RITA MEDICAL SYSTEMS INC
Form 10-Q
August 09, 2005
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2005

OR

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

For the transition period from _____ to _____

Commission file number 000-30959

RITA MEDICAL SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3199149**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

46421 Landing Parkway

Fremont, CA 94538

(Address of principal executive offices, including zip code)

510-771-0400

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes x No ¨

As of July 28, 2005, there were 41,652,275 shares of the registrant s common stock outstanding.

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PART 1. FINANCIAL INFORMATION

Item 1. Financial Statements

RITA MEDICAL SYSTEMS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

	June 30, 2005 (unaudited)	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	$ 4,262	$ 12,978
Marketable securities		880
Accounts and note receivable, net	6,952	6,410
Inventories	7,774	7,126
Prepaid and other current assets	976	792
Total current assets	19,964	28,186
Long term note receivable, net	133	177
Property and equipment, net	1,821	1,966
Goodwill	91,339	91,339
Intangible assets	30,142	30,600
Other assets	149	41
Total assets	$ 143,548	$ 152,309
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 3,964	$ 2,572
Accrued liabilities	3,197	4,159
Current portion of long term debt	601	7,200
Total current liabilities	7,762	13,931
Long term debt, less current portion	9,385	9,632
Other long term liabilities	74	90
Total liabilities	17,221	23,653
Commitments and contingencies (see Note 15)		
Stockholders equity		

Common stock, $0.001 par value:		
Authorized: 150,000 shares at June 30, 2005 Issued and outstanding: 41,652 shares at June 30, 2005 and 41,350 shares at December 31, 2004	42	41
Additional paid-in capital	217,636	216,893
Accumulated other comprehensive loss		(2)
Accumulated deficit	(91,351)	(88,276)
Total stockholders equity	126,327	128,656
Total liabilities and stockholders equity	$ 143,548	$ 152,309

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

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RITA MEDICAL SYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data, unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2005	2004	2005	2004
Sales	$ 11,955	$ 4,659	$ 23,160	$ 9,303
Cost of goods sold	4,623	1,670	9,428	3,285
Gross profit	7,332	2,989	13,732	6,018
Operating expenses:				
Research and development	999	981	2,038	1,824
Selling, general and administrative	7,415	4,018	14,183	8,384
Restructuring charges			60	
Total operating expenses	8,414	4,999	16,281	10,208
Loss from operations	(1,082)	(2,010)	(2,549)	(4,190)
Interest expense	(211)		(498)	
Interest income and (other expense), net	(94)	7	(28)	17
Net loss	$ (1,387)	$ (2,003)	$ (3,075)	$ (4,173)
Net loss per common share, basic and diluted	$ (0.03)	$ (0.11)	$ (0.07)	$ (0.23)
Shares used in computing net loss per common share, basic and diluted	41,548	18,025	41,503	18,012

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

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RITA MEDICAL SYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands, unaudited)

	Six months ended June 30,	
	2005	**2004**
Cash flows from operating activities:		
Net loss	$ (3,075)	$ (4,173)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,909	792
Loss on disposal of property and equipment		23
Amortization of stock-based compensation	34	101
Allowance for doubtful accounts	(138)	(47)
Provision for obsolete inventories	61	39
Changes in operating assets and liabilities:		
Accounts and note receivable	(434)	(102)
Inventories	(709)	489
Prepaid and other current assets	(184)	329
Accounts payable	1,392	420
Accrued liabilities	(1,463)	(769)
Deferred maintenance revenue	(7)	1
Net cash used in operating activities	(2,614)	(2,897)
Cash flows from investing activities:		
Purchase of property and equipment	(353)	(198)
Purchase of marketable securities	(81)	(712)
Sales and maturities of marketable securities	963	4,181
Capitalization of merger-related costs		(389)
Cash used in acquistion of product license	(50)	
Note receivable, other assets and other long term liabilities	(41)	60
Net cash provided by investing activities	438	2,942
Cash flows from financing activities:		
Principal payments on debt	(6,846)	
Proceeds from issuance of common stock, net of issuance costs	306	179
Net cash provided by (used in) financing activities	(6,540)	179
Net increase (decrease) in cash and cash equivalents	(8,716)	224
Cash and cash equivalents at beginning of period	12,978	3,780

Cash and cash equivalents at end of period	$ 4,262	$ 4,004
Supplemental disclosure of non-cash investing and financing activities:		
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, 2004, as amended, and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X promulgated by the Securities and Exchange Commission. However, 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 for the year ended December 31, 2004 contained in the Company s annual report on Form 10-K as amended.

