker reviews financial information on a consolidated basis, accompanied by disaggregated information about sales by groups of similar products for purposes of making operating decisions and assessing financial performance. However, significant expenses such as research and development, sales and marketing and corporate administration are not allocated to product groups or geographical regions, but rather are employed by the entire enterprise. For this reason, the Company's chief operating decision maker evaluates resource allocation on an enterprise-wide basis, and not on a product or geographic basis. Accordingly, the Company has concluded that it operates in only one reportable segment, the medical oncology products business.

Sales for the Company's three medical oncology product groups for the three and nine month periods ended September 30, 2006 and 2005 are as follows (in thousands):

	Three months ended September 30, 2006		Nine months ended September 30, 2005	
Localized therapy products*	\$ 7,268	\$ 4,714	\$ 20,280	\$ 14,404
Specialty access catheter products	5,637	6,477	17,944	19,947
<b>Total medical oncology product sales</b>	<b>\$ 12,905</b>	<b>\$ 11,191</b>	<b>\$ 38,224</b>	<b>\$ 34,351</b>

\* Includes radiofrequency products and embolization products

Sales for the Company's domestic and international selling regions for the three and nine month periods ended September 30, 2006 and 2005 are as follows (in thousands):

	Three months ended September 30, 2006		Nine months ended September 30, 2005	
Domestic	\$ 10,781	\$ 9,608	\$ 31,362	\$ 28,995
International	2,124	1,583	6,862	5,356
<b>Total medical oncology product sales</b>	<b>\$ 12,905</b>	<b>\$ 11,191</b>	<b>\$ 38,224</b>	<b>\$ 34,351</b>

**14. Commitments and contingencies**

The Company is, and may in the future be, involved in litigation relating to claims arising from the ordinary course of business. Management is not currently aware of any matters that will have a material adverse effect on the financial position, results of operations or cash flows of the Company.

As of September 30, 2006, the Company had no future minimum payments due under capital leases, but does have commitments under operating leases related to facility rental and office equipment. Also as of September 30, 2006, the Company had \$9.7 million in convertible notes outstanding. The convertible notes are due in 2008. Also, on January 31, 2006, the Company entered into a Credit Agreement with CapitalSource, which provides for a revolving credit facility in principal amount of up to \$7.0 million. Under the agreement the Company is required to pay CapitalSource a monthly collateral management fee equal to 0.05% of the average outstanding principal amount of the revolving facility during the month and an unused line fee in an amount equal to 0.04% per month of the difference derived by subtracting the daily average amount of the balances under the facility outstanding during the preceding month from the facility cap of \$7.0 million. To date, no borrowings have been made under the revolving credit facility.

The following table sets forth future minimum payments due under operating leases, debt agreements and the revolving credit facility as of September 30, 2006. It further includes the Company's commitment, subject to increase in certain future circumstances, to purchase inventory of the LC Bead embolization product under our April 26, 2006 supply and distribution agreement with Biocompatibles UK Limited (in thousands):



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	Operating Leases	Debt	Unused Line Fee	Inventory Purchase Commitment	Total
Fiscal year ended December 31,					
2006 (remaining three months)	\$ 101	\$	\$ 8	\$ 804	\$ 913
2007	393		34	2,000	2,427
2008	349	9,700	34	1,941	12,024
2009	350		3	809	1,162
2010 and thereafter	132				132
Total of future minimum payments	\$ 1,325	\$ 9,700	\$ 79	\$ 5,554	\$ 16,658

The Company's purchase orders for products are based on its current manufacturing needs and are fulfilled by its vendors within short time horizons. In addition, some of the purchase orders represent authorizations to purchase rather than binding agreements. Except for the inventory purchase commitment referred to above, the Company generally does not have significant agreements for the purchase of raw materials or other goods specifying minimum quantities and pre-determined prices that exceed our expected requirements. Therefore, agreements for the purchase of raw materials and other goods and services, except for the inventory purchase commitment referred to above, are not included in the table above. Agreements for outsourced services generally contain clauses allowing for cancellation without significant penalty, and are therefore not included in the table above.

**15. Comprehensive income (loss)**

Comprehensive income (loss) generally represents all changes in stockholders' equity except those resulting from investments or contributions by stockholders. The Company's unrealized gains and losses on available-for-sale securities represent the only components of comprehensive loss that are excluded from the Company's net loss. These components are not significant individually, or in the aggregate, and therefore, no separate statement of comprehensive loss has been presented.

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations and other parts of this quarterly report on Form 10-Q contain forward-looking statements that involve risks and uncertainties. Words such as "anticipates," "expects," "intends," "plans," "believes," "estimates," "should," and similar expressions identify such forward-looking statements. These statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or forecasted. Factors that might cause such a difference include, but are not limited to, those discussed in the section entitled "Factors That May Affect Future Results" and those appearing elsewhere in this quarterly report on Form 10-Q and in our annual report on Form 10-K for the fiscal year ended December 31, 2005. Readers are cautioned not to place undue reliance on these forward-looking statements that reflect management's analysis only as of the date hereof. We assume no obligation to update these forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements.

#### **Business Overview**

We are a diversified medical device oncology company that develops, manufactures and markets innovative products for cancer patients. Our localized therapy products include radiofrequency ablation (RFA) systems for treating cancerous tumors, the HABIB 4X resection device, which is a radiofrequency product designed to limit blood loss in surgical resection procedures, and the LC Bead, an embolization product. Our specialty access catheter products include percutaneous vascular ports and specialty access catheters. The HABIB 4X resection device and the LC Bead are products we distribute under license. Founded in 1994 on our core radiofrequency ablation platform, we are a leader in radiofrequency ablation for the treatment of solid cancerous and benign tumors in solid organs. We pioneered radiofrequency technology and have led the market in clinical training and clinical acceptance. In July 2004, we merged with Horizon Medical Products, Inc. ("Horizon") in order to add Horizon's specialty access catheter (SAC) product line to our product portfolio. Our SAC products include implantable infusion ports for the delivery of systemic chemotherapy, tunneled central venous catheters, safety needles, peripherally inserted central catheters ("PICCs"), dialysis catheters and specialty catheters for stem cell transplant procedures.

Our goal for the future is to remain a leading provider of minimally invasive medical devices for the treatment of solid cancerous or benign tumors and to achieve improved financial results for our stockholders. Our strategies to achieve these goals are as follows:

*Increase Our Penetration of the Liver Cancer Market:* This strategy encompasses our efforts to:

increase awareness among key physicians;

conduct additional clinical research to provide data supporting the expanded use of our products; and

increase patient awareness with marketing efforts;

*Expand the Application of Our Proprietary Radiofrequency Technology to Markets Beyond Liver Cancer, such as Kidney Cancer, Lung Cancer and Breast Cancer;*

*Increase our Market Share for our Specialty Access Catheter Product Line;*

*Acquire Distribution Rights to Products that Complement our Existing Technology and Leverage our Sales Force; and*

*Continue to Advance Technology and Develop New Products.*

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Our efforts to increase our penetration of the liver cancer market have historically centered on investment in our domestic sales group. Our sales in the United States have historically been more profitable than our sales in international markets because direct selling, which avoids distributor discounts, permits higher average selling prices for our products. Accordingly, we have made significant investments in our domestic sales force in an effort to increase sales growth in the United States. Additionally, we introduced our premium-priced Starburst Xli and Xlie families of disposable needles in the domestic markets earlier than in international markets. These actions have for some time resulted in a growing percentage of radiofrequency ablation product sales derived from the domestic market. The SAC products acquired in the merger with Horizon are also heavily concentrated in the domestic market and we believe the merger permits wider and more efficient sales force coverage of the domestic market. However, with the intent to improve our margins and to increase our sales internationally, we began to sell directly in Germany, France and the United Kingdom during the fourth quarter of 2005. We believe this change has and will continue to result in higher international sales growth in 2006 compared to 2005, although selling expenses will increase as a result of this change.

Our merger with Horizon in 2004 was intended to leverage our existing sales force and provide an opportunity for increased operating efficiencies. We believe that improved costs will help us to pursue our strategic objective of increased

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market share in our SAC product lines. The Horizon merger, after our consolidation of manufacturing operations, resulted in higher production volumes which should result in lower costs because our costs are volume dependent. We acknowledge, however, that achievement of lower costs is dependent on more than just production volume. Technology in our marketplace has evolved rapidly and we have, from time to time, recognized relatively high expenses related to excess, obsolete and expiring inventory as our product lines have changed. We may experience similar product changes and related obsolete inventory provisions in the future. Additionally, our costs are burdened by the amortization of intangible assets related to our product technology. We expect these amortization charges to continue through 2016, although in 2005 we recognized partial impairment of our Horizon product technology asset as a result of not achieving the volume of sales anticipated at the date of merger. As a result of the impairment, total amortization charges affecting our costs are expected to be lower in future years.

In addition to the product technology asset described above, in 2005 we also impaired merger-related assets for the value of trademarks and our Isomed distribution contract because our SAC sales have not achieved the levels anticipated at the date of the merger. The amortization of these assets is a component of our operating expenses. As a result of the 2005 impairment, the impact of amortization expense will be lower in 2006 than in comparable periods in 2005 or 2004. Additional impairment of merger-related intangible assets may be required if sales of SAC products do not achieve anticipated volumes.

We believe that continual enhancement of our product technology is an important factor in maintaining our market leadership position in radiofrequency ablation technology, developing our technology to penetrate markets beyond liver cancer and improving our market share positions in both the RF and SAC markets. In 2001, we commercially launched our StarBurst XLi family of disposable devices and significantly expanded our direct domestic sales organization and our international distribution network. In 2002, the XLi family of disposable devices gained wide acceptance with our customers in the United States. In 2003, we introduced our next generation in infusion technology, the Xli-Enhanced ( Xlie ) disposable device. The Xlie device builds upon our established infusion expertise, making the ablation process easier and more efficient than it was with previous generations of our devices. In the third quarter of 2004, we merged with Horizon and acquired our SAC product line. In the second quarter of 2005, we introduced our HABIB 4X resection device, which is part of our RF product line, in our European markets, and in the third quarter of 2005 we received FDA approval for sale of the device in the United States. In November 2005, we received FDA approval to market our OmniPICC PI power injectable peripherally inserted central catheter that permits power injection delivery of contrast media in radiological imaging and interventional procedures. In the second quarter of 2006 we began to distribute in the United States embolization beads used to block the blood supply to tumors. In October of 2006, we received FDA approval to market a laproscopic version of the HABIB 4X resection device which we intend to begin selling commercially in the fourth quarter of 2006. In the future we will continue to consider other product licensing opportunities that align with our strategy. Also, in the future, we will continue to make investments aimed at adapting our radiofrequency technology for use in applications other than liver and bone cancer, with a particular emphasis on research in the areas of lung and breast cancer which we believe offer large market opportunities. We will also continue to develop our SAC product line to add greater value to our customers while reducing cost which we believe will result in a higher market share for these products.

We must also remain focused on activities that improve our financial results and provide a greater return to our stockholders. We believe that consolidation of operations following the Horizon merger, completed in mid-2005, has improved our overall cost structure. As a result, we expect our gross margin rate in 2006 to improve compared to our 2005 gross margin rate. Beyond 2006, our margins may be unfavorably impacted by the introduction and growth of new products, such as the LC Bead , or changes in the sales or channel mix of our existing products. Also, in August 2005, we issued \$9.7 million in convertible notes at a coupon rate of 6.5%. We used these funds to repay other debt that bore a higher interest rate, so we expect to have lower interest expense in 2006 than in 2005. We enhanced our liquidity in January 2006 with the signing of a revolving credit agreement that provides for as much as \$7 million in borrowing capacity, although line availability given our current collateral and financial metrics results in a current availability of approximately \$5 million. Our 2006 results will also be affected by factors that we believe will increase costs and reduce earnings. We intend to increase our investments in marketing and research and development for new RF products intended for application in the treatment of breast cancer and also invest in a minimally invasive resection device. We therefore expect that our research and development expense will increase in the fourth quarter of 2006, compared to the first three quarters of 2006. In addition, adoption of SFAS 123(R) will result in increased expense over the remainder of 2006 and in future years, compared to 2005.

**Critical Accounting Policies and Estimates**

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States requires us to make judgments, assumptions, and estimates that affect the amounts reported in the Consolidated Financial Statements and accompanying notes. We consider certain accounting policies related to revenue recognition, valuation of inventories, accounts receivable, acquired intangibles and impairment of long-lived assets including goodwill to be critical policies due to the estimation process involved in each. Management discusses its estimates and judgments with the Audit Committee of our Board of Directors.



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For a more detailed description of the application of these and other accounting policies, see Note 2 of the Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005 (the "2005 Form 10-K"). Reference is also made to the discussion of the application of these critical accounting policies and

estimates contained in Management's Discussion and Analysis in our 2005 Form 10-K. During the nine months ended September 30, 2006, there were no significant or material changes in the application of critical accounting policies that would require an update to the information provided in the 2005 Form 10-K except for the following addition to the critical accounting policies:

*Stock-based Compensation Expense*

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment, (SFAS 123(R)) which requires the measurement and recognition of compensation expense for all share-based payment awards made to our employees and directors including employee stock options and employee stock purchases related to the 2000 Employee Stock Purchase Plan based on estimated fair values. We adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006. Our Consolidated Financial Statements as of and for the three and nine month periods ended September 30, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, our Consolidated Financial Statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in our Consolidated Statement of Operations. Prior to the adoption of SFAS 123(R), we accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). As stock-based compensation expense recognized in the Consolidated Statement of Operations for the three and nine month periods ended September 30, 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The estimated average forfeiture rates for the three and nine month periods ended September 30, 2006 of approximately 11.1% for non-officer grants and 3.2% for officer grants were based on historical forfeiture experience. In our pro forma information required under SFAS 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

Stock-based compensation expense recognized under SFAS 123(R) for the three and nine month periods ended September 30, 2006 was approximately \$672,000 and \$2,151,000, respectively, determined by the Black-Scholes valuation model. Additionally, for the three and nine month periods ended September 30, 2006 we recognized approximately \$23,000 in stock-based compensation expense related to issuance of common stock to some of our directors as a portion of the retainer they received in exchange for their duties on our Board. For the three and nine month periods ended September 30, 2006, the amounts of stock-based compensation expense related to stock options were approximately \$660,000 and \$2,093,000, respectively. For the three and nine month periods ended September 30, 2006, the amounts of stock-based compensation expense related to employee stock purchase plan purchases were approximately \$12,000 and \$58,000, respectively. As of September 30, 2006, total unrecognized forfeiture adjusted compensation costs related to unvested stock options was approximately \$5.4 million, which is expected to be recognized as an expense over a weighted average period of approximately 2.6 years. Subsequent to the adoption of SFAS 123(R), we have not made any changes in the type of incentive equity instruments or added any performance conditions to the incentive options. See Note 3 to the Consolidated Financial Statements for additional information.



**Table of Contents****Results of Operations**

The following table sets forth the percentage of net revenue represented by certain items in our Condensed Consolidated Statements of Operations for the quarter ended September 30, 2006 and the four preceding fiscal quarters:

	Q3 2006	Q2 2006	Q1 2006	Q4 2005	Q3 2005
Domestic sales	84%	82%	81%	86%	86%
International sales	16%	18%	19%	14%	14%
Total sales	100%	100%	100%	100%	100%
Cost of goods sold	36%	38%	39%	47%	40%
- Intangible asset impairment	0%	0%	0%	30%	0%
Gross profit	64%	62%	61%	23%	60%
<b>Operating expenses:</b>					
Research and development	11%	11%	10%	8%	8%
Selling, general and administrative	60%	61%	66%	57%	56%
Intangible asset impairment	0%	0%	0%	16%	0%
Total operating expenses	71%	72%	76%	81%	64%
Loss from operations	(7)%	(10)%	(15)%	(58)%	(5)%
Interest expense	(1)%	(1)%	(1)%	(2)%	(2)%
Interest income and other expense, net	1%	(1)%	0%	0%	1%
Net loss	(7)%	(12)%	(16)%	(60)%	(6)%

Three months ended September 30, 2006 and 2005

The following table provides additional detail on our sales results for the quarters ended September 30, 2006 and 2005, respectively (in thousands):

	Three months ended September 30,		Growth	%
	2006	2005		
<b>Domestic sales:</b>				
Localized therapy products*	\$ 5,635	\$ 3,685	\$ 1,950	53%
Specialty access catheter products	5,146	5,923	(777)	(13)%
Total domestic sales	\$ 10,781	\$ 9,608	\$ 1,173	12%
<b>International sales:</b>				
Localized therapy products*	\$ 1,633	\$ 1,029	\$ 604	59%
Specialty access catheter products	491	554	(63)	(11)%
Total international sales	\$ 2,124	\$ 1,583	\$ 541	34%
Total localized therapy products*	\$ 7,268	\$ 4,714	\$ 2,554	54%
Total specialty access catheter products	5,637	6,477	(840)	(13)%
Total sales	\$ 12,905	\$ 11,191	\$ 1,714	15%

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\* Localized therapy products include RF products, consisting of radiofrequency ablation (RFA) and radiofrequency resection products such as the HABILIB 4X device, and the LC Bead embolization products

For the quarter ended September 30, 2006, sales totaled \$12.9 million, an increase of 15% or \$1.7 million from \$11.2 million in the quarter ended September 30, 2005. Sales of our localized therapy products grew \$2.6 million, \$2.0 million domestically and \$0.6 million internationally. Sales of SAC products fell \$0.8 million, decreasing approximately \$0.7 million domestically and \$0.1 million internationally reflecting lower unit sales volumes. Domestic localized therapy sales growth was primarily due to sales of our Habib 4X resection device and LC Bead embolization product. Internationally, our localized therapy sales continued to reflect the impact of our 2005 decision to sell directly to our customers, rather than through distributors, in Germany, France and the United Kingdom. We believe that our shift to direct distribution will result in international sales growth rates that outpace domestic sales growth rates over the balance of 2006.