2. Business Combination

On July 29, 2004, the Company merged with Horizon Medical Products, Inc. (Horizon) in a transaction accounted for under the purchase method of accounting. None of Horizon s results of operations prior to that date are included in the Company s condensed consolidated statements of operations. However, the Company has prepared pro forma financial information showing sales and net loss for the combined entity for the three and six month periods ended June 30, 2004, as if the merger occurred as of January 1, 2004. This unaudited pro forma financial information is presented below in comparison to the Company s unaudited sales and net loss for the three and six month periods ended June 30, 2005, but is not intended to represent or be indicative of the consolidated results of operations of the Company that would have been reported had the acquisition been completed as of January 1, 2004, and should not be taken as representative of the future consolidated results of operations or financial condition of the Company (in thousands, except per share amounts):

	Three months ended June 30,		Six months ended June 30,	
	Actual 2005	Pro forma 2004	Actual 2005	Pro forma 2004
Sales	$ 11,955	$ 12,082	$ 23,160	$ 23,812
Net loss	$ (1,387)	$ (2,290)	$ (3,075)	$ (5,820)
Net loss per common share, basic and diluted	$ (0.03)	$ (0.06)	$ (0.07)	$ (0.16)

Restructuring costs of $1,369,000, consisting entirely of severance related to the termination of employees to eliminate certain duplicative activities, have been incurred since completion of the merger. No portion of this amount was incurred during the three months ended June 30, 2005 and $60,000 was incurred during the six months ended June 30, 2005 (see Note 11, Restructuring).

3. Liquidity

As of June 30, 2005, the Company s total assets were $143.5 million, total tangible assets were $22.1 million, total liabilities were $17.2 million, working capital was $12.2 million and cash and cash equivalents totaled $4.3 million. Current and anticipated demand for the Company s products as well as procurement and production affect 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, together with a working capital line of credit that is currently being negotiated, will be sufficient to fund its operating needs for at least the next 12 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 sell additional equity or debt securities, 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 our growth or profitability objectives may require us to curtail operations, perhaps to a significant extent.

4. Reclassifications

Certain prior year balances have been reclassified to conform to current year presentation. In the Company s quarterly report on Form 10-Q for the three month period ended June 30, 2004, investments in variable rate debt obligations featuring interest rate reset intervals of less than 90 days were classified as cash equivalents. The Company s Consolidated Statement of Cash Flows for the six

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months ended June 30, 2004 has been modified from past presentation to give effect to purchases and sales or maturities of such securities in the determination of net cash provided by (used in) investing activities. For the six months ended June 30, 2004, net cash provided by investing activities increased by $400,000. The Company s Consolidated Statements of Operations and Comprehensive Loss for the six months ended June 30, 2005 and 2004 were not affected by this reclassification.

5. Net loss per share

Basic earnings per share figures are calculated based on the weighted-average number of common shares outstanding during the period less the weighted-average number of any common shares subject to repurchase by the Company. Diluted earnings per share further includes the effect of potentially dilutive securities consisting of stock options and warrants 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 stock options and warrants (prior to application of the treasury stock method) were excluded from the computation of diluted net loss per share as of March 31, 2005, March 31, 2004, June 30, 2005 and June 30, 2004, as their effect was antidilutive (in thousands):

	March 31,		June 30,	
	2005	2004	2005	2004
Effect of potentially dilutive securities:				
Options	7,256	2,743	7,472	2,743
Warrants	3,350	25	3,350	25
Total potentially dilutive securities excluded from the computation of net loss per common share as their effect was antidilutive	10,606	2,768	10,822	2,768

6. Accounting for stock-based compensation

During the year ended December 31, 2002, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure. The Company accounts for stock-based employee compensation arrangements in accordance with provisions of Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees and Financial Accounting Standards Board Interpretations (FIN) No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans.

Under APB Opinion No. 25, compensation expense is based on the difference, if any, on the date of the grant between the fair value of the Company s stock and the exercise price. SFAS No. 123 defines a fair value based method of accounting for an employee stock option or similar equity instruments.

The following table illustrates the effect on net loss and net loss per common share for the three and six month periods ended June 30, 2005 and 2004, respectively, if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation granted under all of its stock option plans and its Employee Stock Purchase Plan (in thousands, except per share amounts):

	Three months ended June 30,		Six months ended June 30,	
	2005	2004	2005	2004
Net loss, as reported	$ (1,387)	$ (2,003)	$ (3,075)	$ (4,173)
Add: Stock-based employee compensation expense included in reported net loss	34	(6)	34	101
Deduct: Total stock-based employee compensation determined under the fair value based method for all awards	(508)	(361)	(1,026)	(1,277)
Net loss, pro forma	$ (1,861)	$ (2,370)	$ (4,067)	$ (5,349)
Basic and diluted net loss per common share:				
As reported	$ (0.03)	$ (0.11)	$ (0.07)	$ (0.23)
Pro forma	$ (0.04)	$ (0.13)	$ (0.10)	$ (0.30)

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The determination of stock-based employee compensation, as relating to the Company s stock option plans, under the fair value based method used the following weighted average assumptions:

	Three months ended June 30,		Six months ended June 30,	
	2005	2004	2005	2004
Volatility	78%	76%	78%	76%
Risk-free interest rate	3.94%	3.49%	3.85%	3.14%
Expected life	5 years	5 years	5 years	5 years
Expected dividends	0%	0%	0%	0%

The corresponding assumptions for the the Company s employee stock purchase plan were as follows:

	Three months ended June 30,		Six months ended June 30,	
	2005	2004	2005	2004
Volatility	60%	60%	60%	60%
Risk-free interest rate	1.73%	1.01%	1.73%	1.01%
Expected life	0.5 years	0.5 years	0.5 years	0.5 years
Expected dividends	0%	0%	0%	0%

7. Inventories

The components of the Company s inventories at June 30, 2005 and December 31, 2004, respectively, were as follows (in thousands):

	June 30, 2005	December 31, 2004
Raw materials	$ 3,176	$ 2,776
Work-in-process	1,247	682
Finished goods	3,351	3,668
	$ 7,774	$ 7,126

8. Intangible assets and related amortization

The Company s intangible assets and related accumulated amortization at June 30, 2005 and December 31, 2004, respectively, were as follows (in thousands):

	June 30, 2005			December 31, 2004		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Capitalized patent defense litigation costs	$ 2,755	$ (715)	$ 2,040	$ 2,755	$ (593)	$ 2,162
Capitalized patent license agreements	3,604	(728)	2,876	2,650	(561)	2,089
Intangible assets recorded at merger with Horizon:						
Customer relationships	16,600	(1,014)	15,586	16,600	(461)	16,139
Product technology	6,900	(527)	6,373	6,900	(239)	6,661
Trademarks	3,000	(275)	2,725	3,000	(125)	2,875
Isomed distribution contract	700	(160)	540	700	(73)	627
Loan closing costs	73	(71)	2	73	(32)	41
Non-compete contracts	36	(36)		36	(30)	6
	$ 33,668	$ (3,526)	$ 30,142	$ 32,714	$ (2,114)	$ 30,600

The Company s capitalized patent license agreements include a license acquired during the quarter ended June 30, 2005 from EMcision Limited Incorporated (EMcision). In acquiring this license, the Company made $50,000 in a cash payment, assumed a liability to pay another $500,000 in cash and issued 150,000 shares of its common stock valued at $403,500. Future payments, contingent upon regulatory approval for use of the licensed technology in the United States, are possible and, if made, will increase the carrying value of the EMcision patent license.