Cost of goods sold for the quarter ended September 30, 2006 was \$4.6 million, with a gross margin rate of 64%, compared to \$4.5 million and a gross margin of 60% in the quarter ended September 30, 2005. We believe the improvement in gross margin primarily reflects improved manufacturing efficiency. However, margins were also favorably impacted by an improved sales mix, with a larger percentage of our sales coming from relatively more profitable RF products. Also, our costs

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improved by \$0.1 million because amortization charges were lower than in the 2005 period owing to our 2005 impairment of intangible assets. Cost of goods sold in the quarter ended September 30, 2006 includes approximately \$35,000 in stock compensation expense related to implementation of SFAS 123(R).

Research and development expenses for the quarter ended September 30, 2006 were \$1.4 million, compared to \$0.9 million in the quarter ended September 30, 2005. In the 2006 quarter, spending on our RF-related development work increased by approximately \$0.3 million, and spending on our SAC-related development work increased by approximately \$0.1 million. We expect research and development expenses to increase in the fourth quarter of 2006, compared to the third quarter of 2006. Further, research and development expenses in the quarter ended September 30, 2006 included approximately \$0.1 million in stock compensation expense related to implementation of SFAS 123(R).

Selling, general and administrative expenses for the quarter ended September 30, 2006 were \$7.8 million, compared to \$6.3 million in the quarter ended September 30, 2005. Selling expenses for the 2006 quarter were \$0.8 million higher than in the 2005 quarter, reflecting increased higher compensation and travel expenses domestically and also increased international costs associated with our adoption of direct selling, rather than through distributors, in Germany, France and the United Kingdom. Expenses associated with marketing were \$0.2 million higher in the 2006 quarter, compared to the 2005 quarter, due to increased promotion of our resection and embolization bead products. In the fourth quarter of 2006, marketing spending is also expected to exceed spending in comparable 2005 period. Other selling, general and administrative expenses in the 2006 quarter were \$0.5 million higher than in the 2005 period because the 2006 period included approximately \$0.5 million in stock compensation expense related to implementation of SFAS 123(R).

Interest expense was \$0.2 million for the three months ended September 30, 2006, and was also \$0.2 million for the three months ended September 30, 2005. Other income totaled \$0.1 million for the three months ended September 30, 2006 compared to essentially zero for the three months ended September 30, 2005.

Nine months ended September 30, 2006 and 2005

The following table provides additional detail on our sales results for the nine month periods ended September 30, 2006 and 2005, respectively (in thousands):

	Nine months ended September 30,		Growth	%
	2006	2005		
<b>Domestic sales:</b>				
Localized therapy products*	\$ 15,123	\$ 11,178	\$ 3,945	35%
Specialty access catheter products	16,239	17,817	(1,578)	(9)%
<b>Total domestic sales</b>	<b>\$ 31,362</b>	<b>\$ 28,995</b>	<b>\$ 2,367</b>	<b>8%</b>
<b>International sales:</b>				
Localized therapy products*	\$ 5,157	\$ 3,226	\$ 1,931	60%
Specialty access catheter products	1,705	2,130	(425)	(20)%
<b>Total international sales</b>	<b>\$ 6,862</b>	<b>\$ 5,356</b>	<b>\$ 1,506</b>	<b>28%</b>
<b>Total localized therapy products*</b>	<b>\$ 20,280</b>	<b>\$ 14,404</b>	<b>\$ 5,876</b>	<b>41%</b>
<b>Total specialty access catheter products</b>	<b>17,944</b>	<b>19,947</b>	<b>(2,003)</b>	<b>(10)%</b>
<b>Total sales</b>	<b>\$ 38,224</b>	<b>\$ 34,351</b>	<b>\$ 3,873</b>	<b>11%</b>

\* Localized therapy products include RF products, consisting of radiofrequency ablation (RFA) and radiofrequency resection products such as the HABIB 4X device, and the LC Bead embolization products

For the nine months ended September 30, 2006, sales totaled \$38.2 million, an increase of 11% or \$3.9 million from \$34.4 million in the nine months ended September 30, 2005. Sales of our localized therapy products grew \$5.9 million, of which \$3.9 million was domestic and \$1.9 million was international. Sales of SAC products fell \$2.0 million, decreasing \$1.6 million domestically and \$0.4 million internationally reflecting lower market share and unit sales volumes. Domestic localized therapy sales growth was primarily due to sales of our Habib 4X

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resection device and LC Bead embolization product. Internationally, our localized therapy sales continued to reflect the impact of our 2005 decision to sell directly to our customers, rather than through distributors, in Germany, France and the United Kingdom. We believe that our shift to direct distribution will continue to result in international sales growth that outpaces domestic sales growth in the fourth quarter of 2006.

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Cost of goods sold for the nine months ended September 30, 2006 was \$14.3 million, with a gross margin rate of 63%, compared to \$14.0 million and a gross margin of 59% in the nine months ended September 30, 2005. We believe the improvement in gross margin primarily reflects improved manufacturing efficiency, as the 2005 period was burdened by implementation costs associated with the Horizon merger. However, margins were also favorably impacted by an improved sales mix, with a larger percentage of our sales coming from relatively more profitable RF products, particularly the HABIB 4X resection device. Also, our costs improved by \$0.2 million because amortization charges were lower than in the 2005 period owing to our 2005 impairment of intangible assets. Cost of goods sold in the nine months ended September 30, 2006 includes approximately \$108,000 in stock compensation expense related to implementation of SFAS 123(R).

Research and development expenses for the nine months ended September 30, 2006 were \$4.0 million, compared to \$2.9 million in the nine months ended September 30, 2005. In the 2006 period, spending on our RF-related development work increased by approximately \$0.6 million, partially offset by a \$0.2 million reduction in clinical research spending, while our SAC-related development work increased by approximately \$0.2 million. Further, research and development expenses in the quarter ended September 30, 2006 included approximately \$0.3 million in stock compensation expense related to implementation of SFAS 123(R).

Selling, general and administrative expenses for the nine months ended September 30, 2006 were \$23.8 million, compared to \$20.5 million in the nine months ended September 30, 2005. Selling expenses for the 2006 period were \$1.7 million higher than in the 2005 period, reflecting higher compensation, travel and training expenses domestically and also increased international costs associated with our adoption of direct selling, rather than through distributors, in Germany, France and the United Kingdom. Expenses associated with marketing were \$0.1 million lower in the nine months ended September 30, 2006, compared to the comparable 2005 period, due to reduced investment in reimbursement activities and lower program spending. In the fourth quarter of 2006, and likely throughout 2007, marketing spending is expected to exceed spending in comparable 2005 periods as we intend to introduce new products into the market. Other selling, general and administrative expenses in the 2006 quarter were \$1.7 million higher than in the 2005 period because the 2006 period included approximately \$1.7 million in stock compensation expense related to implementation of SFAS 123(R).

Interest expense was \$0.5 million for the nine months ended September 30, 2006, compared to \$0.7 million for the nine months ended September 30, 2005, reflecting lower interest rates and lower average debt balances. Other expenses, net of interest income, were essentially zero in both of the nine month periods ended September 30, 2006 and 2005, respectively.

## **Liquidity and Capital Resources**

Our balance of cash and cash equivalents on September 30, 2006 was \$6.4 million. We used \$2.7 million in cash in operating activities for the year ended December 31, 2005. In the nine months ended September 30, 2006, operating activities provided \$0.9 million in cash. Our liquidity and capital requirements depend on numerous factors including our research and development expenditures, expenses related to selling, general and administrative operations and working capital to support business growth. Although it is difficult for us to predict future liquidity requirements with certainty, we believe that our current balances of cash and cash equivalents will satisfy our cash requirements for at least the next 12 months. During or after this 12 month period, if cash generated by operations is insufficient to satisfy our liquidity requirements, we may need to issue additional equity or debt securities, borrow from our existing credit facility, obtain an additional credit facility or renegotiate debt repayment terms. There can be no assurance that additional financing will be available to us or, if available, that such financing will be available on terms favorable to us and our stockholders, or that we will be successful in renegotiating debt repayment terms. Failure to obtain sufficient funds on acceptable terms when needed, to make timely debt payments, or to achieve our growth or profitability objectives may require us to curtail operations, perhaps to a significant extent.