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The remaining amortization periods of the Company s intangible assets as of June 30, 2005 are as follows:

	Amortization periods of intangible assets	
Capitalized patent defense litigation costs	8	years
Capitalized patent license agreements	4 - 13	years
Customer relationships	14	years
Product technology	11	years
Trademarks	9	years
Isomed distribution contract	3	years
Loan closing costs	1	month

Aggregate amortization expense for the six months ended June 30, 2005, estimated amortization expense for the six months ended December 31, 2005, and estimated amortization expense for each of the five years ended December 31, 2006 through 2010 is as follows (in thousands):

Aggregate amortization expense:	
For the six months ended June 30, 2005	$ 1,411
Estimated amortization expense:	
For the six months ended December 31, 2005	$ 1,432
For the twelve months ended December 31, 2006	$ 2,796
For the twelve months ended December 31, 2007	$ 2,796
For the twelve months ended December 31, 2008	$ 2,724
For the twelve months ended December 31, 2009	$ 2,534
For the twelve months ended December 31, 2010	$ 2,412

9. Goodwill

In accordance with the Company s policy, the potential impairment of the Company s goodwill will be reviewed annually, or more often if changes in business conditions so dictate. The Company s market capitalization as of June 30, 2005 was approximately $131.6 million, $5.3 million more than the carrying value of the Company s net assets. As of December 31, 2004, the Company s market capitalization exceeded the carrying value of its assets by $31.4 million. However, since July 29, 2004, the date of the Company s merger with Horizon that gave rise to the Company s goodwill asset, there have been dates as of which the Company s market capitalization was less than the carrying value of its net assets. The Company believes that such results reflect only market uncertainty regarding the integration of operations following the merger with Horizon as well as generally lower valuations of companies in our market sector since July 2004. Further, the Company s management continues to believe the price paid for Horizon to be fair, considering the fair value of net assets acquired and operational savings resulting from the merger and the anticipated performance of the combined Company.

For these reasons, and because the Company s market capitalization is in excess of its net assets, both as of June 30, 2005 and also as of the date of this report on Form 10-Q, the Company believes it is not now confronted by an event or circumstance that would more likely than not reduce the fair value of the Company below the carrying amount. However, if in the future the Company s market capitalization decreases below its net assets, the Company will perform a review to assess the potential impairment of its goodwill asset.

10. Debt

The Company has the following debts:

Senior Subordinated Convertible Notes (the Senior Notes): As of June 30, 2005, $8,262,000 was owed under the Senior Notes. This balance reflects a prepayment of $6.5 million that the Company made during the quarter ended March 31, 2005. The balance due under the Senior Notes will come due in July 2008. The Senior Notes currently bear interest, payable quarterly, at 8.0% per annum. This interest rate increased to 14% per annum on July 29, 2005. The Company may prepay the Senior Notes without a penalty prior to their respective maturity dates.

Junior Promissory Note (the Junior Note): As of June 30, 2005, $1,392,500 was owed under the Junior Note. The Junior Note bears interest at a rate of 6% per annum, is payable monthly and matures in March 2007. The monthly principal payment is $22,500 until maturity at which time a balloon payment of $920,000 is due. The Company may prepay the Junior Note without a penalty prior to its maturity date.

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A note payable for the Stepic business purchase (the Stepic Note): As of June 30, 2005, $331,451 was owed under the Stepic Note. The Stepic Note bears interest at 8% and calls for monthly interest and principal payments of approximately $38,000. The Stepic Note is due and scheduled to be fully repaid in March 2006.

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.

Future maturities of debt outstanding as of June 30, 2005 are as follows (in thousands):

Six months ending December 31, 2005	$ 354
Six months ending June 30, 2006	247
Six months ending December 31, 2006	135
Twelve months ending December 31, 2007	988
Twelve months ending December 31, 2008	8,262
	$ 9,986

See also Note 16, Subsequent Event: Convertible Debt Financing.

11. Restructuring

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 merger was completed, is $1,369,000. These charges were accounted for in accordance with SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. As of June 30, 2005, $1,132,000 of the accrued amount has been paid and $237,000 remains unpaid.

12. Segment information

As a result of the merger with Horizon, the Company expanded its customer base and portfolio of products, which resulted in two groups of medical oncology products: radiofrequency ablation (RFA) systems, which consist largely of the products sold by RITA prior to the merger, and specialty access catheter products, which are the products sold by Horizon prior to the merger.

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 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 two medical oncology product groups for the three and six month periods ended June 30, 2005 and 2004 are as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2005	2004	2005	2004
Radiofrequency ablation products	$ 5,162	$ 4,659	$ 9,690	$ 9,303
Specialty access catheter products	6,793		13,470	
Total medical oncology product sales	$ 11,955	$ 4,659	$ 23,160	$ 9,303

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Sales for the Company s domestic and international selling regions for the three and six month periods ended June 30, 2005 and 2004 are as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2005	2004	2005	2004
Domestic	$ 9,738	$ 3,710	$ 19,386	$ 7,381
International	2,217	949	3,774	1,922
Total medical oncology product sales	$ 11,955	$ 4,659	$ 23,160	$ 9,303

13. 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.