For the nine months ended September 30, 2006, net cash provided by operating activities was \$0.9 million. Our net loss of \$4.4 million included non-cash charges of \$5.2 million, specifically \$2.6 million in depreciation and amortization, \$2.2 million in stock-based compensation and a \$0.4 million provision to reserves for uncollectible accounts receivable and inventory. Our working capital accounts, in aggregate, provided \$0.1 million in cash, but this result reflects an investment of \$0.9 million in accounts receivable, inventory and other assets, offset by a \$1.0 million increase in accounts payable, accrued liabilities and deferred revenue. The increase in accounts receivable and inventory was primarily driven by higher sales volumes and operational requirements. The increase in payables and liabilities primarily reflects a \$0.3 million increase in accrued payroll expenses, a \$0.2 million increase in trade payables and royalties due, a \$0.1 million increase in accrued state taxes, a \$0.2 million increase in accrued interest and \$0.2 million in higher accrued professional fees.

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For the nine months ended September 30, 2006, \$1.1 million was used in investing activities. Purchases of property and equipment totaled \$0.7 million. We also paid \$0.5 million to EMCision Limited Incorporated in conjunction with our license to sell our Habib 4X resection device. These amounts were offset by a \$0.1 million reduction in other assets, consisting primarily of a long-term note and long-term prepaid insurance.

Financing activities for the nine months ended September 30, 2006 provided \$1.1 million in cash, reflecting proceeds from issuance of common stock and option exercises in the amount of \$1.2 million partially offset by debt payments of \$0.1 million.

On January 31, 2006 we entered into a Credit Agreement with CapitalSource, which provides for a revolving credit facility in the principal amount of up to \$7 million and we had availability as of September 30, 2006 of approximately \$5 million. Under the agreement we are required to pay CapitalSource a monthly collateral management fee equal to 0.05% per month of the average outstanding principal amount of the revolving facility during the month and an unused line fee in an amount equal to 0.04% per month of the difference derived by subtracting the daily average amount of the balances under the facility outstanding during the preceding month from the facility cap of \$7.0 million. Payments of the monthly unused line fee have totaled \$22,000 for the nine months ended September 30, 2006. To date, we have made no borrowings under this facility.

On August 5, 2005, we completed a private placement of subordinated Senior Convertible Notes (the New Notes ) with an aggregate principal amount of \$9.7 million. The New Notes were issued pursuant to a Securities Purchase Agreement (the Purchase Agreement ) among us and Atlas Master Fund, Ltd., which is not related to us. No warrants or other securities were issued in conjunction with the Purchase Agreement and we incurred no financing costs other than normal and customary legal and other professional expenses. The New Notes are convertible into shares of our common stock at an initial conversion price of \$4.03 per share of common stock. The conversion price of \$4.03 per share of common stock was greater than the per share fair market value of the Company's common stock on the date of issuance of the New Notes. The conversion price is subject to adjustment in certain circumstances, including common stock splits or like events. Until conversion or maturity, the New Notes bear interest at the rate of 6.5% per annum, payable semiannually in cash. Absent conversion, the New Notes mature on August 5, 2008 (the Maturity Date ). If on the Maturity Date the closing price of the common stock has been at or above 102% of the then current conversion price for at least 10 consecutive business days immediately preceding the Maturity Date, then any remaining principal outstanding under the New Notes shall automatically be converted into common stock, subject to certain conditions. The issuance of the New Notes was deemed to be exempt from registration under the Securities Act of 1933 in reliance upon Section 4(2) thereof as transactions by an issuer not involving any public offering. A filing of a registration statement on Form S-3 was required by the Purchase Agreement. Timely filing of the registration statement was made and was declared effective by the SEC. All of the funds raised by the private placement were used to repay previously existing debt.

Prior to August 2000, we financed our operations principally through private placements of convertible preferred stock, raising approximately \$37.9 million net of expenses. On August 1, 2000, we completed our initial public offering of 3.6 million common shares at a price of \$12 per share, raising approximately \$39.0 million net of expenses. All outstanding convertible preferred shares were converted to common shares at that time. To a lesser extent, we also financed our operations through equipment financing and other loans that were fully repaid as of December 31, 2002. In January of 2003, we raised an additional \$8.3 million, net of expenses, through a private placement of our common shares. In November of 2004, we raised an additional \$11.1 million, net of expenses, through a second private placement of our common shares.

As of September 30, 2006, we had no future minimum payments due under capital leases, but we do have commitments under operating leases related to facility rental and office equipment. The New Notes, with an aggregate principal amount of \$9.7 million, remained outstanding at September 30, 2006. The New Notes are due in 2008.

The following table sets forth our future minimum payments due under operating leases, debt agreements and the revolving credit facility as of September 30, 2006. It further includes our commitment, subject to increase in certain future circumstances, to purchase inventory of the LC Bead embolization product under our April 26, 2006 supply and distribution agreement with Biocompatibles UK Limited (in thousands):

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	Operating Leases	Debt	Unused Line Fee	Inventory Purchase Commitment	Total
Fiscal year ended December 31,					
2006 (remaining three months)	\$ 101	\$	\$ 8	\$ 804	\$ 913
2007	393		34	2,000	2,427
2008	349	9,700	34	1,941	12,024
2009	350		3	809	1,162
2010 and thereafter	132				132
Total of future minimum payments	\$ 1,325	\$ 9,700	\$ 79	\$ 5,554	\$ 16,658

Our purchase orders for products are based on our current manufacturing needs and are fulfilled by our vendors within short time horizons. In addition, some of our purchase orders represent authorizations to purchase rather than binding agreements. Other than the distribution agreement with Biocompatibles, we generally do not have significant agreements for the purchase of raw materials or other goods specifying minimum quantities and pre-determined prices that exceed our expected requirements. Therefore, agreements for the purchase of raw materials and other goods and services, excepting the commitments under the distribution agreement with Biocompatibles, are not included in the table above. Agreements for outsourced services generally contain clauses allowing for cancellation without significant penalty, and are therefore not included in the table above.

**Off-Balance Sheet Arrangements**

We had no off-balance sheet arrangements as of September 30, 2006.

**Recent Accounting Pronouncements**

In December 2004, the Financial Accounting Standards Board ( FASB ) issued Statement of Accounting Standards (SFAS) No. 123(R),

Share-Based Payment , which replaces SFAS No. 123. SFAS No. 123(R) requires public companies to recognize an expense for share-based payment arrangements including stock options and employee stock purchase plans. The statement eliminates a company's ability to account for share-based compensation transactions using APB 25, and generally requires instead that such transactions be accounted for using a fair-value based method. SFAS No. 123(R) requires an entity to measure the cost of employee services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant, and to recognize the cost over the period during which the employee is required to provide service in exchange for the award. SFAS No. 123(R) became effective for us in the quarter ending March 31, 2006. The impact of SFAS No. 123(R) was approximately \$2.2 million for the nine months ended September 30, 2006 and it is likely that the adoption of SFAS No. 123(R) will continue to have a material impact on our financial position and results of operations in the future.

In March 2005, the SEC released Staff Accounting Bulletin No. 107 ( SAB 107 ), Share-Based Payment, which provides interpretive guidance related to the interaction between SFAS No. 123(R) and certain SEC rules and regulations. It also provides the SEC staff's views regarding valuation of share-based payment arrangements. Management is currently evaluating the impact SAB 107 will have on our consolidated financial statements.

In November 2005, the FASB issued FASB Staff Position, or FSP, FAS 115-1 and FAS 124-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments, or FSP 115-1, which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and on measuring such impairment loss. FSP 115-1 also includes accounting considerations subsequent to the recognition of other-than-temporary investment impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. We are currently evaluating the effect that the adoption of FSP 115-1 will have on our consolidated results of operations and financial condition but do not expect FSP 115-1 to have a material impact.

In March 2005, the FASB issued FASB Interpretation (FIN) No. 47, Accounting for Conditional Asset Retirement Obligations An Interpretation of FASB Statement No. 143. FIN No. 47 was issued to address diverse accounting practices regarding the timing of liability recognition for legal obligations associated with the retirement of tangible long-lived assets when the timing or method of settlement of the related obligations are conditional on future events. FIN No. 47 concludes that liability should be recognized when incurred if the liability can be reasonably estimated. FIN No. 47 is effective for reporting periods after December 31, 2005. We do not believe the adoption of FIN No. 47 will have a material impact on our consolidated financial position, results of operations or cash flows when effective.