14. Recent accounting pronouncements

In March 2004, the Financial Accounting Standards Board (FASB) issued EITF Issue No. 03-1 (EITF 03-1), The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments which provides new guidance for assessing impairment losses on investments. Additionally, EITF 03-1 includes new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB delayed the accounting provisions of EITF 03-1; however, the disclosure requirements remain effective for annual periods ending after June 15, 2004. The Company will evaluate the impact of EITF 03-1 once the final guidance is issued.

Effective April 1, 2004, the SEC adopted Staff Accounting Bulletin No. 105, Application of Accounting Principles to Loan Commitments (SAB 105). SAB 105 clarifies the requirements for the valuation of loan commitments that are accounted for as derivatives in accordance with SFAS 133. Management does not expect the implementation of this new bulletin to have any impact on the Company s financial position, results of operations and cash flows. The Company does not have any loan commitments.

In July 2004, the EITF issued a draft abstract for EITF Issue No. 04-08, The Effect of Contingently Convertible Debt on Diluted Earnings per Share (EITF 04-08). EITF 04-08 reflects the Task Force s conclusion that contingently convertible debt should be included in diluted earnings per share computations regardless of whether the market price trigger has been met. EITF 04-08 is effective for reporting periods ending after December 15, 2004. Prior period earnings per share amounts presented for comparative purposes are required to be restated to conform to this consensus and the Company is required to include the shares issuable upon the conversion of the Debt in the diluted earnings per share computation for all periods during which contingently convertible notes are outstanding. In August 2005, the Company issued contingently convertible debt (see Note 16, Subsequent Event: Convertible Debt Financing). Although the Company has not yet quantified the impact of this

standard on its financial statements, it is likely that adoption of this standard will have a material impact on the Company s results of operations, financial position, and cash flows.

In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning in the second quarter of fiscal 2006. The Company does not believe the adoption of SFAS No. 151 will have a material effect on its consolidated financial position, results of operations or cash flows.

In December 2004, the FASB issued Statement of Accounting Standards (SFAS) No. 123R, Share-Based Payment , which replaces SFAS No. 123. SFAS No. 123R 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. 123R 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. In April 2005, the SEC amended the compliance dates for SFAS 123(R), to allow companies to implement the standard at the beginning of their next fiscal year, instead of the next reporting period beginning after June 15, 2005. SFAS No. 123R is effective for the Company in the quarter ending March 31, 2006. Upon adoption of SFAS 123R, companies are allowed to select one of three alternative transition methods, each of which has different financial reporting implications. Management is currently evaluating the transition methods, valuation methodologies and other assumptions for employee stock options in light of SFAS No. 123R. Current estimates of option values using the Black-Scholes method may not be indicative of results from valuation methodologies ultimately implemented by the Company upon adoption of SFAS No. 123R. Although the Company has not yet fully quantified the impact this standard will have on its financial statements, it is likely that the adoption of SFAS No. 123R will have a material impact on the Company s financial position and results of operations.

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In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standard (SFAS) No. 153, Exchanges of Nonmonetary Assets - an amendment of APB Opinion No. 29, which amends Opinion 29 by eliminating the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for fiscal years beginning after June 15, 2005, and implementation is done prospectively. Management does not expect the implementation of this new standard to have a material impact on the Company s financial position, results of operations and cash flows.

In December 2004, the FASB issued and made effective two Staff Positions (FSP) that provide accounting guidance on how companies should account for the effect of the American Jobs Creation Act of 2004 that was signed into law on October 22, 2004. In FSP FAS 109-1, Application of FASB Statement No. 109, Accounting for Income Taxes, to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004, the FASB concluded that the special tax deduction for domestic manufacturing, created by the new legislation, should be accounted for as a special deduction instead of a tax rate reduction. As such, the special tax deduction for domestic manufacturing is recognized no earlier than the year in which the deduction is taken on the tax return. FSP FAS 109-2, Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004, allows additional time to evaluate the effects of the new legislation on any plan for reinvestment or repatriation of foreign earnings for purposes of applying FASB Statement No. 109. The Company does not anticipate that this legislation will impact its results of operations or financial condition.