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In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* a replacement of APB Opinion No. 20 and FASB Statement No. 3. SFAS No. 154 replaces APB Opinion No. 20, *Accounting Changes*, and FASB Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements* and changes the requirements for the accounting for and reporting of a change in accounting principle. This statement applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. When a pronouncement includes specific transition provisions, those provisions should be followed. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 31, 2005. We do not believe the adoption of SFAS No. 154 will have a material effect on our consolidated financial position, results of operations or cash flows.

In June 2005, the Emerging Issues Task Force ( EITF ) issued a draft abstract for EITF Issue No. 05-6, *Determining the Amortization Period for Leasehold Improvements Purchased after Lease Inception or Acquired in a Business Combination*. This draft issue was subsequently finalized. The conclusion of the EITF was that leasehold improvements placed in service significantly after and not contemplated at or near the beginning of the lease term should be amortized over the shorter of the useful life of the assets or a term that includes both required lease periods and renewals that are reasonably assured (as defined in paragraph 5 of Statement 13) as of the date the leasehold improvements are purchased. We do not believe the adoption of EITF Issue No. 05-6 will have a material impact on our consolidated financial position, results of operations or cash flows when effective.

In February 2006, the FASB issued a final FSP, FAS 123(R)-4, *Classification of Options and Similar Instruments Issued as Employee Compensation That Allow for Cash Settlement upon the Occurrence of a Contingent Event*. The guidance in this FSP FAS 123(R)-4 amends paragraphs 32 and A229 of FASB Statement No. 123(R) to incorporate the concept articulated in footnote 16 of FAS 123(R). As a result, a cash settlement feature that can be exercised only upon the occurrence of a contingent event that is outside the employee's control does not meet the condition in paragraphs 32 and A229 until it becomes probable that the event will occur. Originally under FAS 123(R), a provision in a share-based payment plan that required an entity to settle outstanding options in cash upon the occurrence of *any contingent event* required classification and accounting for the share based payment as a liability. This caused an issue under certain awards that require or permit, at the holder's election, cash settlement of the option or similar instrument upon (a) a change in control or other liquidity event of the entity or (b) death or disability of the holder. With this new FSP, these types of cash settlement features will not require liability accounting so long as the feature can be exercised only upon the occurrence of a contingent event that is outside the employee's control (such as an initial public offering) until it becomes probable that event will occur. The guidance in this FSP shall be applied upon initial adoption of Statement 123(R). An entity that adopted Statement 123(R) prior to the issuance of the FSP shall apply the guidance in the FSP in the first reporting period beginning after February 2006. Early application of FSP FAS 123(R)-4 is permitted in periods for which financial statements have not yet been issued. We do not anticipate that this new FSP will have any material impact on our financial condition or results of operations.

In February 2006, the FASB issued SFAS 155 *Accounting for Certain Hybrid Financial Instruments*, an amendment of FASB Statements No. 133 and 140. This Statement amends FASB Statements No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. This statement resolves issues addressed in Statement 133 Implementation Issue No. D1, *Application of Statement 133 to Beneficial Interests in Securitized Financial Assets*. This statement:

- a. Permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation
- b. Clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement 133
- c. Establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation
- d. Clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives
- e.

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Amends Statement 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument.

This statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. The fair value election provided for in paragraph 4(c) of this statement may also be applied upon adoption of this statement for hybrid financial instruments that had been bifurcated under paragraph 12 of Statement 133 prior to the adoption of this statement. Earlier adoption is permitted as of the beginning of an entity's fiscal year, provided the entity has not yet issued financial statements, including financial statements for any interim period for that fiscal year. Provisions of this statement may be applied to instruments that an entity holds at the date of adoption on an instrument-by-instrument basis. We are currently evaluating the impact of SFAS 155.

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In March 2006, the FASB issued SFAS No. 156, *Accounting for Servicing of Financial Assets* which amends SFAS No. 140. SFAS 156 requires that all separately recognized servicing assets and servicing liabilities be initially measured at fair value, if practicable. The statement permits, but does not require, the subsequent measurement of servicing assets and servicing liabilities at fair value. SFAS 156 is effective for fiscal years beginning after September 15, 2006. We do not expect the adoption of SFAS 156 to have a material impact on our consolidated financial statements.

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109 ( *FIN 48* ), which clarifies the accounting for uncertainty in tax positions. This Interpretation requires that we recognize the impact of a tax position in our financial statements if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 will be effective as of the beginning of the Company's 2007 fiscal year. We are currently evaluating the impact of FIN 48 on our financial position and results of operations.

In September 2006, the FASB issued SFAS No. 157 ( *FAS 157* ), *Fair Value Measurements*. Among other requirements, FAS 157 defines fair value and establishes a framework for measuring fair value and also expands disclosure about the use of fair value to measure assets and liabilities. The provisions of FAS 157 will be effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact of FAS 157 on our financial position and results of operations.

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements* ( *SAB 108* ), which provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The guidance is applicable for fiscal years ending after November 15, 2006. We do not believe SAB 108 will have a material impact on our consolidated financial statements.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We assumed fixed rate borrowings in conjunction with our merger with Horizon. Essentially all of these borrowings were refinanced in August of 2005 through the purchase agreement under which the Company issued its senior convertible notes. As of September 30, 2006, these notes comprise all of the Company's outstanding debt. As of September 30, 2006, the balance of the senior convertible notes and related interest rate were as follows:

	<b>Balance</b>	<b>Interest</b>
	<b>Outstanding</b>	<b>Rate</b>
Senior Convertible Notes	\$ 9,700,000	6.5 %

Changes in interest rates will affect the fair market value of this borrowing. Otherwise, our market risk disclosures have not changed significantly from those set forth in Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2005 Form 10-K.

**Item 4. Controls and Procedures****Evaluation of Disclosure Controls and Procedures**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that as of December 31, 2005, our internal controls over financial reporting were effective based on those criteria.



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Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by Stonefield Josephson, Inc., an independent registered public accounting firm, as stated in their attestation report which is included in our 2005 Form 10-K.

For the three and nine month periods ended September 30, 2006, the Company has maintained its disclosure controls and procedures designed to ensure that information required to be disclosed in the Company's Securities Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities Exchange Commission's rules and forms and that such information is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required financial disclosure. Accordingly, management believes that the financial statements included in this quarterly report on Form 10-Q for the three and nine month periods ended September 30, 2006, present fairly in all material respects, and in accordance with generally accepted accounting principles in the United States of America, our financial condition, results of operations and cash flows for the periods presented.

## **PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings.** Not applicable.

### **Item 1A. Risk Factors.**

There are no material changes to the risk factors described under the title "Factors That May Affect Future Results" in our 2005 Annual Report on Form 10-K other than the following:

We have added new risk factors entitled:

If we are not successful in developing new radiofrequency and vascular access products, it may negatively impact our revenues and results of operations,

We do not have experience as a distributor of LC Beads, and if we are unable to profitably sell LC Beads and/or meet our minimum quantity requirements, our financial results will be adversely affected,

Our reliance on only one or two suppliers for several of our products or key components of our products could harm our ability to meet demand for our products in a timely manner or within budget,

Our RF and SAC products and the LC Bead product we distribute are subject to product defects, recalls or failures, which could harm our financial results, and

If we are unable to protect our intellectual property rights or if we are found to infringe the rights of others, we may lose market share to our competitors and our business could suffer.

The new risk factor entitled "Our reliance on only one or two suppliers for several of our products or key components of our products could harm our ability to meet demand for our products in a timely manner or within budget" is intended to consolidate the following three related risk factors present in our 2005 Form 10-K, which have been removed from the identified risk factors in this quarterly report on Form 10-Q for the period ended September 30, 2006:

We are dependent on two third-party suppliers for the supply of our generators, and any failure to deliver generators to us could result in lower than expected sales,

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We are dependent on two suppliers as the only sources of a component that we use in our radiofrequency ablation disposable electrodes, and any disruption in the supply of this component could negatively affect our business, and

We are dependent on one supplier as our only source of an accessory device used in conjunction with our Starburst Xlie line of disposable devices, and any disruption in the supply of this device could negatively affect our sales.

Additionally, we believe that the integration of our operations with those of Horizon Medical was essentially complete as of June 30, 2005. Therefore, we believe that the risk factor entitled "We may be unable to realize all of the anticipated benefits of our merger with Horizon Medical Products" is no longer of value to investors and it has been removed from the identified risk factors in this quarterly report on Form 10-Q for the period ended September 30, 2006.