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 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 the Company s consolidated financial statements.

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. The Company does not believe the adoption of SFAS No. 154 will have a material effect on its consolidated financial position, results of operations or cash flows.

15. Commitments and contingencies

The Company has commitments for operating leases related to facility rental and office equipment. Future minimum payments under operating leases are as follows (in thousands):

Six months ending December 31, 2005	$ 213
Year ending December 31, 2006	404
Year ending December 31, 2007	383
Year ending December 31, 2008	350
Year ending December 31, 2009	355
Year ending December 31, 2010 and thereafter	116

Total of future minimum operating lease payments	$ 1,821

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.

16. Subsequent event: Convertible Debt Financing

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 common stock of the Company at an initial conversion price of $4.03 per share of common stock. The conversion price is subject to adjustment in certain circumstances. 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.

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The securities sold pursuant to the Purchase Agreement have not yet been registered under the Securities Act of 1933 and may not be offered or sold in the United States in the absence of an effective registration statement or exemption from registration requirements. Pursuant to the Purchase Agreement, the Company is required to file a registration statement on Form S-3 within 30 days after the closing of the transaction for purposes of registering the resale of the shares of Common Stock issuable upon conversion of the Notes. If (i) the registration statement is not declared effective within 60 days after the filing in the event that the SEC does not undertake a review of the registration statement, or (ii) such registration statement is not declared effective within 120 days after the filing in the event that the SEC does undertake a review of the registration statement, then the Company has agreed to make pro-rata payments to each purchaser in an amount equal to 1% of the aggregate purchase price paid by each purchaser for the New Notes for each 30-day period following the applicable deadline or during any period in which sales cannot be made (the Default Fee), provided that in no event shall the aggregate amount of cash to be paid as Default Fees exceed 12% of the aggregate purchase price paid by each purchaser for the New Notes.

The consummation of the Purchase Agreement and the issuance of the New Notes triggered an event of default under the note purchase agreement governing the Company s Senior Notes held by Medtronic and ComVest (the Note Purchase Agreement). Accordingly, as of August 5, 2005, ComVest and Medtronic may, by written notice to the Company, declare the unpaid principal amount of the Senior Notes to be immediately due and payable, together with the interest accrued thereon and all fees, costs, expenses, indemnities and other obligations (as defined in the Note Purchase Agreement). The Company is not currently aware of any material fees, costs or expenses. Alternatively, Medtronic and ComVest may convert any portion of the principal amount of the Senior Debt into shares of the Company s common stock at a price equal to 90% of the five day average of the closing price of the Company s common stock before the date of the notice. As of August 9, 2005, the aggregate unpaid principal amount of the Senior Notes is $8,262,000, and the aggregate amount of accrued interest payable on the 2002 Senior Notes is $115,894.

Pursuant to the terms of the New Notes, the Company must repay the Senior Notes within 21 days of the issuance of the New Notes, or August 26, 2005. Failure to repay the Senior Notes will result in an Event of Default (as defined in the Notes). ComVest and Medtronic were sent notice of the Company s intent to prepay the Senior Notes on August 5, 2005. Unless ComVest and / or Medtronic elect to convert their debt into shares of the Company s common stock, the Company will use the proceeds from the private placement to retire the Senior Notes on or about August 9, 2005. Further, the Company plans to use the proceeds from the private placement to retire its Junior Note held by Bank of America prior to August 12, 2005.

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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 , s 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, 2004, as amended. 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.

Overview

We develop, manufacture and market innovative products for cancer patients, including radiofrequency ablation (RFA) systems for treating cancerous tumors as well as percutaneous vascular and spinal access systems. 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.

On July 29, 2004, the Company merged with Horizon Medical Products, Inc. (Horizon) in a transaction accounted for under the purchase method of accounting. None of Horizon s results of operations prior to that date are included in the Company s condensed consolidated statements of operations. We believe the merger will lead to higher sales and greater profitability than either or both of the pre-merger companies on a standalone basis due to a larger, more effective sales group, consolidation of manufacturing resulting in lower product costs, and reduced administrative expenses.