In addition to the other information in this report, the following factors should be considered carefully in evaluating our business and prospects:

**We are heavily dependent on our RF product line, our line of SAC products and the development and introduction of new products in order to achieve our sales goals and our profitability and cash flow targets. Failure to achieve and grow market acceptance for either product line or for new products could harm our results of operations and**

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### **financial condition, including recognition of additional asset impairment charges, and could limit our ability to fund our research and development projects.**

The majority of our sales are expected to come from the sale of our RF products and our line of SAC products. To date, our original sales expectations at the time of the consummation of the Horizon merger have not been met. Sales of our SAC products declined on a quarterly basis throughout 2005 and, also, SAC product sales in the nine month period ended September 30, 2006 were lower than sales for the nine month period ended September 30, 2005. As a result of not meeting sales expectations for our SAC products, in 2005 we recognized an impairment of some of the intangible assets originally established upon consummation of the Horizon merger. Our future financial performance will primarily depend upon physician adoption and patient awareness of our RF, SAC and embolization products for existing indications or, presuming FDA approval, new indications as well as from sales of new products. Our profitability and cash flows as well as our ability to fund our research and development projects will suffer if physician adoption and patient awareness of our products do not meet our expectations. Furthermore, we may be required to recognize additional asset impairment charges in the future if sales expectations of our SAC product line are not met.

### **If we become unable to meet customer demand through disruption of manufacturing operations, our business could suffer.**

We have transitioned our California-based manufacturing operations for our RF products to our Manchester, Georgia location. Our initial production of RF products in that location resulted in relatively low product yields and relatively high unit costs. If we become unable to meet customer demand for our products, our business could suffer. Additionally, changes to our manufacturing processes, such as our plan to implement a new sterilization method for our products or our plans to introduce new products such as a laproscopic version of the HABIB 4X device, could result in a disruption of operations and, if so, our business could suffer.

### **We may need to obtain additional capital to improve our cash liquidity to continue present operations and such additional capital could result in dilution to our stockholders or additional debt repayment obligations.**

We may need to raise additional funds in the future for our business operations and to execute our business strategy. We may seek to sell additional equity or debt securities or utilize our existing credit facility if it is available or to obtain another credit facility. The sale of additional equity or convertible debt securities could result in additional dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights that are senior to holders of common stock and could contain covenants that would restrict our operations. Any additional financing, including the use of our existing credit facility or any new credit facility, may not be available in amounts or on terms acceptable to us, or at all. Failure to obtain sufficient funds on acceptable terms when needed or to make timely debt payments may require us to curtail operations, perhaps to a significant extent.

### **If we are not successful in developing new radiofrequency and vascular access products, it may negatively impact our revenues and results of operations.**

We face technical challenges in developing new radiofrequency and vascular access products, obtaining regulatory approval of such products, and producing such products in sufficient quantities once developed. We believe that the continued introduction of such new products is essential to the Company's future growth. Technical, manufacturing and regulatory difficulties may delay or prevent the introduction of such new products, which would negatively impact our revenues and results of operations.

### **We do not have experience as a distributor of LC Beads, and if we are unable to profitably sell LC Beads and/or meet our minimum quantity requirements, our financial results will be adversely affected.**

In April 2006, we acquired the rights from Biocompatibles UK Limited to be the exclusive distributor in the United States and Canada of Biocompatibles' LC Bead embolization product. The LC Bead product is designed to block the blood supply to tumors. As part of our agreement with Biocompatibles, we agreed to purchase minimum quantities of the LC Bead product during specified periods and further agreed that such purchases will be at or above a stated purchase price. Prior to April 2006, we had no experience as a distributor of LC Beads or any similar embolic bead product. If we are unable to profitably sell the LC Bead product in the required quantities, our revenues, profits and cash flows will be adversely affected and we may need to obtain additional capital.

### **Our reliance on only one or two suppliers for several of our products or key components of our products could harm our ability to meet demand for our products in a timely manner or within budget.**

Some of our products or components necessary for the assembly of our products, including the HABIB 4X bipolar resection device, radiofrequency generators, several of our radiofrequency ablation products and our LC Bead





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embolization product are currently provided to us by only one or two suppliers. We purchase such products or components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. The disruption or termination of the supply of products or components could cause a significant increase in our costs, which could affect our profitability. A disruption or termination in the supply of products or components could also result in our inability to meet demand for our products, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. Furthermore, if we are required to change the manufacturer of our products or components of our products, we may be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could harm our ability to meet demand for our products in a timely manner or within budget.

### **We are dependent on one third-party contractor for the supply of our HABIB 4X bipolar resection device, and any failure to deliver this product to us could result in lower than expected sales.**

We are dependent on one supplier to manufacture our HABIB 4X bipolar device. During the quarter ended September 30, 2005, we received reports that the sterile packaging of some of these devices delivered to customers in the United States had been compromised during shipping. We inspected the first manufacturing lots received in the U.S. from our supplier and determined that a problem existed. As a result, we rejected subsequent product shipments from the manufacturer and requested that all products previously shipped to U.S. customers be returned for replacement. As a result, we were not able to sell as many HABIB 4X bipolar resection devices in the third quarter of 2005 as we had expected. We resumed shipment of HABIB 4X bipolar resection devices in the United States in November 2005 after a packaging redesign was implemented and validated by the manufacturer, and approved by us. The third quarter 2005 failure in shipments and any other future delay or failure in shipments of HABIB 4X bipolar resection devices to us has resulted in, and in the future may result in, our failure to ship the products to customers, resulting in lower than expected sales.

### **Our RF and SAC products and the LC Bead product we distribute are subject to product defects, recalls or failures, which could harm our financial results.**

Like other medical devices, our RF and SAC products and the LC Bead product we distribute can experience and in the past have experienced performance problems in the field that require corrective action. If our suppliers fail to produce components to our specifications, or if the suppliers or we use defective materials or poor workmanship in the manufacturing process, the reliability and performance of our products will be compromised. We cannot assure you that our testing procedures will adequately identify all defects in our products or that component failures, manufacturing errors, or inadequate packaging, which could result in an unsafe condition or injury to the operator or the patient, will not occur. If any defects occur, we may incur warranty or repair costs, be subject to claims for damages related to product defects, be required to recall products, or experience manufacturing, shipping or other delays or interruptions as a result of these defects. Any recall would divert management attention and financial resources and could expose us to product liability or other claims, which may not be adequately covered by insurance, and may harm our reputation with customers which would in turn harm our financial results.

### **Any material weaknesses identified in our internal control over financial reporting or disclosure controls and procedures could have an adverse effect on our business. Additionally, we have expended substantial resources to comply with the Sarbanes-Oxley Act and may be required to expend significant resources in the future.**

For the year ended December 31, 2004, we identified material weaknesses in our procurement process which prior to adjustment, could have resulted in a material misstatement of our annual or interim financial statements. As a result of these material weaknesses, we determined that we did not maintain effective internal control over financial reporting as of December 31, 2004. These material weaknesses have been remediated and no material weaknesses in our internal control over financial reporting have been identified for the year ended December 31, 2005 or for the three and nine month periods ended September 30, 2006. However, because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. A material misstatement in our future annual or interim financial statements could result and our business could suffer. Additionally, we have expended substantial resources to comply with the Sarbanes-Oxley Act and investigate our internal control over financial reporting, and we may be required to expend significant resources in the future. For example, we are currently evaluating and may need to expand or upgrade our enterprise resource planning computer systems. Such a transition would be costly, time consuming and difficult to execute.

### **We have limited experience manufacturing our RF and SAC disposable devices in substantial quantities, and if we are unable to hire sufficient additional personnel or to purchase additional equipment or are otherwise unable to meet customer demand, our business could suffer. Also, we have consolidated our manufacturing operations at our Manchester, Georgia location, and, prior to September 30, 2004, personnel at that location had essentially no experience in manufacturing our radiofrequency ablation disposable devices.**



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To be successful, we must manufacture our products in substantial quantities in compliance with regulatory requirements at acceptable costs. If we do not succeed in manufacturing quantities of our disposable devices that meet customer demand, we could lose customers and our business could suffer. At the present time, we have limited high-volume manufacturing experience. Our manufacturing operations are currently focused on the in-house assembly of our disposable devices. As we increase our manufacturing volume and the number of product designs for our disposable devices, the complexity of our manufacturing processes will increase. Because our manufacturing operations are primarily dependent upon manual assembly, if demand for our products increases we will need to hire additional personnel and may need to purchase additional equipment. If we are unable to sufficiently staff and equip our manufacturing operations, or are otherwise unable to meet customer demand for our products, our business could suffer.

### **We have a history of losses and may never achieve profitability.**

In the nine months ended September 30, 2006, we incurred a net loss of \$4.4 million. We incurred net losses of \$11.0 million in 2005, \$9.3 million in 2004 and \$11.1 million in 2003. At September 30, 2006, we had an accumulated deficit of \$103.7 million. To become profitable we must increase our sales and limit the growth of our operating expenses. If our sales do not grow, or if expenses grow excessively, we may not be able to achieve or maintain profitability in the future. We expect that the implementation of SFAS 123(R) will negatively impact our ability to achieve profitability in 2006 and beyond.

### **Because we face significant competition from companies with greater resources than we have, we may be unable to compete effectively.**

The markets for our products are intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants.

In the market for radiofrequency ablation products, we compete directly with two companies both domestically and internationally: RadioTherapeutics Corporation, a division of Boston Scientific, and Radionics, Inc., a division of Tyco Healthcare, which is a division of Tyco International. Boston Scientific and Tyco International are publicly traded companies with substantially greater resources than we have. Both RadioTherapeutics and Radionics sell products that use radiofrequency energy to ablate soft tissue. Furthermore, in April 2003, we entered into a license agreement with Boston Scientific, its affiliates and licensors, pursuant to which we granted Boston Scientific rights to manufacture and sell products using our infusion technology. As a result, Boston Scientific may develop and sell some competing products that would, in the absence of this license agreement, infringe our patents.

In the market for specialty access catheters and ports, we compete directly with C.R. Bard Inc, Boston Scientific and Sims Deltec, Inc. All of these competitors are publicly traded companies with substantially greater resources and broader product offerings than what we have. The product offerings of these competitors and their selling prices may, in some cases, require us to reduce prices for our SAC products.

We are also aware of several companies in international markets that sell products that compete directly with ours. These companies are affecting our international market share and may erode that share in the future. In addition, one of these companies, Berchtold Corporation, has received FDA clearance for using radiofrequency energy to ablate soft tissue.

### **Alternative therapies could prove to be superior to our RF products or our implantable specialty access products, and physician adoption of our products could be negatively affected.**

In addition to competing against other companies offering products that use radiofrequency energy to ablate soft tissue or implantable vascular products, we also compete against companies developing, manufacturing and marketing alternative therapies that address solid cancerous and benign tumors. If these alternative therapies prove to offer treatment options that are perceived to be superior to our products or to have less severe side effects than those resulting from our products, physician adoption of our products could be negatively affected and our sales could decline.

### **We currently lack long-term data regarding the safety and efficacy of our RF products and may find that long-term data does not support our short-term clinical results or that further short or long-term studies do not support the safety and efficacy of our RF products in various applications. If the safety or efficacy of our RF products is questioned, our sales could decline.**

Our RF products are supported by clinical follow-up data in published clinical reports or scientific presentations covering periods from five months to five years after RF. If additional studies in liver cancer or in other applications fail to confirm or demonstrate the effectiveness of our RF products, our sales could decline. If longer-term patient follow-up or clinical studies indicate that our procedures cause unexpected, serious complications or other unforeseen negative effects, we could be subject to significant liability. Further, because some of our data has been produced in studies that were



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retrospective, not randomized, or included small patient populations and because, in certain circumstances, we rely on clinical data developed by independent third party physicians, our clinical data may not be reproduced in wider patient populations.

### **If we are unable to protect our intellectual property rights or if we are found to infringe the rights of others, we may lose market share to our competitors and our business could suffer.**

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products, and yet we may be unable to do so. A number of companies in our markets, as well as universities and research institutions, have issued patents and have filed patent applications that relate to the use of radiofrequency energy to ablate soft tissue or to the design or manufacture of implantable vascular products.

Under certain circumstances these patent applications could result in lawsuits against us. Our pending United States and foreign patent applications may not issue or may issue and be subsequently successfully challenged by others. In addition, our pending patent applications include claims to material aspects of our products that are not currently protected by issued patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

In the event a competitor infringes on our patent or other intellectual property rights, enforcing those rights, such as by filing a lawsuit, may be difficult and time consuming. It may also be difficult or impossible to enforce our intellectual property rights outside of the United States, particularly in countries where laws are less protective of intellectual property rights. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time consuming and could divert management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against a challenge. In addition, confidentiality agreements executed by our employees, consultants and advisors 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. If we are unable to protect our intellectual property rights, we could lose market share to our competitors and our business could suffer.

### **Our dependence on international sales, which account for a significant portion of our total sales, could harm our business.**

Because our future profitability will depend in part on our ability to increase product sales in international markets, we are exposed to risks specific to business operations outside the United States. These risks include:

the risk of expanding and maintaining a direct sales force in Germany, France and the United Kingdom;

the challenge of managing international sales in other international markets without direct access to the end customer;

lower average selling prices for our products, due to distributor discounts;

the risk of inventory build-up by our distributors which could negatively impact sales in future periods;

obtaining reimbursement for procedures using our devices in some foreign markets;

the burden of complying with complex and changing foreign regulatory requirements;

longer accounts receivable collection time;

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significant currency fluctuations, which could cause our distributors to reduce the number of products they purchase from us because the cost of our products to them could increase relative to the price they could charge their customers;

reduced protection of intellectual property rights in some foreign countries; and

contractual provisions governed by foreign laws.

**We are substantially dependent on our Italian distributor and if we lose this distributor, or if this distributor significantly reduces its product demand, our international and total sales could decline.**

We are substantially dependent on M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, which accounted for 14% and 19% of our international sales for the nine months ended September 30, 2006 and the year ended December 31, 2005, respectively. International sales accounted for 18% and 16% of our total sales for the nine months ended September 30, 2006 and the year ended December 31, 2005, respectively. The loss of this distributor, or a significant decrease in demand from this distributor, could cause our sales to decline substantially.

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### **Our relationships with third-party distributors could negatively affect our sales.**

We currently sell our products in selected international markets and some areas of our domestic market through third-party distributors over whom we have limited control, and, if they fail to adequately support our products, our sales could decline. In the past, we have terminated agreements with distributors and although we contracted with replacement distributors, we expended significant time and resources in doing so, and our sales in the affected markets suffered during the transition period. During 2005, we terminated distributor agreements to initiate direct sales efforts in Germany, France and the United Kingdom. We may in the future terminate distributor agreements with the intent to locate new distributors or with the intent to initiate direct sales efforts in specific markets. If our distributors or we terminate other distributor agreements, we could incur similar or more burdensome expenses, we could expend significant time and resources in finding replacement distributors or in establishing a direct sales force, and our sales could decrease during any related transition period.

We are aware that some of our distributors have, in the past, built up inventory of our products. As a result, future sales to these distributors could be negatively impacted. Sales to our Japanese distributor in 2004 and 2003 and to a domestic distributor in the three months ended September 30, 2004 were so affected. In addition, while our distributors have no price protection and may only return undamaged products per our return policies, if we permit the return of products in excess of our provision for returns, we will have to adjust our revenues relating to these products. This may also impact our revenue recognition policy on future distributor sales.

We have, in the past, experienced collection difficulties, particularly in our international markets. Although these difficulties have been resolved, we may encounter new difficulties with collections that require further increases in our allowance for doubtful accounts in the future, and we may require specific accounts to post letters of credit or pay in advance to minimize our credit risk. Further, we may, in the future, terminate relationships with some of our distributors, making collection of accounts receivable with these customers difficult. Also, the change to direct selling in Germany, France and the United Kingdom may present us with new collections difficulties as we have only very limited collection experience with hospital customers in these countries. We believe our allowance for doubtful accounts sufficiently reflects this possibility, but additional provisions to the allowance for doubtful accounts are could be required. Additional future increases in our allowance for doubtful accounts would reduce our profits or increase our losses.

### **Our business is dependent upon reimbursement from government programs, such as Medicare and Medicaid, and we may face limitations on such third-party reimbursement, which could harm our operating results.**

In the United States, our products are purchased primarily by hospitals and medical clinics, which then bill various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans, for the healthcare services provided to patients. Government agencies, private insurers and other payors determine whether to provide coverage for a particular procedure and reimburse hospitals for medical treatment at a fixed rate based on the diagnosis-related group, or DRG, established by the United States Centers for Medicare and Medicaid Services. The fixed rate of reimbursement is based on the procedure performed and is unrelated to the specific devices used in that procedure. If a procedure is not covered by a DRG, payors may deny reimbursement. In addition, third-party payors may deny reimbursement if they determine that the device used in a treatment was unnecessary, inappropriate or not cost-effective, experimental or used for a non-approved indication.

There can be no assurance that reimbursement for the use of our products will continue at current levels, or that future reimbursement policies of third-party payors will not adversely affect our ability to sell our products on a profitable basis. Failure by hospitals and other users of our products to obtain reimbursement from third-party payors, or changes in government and private third-party payors' policies toward reimbursement for procedures employing our products, would have a material adverse effect on our business, results of operations and financial condition.

### **If customers in markets outside the United States experience difficulty obtaining reimbursement for procedures using our products, international sales could decline.**

Certain of the markets outside the United States in which we sell our products require that specific reimbursement codes be obtained before reimbursement for procedures using our products can be approved. As a result, in countries where specific reimbursement codes are strictly required and have not yet been issued, reimbursement has been denied on that basis. If our distributors or we are unable to either obtain the required reimbursement codes or develop an effective strategy to resolve the reimbursement issue, physicians in foreign markets may be unwilling to purchase our products, negatively impacting our international sales.

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### **We depend on key employees in a competitive market for skilled personnel and without additional employees we cannot grow or achieve profitability.**

We are highly dependent on the principal members of our management team, including our Chief Executive Officer as well as key staff in the areas of finance, sales, operations and research and development, many of whom are highly skilled and potentially difficult to replace. Our future success will depend in part on the continued service of our staff and our ability to identify, hire and retain additional personnel. The markets for qualified management personnel in Northern California, where our headquarters are located, and Georgia, where our primary operating facilities are located, are competitive and expected to remain so. In addition, our Manchester, Georgia facility is located in a rural area and the number of skilled personnel is limited. Because the environment for qualified personnel is so competitive, costs related to compensation may increase significantly. If we are unable to attract and retain both the management team and key personnel we need to support and grow our business, our business will suffer.

### **We are subject to, and may in the future be subject to, costly and time-consuming product liability actions or other patient-related actions.**

We manufacture medical devices that are used on patients in both minimally invasive and open surgical procedures and, as a result, we are and may in the future be subject to product liability lawsuits or other lawsuits based on patient-related claims. Any claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, we may have to pay amounts awarded by a court in excess of policy limits or beyond the scope of our policy. Finally, even a meritless or unsuccessful claim could be time consuming and expensive to defend and could result in the diversion of management's attention from managing our core business.

### **Any failure in our physician training efforts could result in lower than expected product sales.**

It is critical to our sales effort to train a sufficient number of physicians and to instruct them properly in the procedures that utilize our products. We have established formal physician training programs and rely on physicians to devote adequate time to understand how and when our products should be used. If physicians are not properly trained, they may misuse or ineffectively use our products. Such use may result in unsatisfactory patient outcomes, patient injury and related liability or negative publicity that could have an adverse effect on our product sales.

### **We may incur significant costs related to a class action lawsuit due to the likely volatility of our stock.**

Our stock price is likely to fluctuate owing to market uncertainty about our ability to successfully increase our sales, lower our costs and expenses and manage our cash. Our stock price may also fluctuate for a number of other reasons including:

our ability to repay debt;

our ability to successfully commercialize our products;

our ability to comply with Section 404 of the Sarbanes-Oxley Act of 2002;

conclusions that our internal control over financial reporting are ineffective;

announcements regarding patent litigation or the issuance of patents to us or our competitors;

quarterly fluctuations in our results of operations;



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announcements of technological or competitive developments by us or our competitors;

product liability claims;

regulatory developments regarding us or our competitors;

acquisitions or strategic alliances by us or our competitors;

changes in estimates of our financial performance or changes in recommendations by securities analysts; and

general market conditions, particularly for companies with small market capitalizations.

Securities class action litigation is often brought against a company after a period of volatility in the market price of its stock. If our future quarterly operating results are below the expectations of securities analysts or investors, the price of our common stock would likely decline. Stock price fluctuations may be exaggerated if the trading volume of our common stock is low. Any securities litigation claims brought against us could result in substantial expense and divert management's attention from our core business.

**Complying with the FDA and other domestic and foreign regulatory authorities is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.**

We are subject to a host of federal, state, local and foreign regulations regarding the manufacture and marketing of our products. In particular, our failure to comply with FDA regulations could result in, among other things, seizures or recalls of

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our products, an injunction, substantial fines and/or criminal charges against our employees and us. The FDA's medical device reporting regulations require us to report any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned in a way that would be likely to cause or contribute to a death or serious injury if the malfunction recurred.

Sales of our products outside the United States are subject to foreign regulatory requirements that vary from country to country. The time required to obtain approvals from foreign countries may be longer than that required for FDA approval or clearance, and requirements for foreign licensing may differ from FDA requirements. For example, some of our newer RF products have not received approval in Japan. Any failure to obtain necessary regulatory approvals for our new products in foreign countries could negatively affect revenues.

### **Product introductions or modifications may be delayed or canceled as a result of the FDA regulatory process, which could cause our revenues to be below expectations.**

Unless we are exempt, we must obtain the appropriate FDA approval or clearance before we can sell a new medical device in the United States. Obtaining this approval or clearance can be a lengthy and time-consuming process. To date, all of our products have received clearances from the FDA through premarket notification under Section 510(k) of the Federal Food, Drug and Cosmetic Act or are exempt from the 510(k) clearance process. However, if the FDA requires us to submit a new premarket notification under Section 510(k) for modifications to our existing products, or if the FDA requires us to go through a lengthier, more rigorous examination than we now expect, our product introductions or modifications could be delayed or canceled which could cause our revenues to be below expectations. The FDA may determine that future products will require the more costly, lengthy and uncertain premarket approval process.

In addition, modifications to medical device products cleared via the 510(k) process may require a new 510(k) submission. We have, in the past, made minor modifications to the RITA system and to our implantable vascular products. Using the guidelines established by the FDA, we have determined that some of these modifications do not require us to file new 510(k) submissions. If the FDA disagrees with our determinations, we may not be able to sell the RITA system or our implantable vascular products until the FDA has cleared new 510(k) submissions for these modifications, or it may require us to recall previously sold products. In addition, we intend to request additional label indications, such as approvals or clearances for the ablation of tumors in additional organs, including lung, breast, prostate, uterus and kidney, for our current products. The FDA may either deny these requests outright, require additional extensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of approval or clearance. Therefore, obtaining necessary approvals or clearances for these additional applications could be an expensive and lengthy process. In addition, in the course of the FDA process leading to clearance or approval for a new indication, the FDA may request an advisory panel meeting or meetings to discuss the clinical data, the appropriate study design or other criteria for clearance or approval. In the event that the advisory panel advises FDA that the clinical data are inadequate or the study design or other criteria are inappropriate, and the FDA concurs, the FDA clearance or approval process could be lengthened and anticipated revenues from that new indication would be delayed.

### **We may acquire technologies or companies in the future, which could result in the dilution of our stockholders and disruption of our business, and reduce our revenues.**

We are continually evaluating business alliances and external investments in technologies related to our business. Acquisitions of companies, divisions of companies, businesses or products entail numerous risks, any of which could materially harm our business in several ways, including:

diversion of management's attention from our core business objectives and other business concerns;

failure to integrate efficiently businesses or technologies acquired in the future with our pre-existing business or technologies;

potential loss of key employees from either our pre-existing business or the acquired business;

dilution of our existing stockholders as a result of issuing equity securities; and

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assumption of liabilities of the acquired company.

Some or all of these problems may result from future acquisitions or investments. Furthermore, we may not realize any value from such acquisitions or investments.

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**Our certificate of incorporation, our bylaws, Delaware law and our stockholder rights plan contain provisions that could discourage a takeover.**

Provisions of our certificate of incorporation, our bylaws, Delaware law and our stockholder rights plan contain provisions that may discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable.

**Our executive officers and directors could exert significant influence over matters requiring stockholder approval.**

Our executive officers and directors, and their respective affiliates, own approximately 4.2% of our outstanding common stock as of September 30, 2006. These stockholders may, as a practical matter, be able to exert significant influence over matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. This concentration of voting stock could have the effect of delaying or preventing a merger or acquisition or other change of control that a stockholder may consider favorable.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.** None.

**Item 3. Defaults Upon Senior Securities.** Not applicable.

**Item 4. Submission of Matters to a Vote of Security Holders.** Not applicable.

**Item 5. Other Information.**

Commencing in the third quarter of 2006, the Company began paying its non-employee directors a quarterly retainer as compensation for attendance at meetings of the Board of Directors or any committee of the Board of Directors pursuant to the terms of the 2000 Directors' Stock Plan. For 2006, the Board has determined that the retainer will be \$5,000 per quarter, payable in cash and/or stock, for each non-employee director other than the Chairman of the Board, who will be entitled to receive a retainer of \$10,000 per quarter, payable in cash and/or stock.

**Item 6. Exhibits.**

(a) Exhibits:

- 10.102 Offer Letter between the Company and Juan (John) Soto dated August 11, 2006 in connection with his reassignment to the United States office
- 31.1 Rule 13a-14(a) / 15d-14(a) Certification of Chief Executive Officer
- 31.2 Rule 13a-14(a) / 15d-14(a) Certification of Chief Financial Officer
- 32.1 Section 1350 Certification of Chief Executive Officer
- 32.2 Section 1350 Certification of Chief Financial Officer

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**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.

RITA MEDICAL SYSTEMS, INC

By: /s/ Joseph DeVivo  
Joseph DeVivo

President and Chief Executive Officer

Date: November 7, 2006

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