Horizon operated as a specialty medical device company focused on manufacturing and marketing vascular products, particularly oncology product lines including implantable vascular ports, tunneled catheters and stem cell transplant catheters used in cancer treatment protocols (collectively, specialty access catheter or SAC products). Each Horizon common stockholder received 0.4212 of a share of the Company s common stock for each share of Horizon common stock held. The Company thereby issued approximately 18.7 million shares of its common stock to acquire all issued and outstanding shares of Horizon common stock, and further assumed all outstanding Horizon options and warrants that, upon exercise, will result in the issuance of approximately 3.9 million shares of the Company s common stock. The fair value of shares issued by the Company was approximately $91.6 million based on a price per share of $4.896, the Company s average closing price the day the proposed merger was announced (May 13, 2004), the two business days preceding the announcement and the two business days following the announcement. The fair value of options and warrants, all of which were fully vested when assumed by the Company was determined to be approximately $15.4 million using the Black-Scholes valuation model. Costs incurred to effect the merger and to be included as a component of purchase price were $2.3 million. The total purchase price was approximately $109.3 million. The fair value of assets acquired, net of liabilities assumed, was approximately $18.0 million, resulting in goodwill of $91.3 million. We believe the merger will lead to higher sales and greater profitability due to a larger, more effective sales group, consolidation of manufacturing resulting in lower product costs, and reduced administrative expenses.

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Management relies on certain statistical measurements to assess trends in sales growth and the effectiveness of our selling strategies. The following table, derived from our Consolidated Statements of Operations and other unaudited data for the three and six month periods ended June 30, 2005 and 2004, and for the years ended December 31, 2004, 2003 and 2002, sets forth some of these measurements:

	Three months ended June 30,		Six months ended June 30,		Years ended December 31,		
	2005	2004	2005	2004	2004	2003	2002
Total sales (in thousands)	$ 11,955	$ 4,659	$ 23,160	$ 9,303	$ 28,215	$ 16,607	$ 17,393
Percentage of sales: United States	81%	80%	84%	79%	84%	80%	74%
Percentage of sales: International	19%	20%	16%	21%	16%	20%	26%
Percentage of sales: Radiofrequency products	43%	100%	42%	100%	62%	100%	100%
Percentage of sales: Specialty access catheters	57%	0%	58%	0%	38%	0%	0%
Gross margin	61%	64%	59%	65%	60%	63%	60%

Consolidation of Horizon s results did not begin until the closing date of the merger, July 29, 2004. Therefore, the percentages shown for historical periods must be used with caution, as they may not be indicative of future results.

Prior to completion of the Horizon merger, our products were sold in the United States exclusively through our direct sales force and internationally through distribution partners. Horizon, in contrast, made use of domestic distribution partners in selected areas of the United States. Since completion of the merger, we have begun to distribute our radiofrequency ablation products through two of these domestic distribution partners. However, direct sales will remain our predominant mode of domestic distribution for the foreseeable future.

Our sales in the United States are 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, and we introduced our premium-priced Starburst Xli and Xlie families of disposable needles in this region earlier than in Europe or other regions. These actions have for some time resulted in a growing percentage of radiofrequency ablation product sales derived from the domestic market, although in the second quarter of 2005 this trend was reversed with stronger radiofrequency sales growth in our international markets, at least in part because of the introduction of a new product, our Habib 4X Sealer, in Europe. However, the specialty access catheter products acquired in the merger with Horizon are heavily concentrated in the domestic market, and, further, the merger permits wider and more efficient sales force coverage of the domestic market, which should continue the long-term trend towards relatively rapid growth in our domestic business. We expect 2005 sales growth in the United States to continue to outpace international growth because we believe the principal impact of the Horizon merger will be upon the domestic market and because introduction of premium products to our international distributors will have a relatively small impact on growth due to pricing limitations.

Prior to completion of the Horizon merger, essentially all of our sales came from the sale of our disposable devices and radiofrequency generators used in the treatment of cancerous liver tumors. The merger with Horizon expanded our product offering and has resulted in additional sales, primarily from the specialty access catheter and port product lines used in cancer treatment protocols. Going forward, we expect that approximately 95% of our sales will be derived from our RFA and SAC disposable products, with the balance of our sales coming from hardware products. We believe that the broader product line and larger sales group resulting from the merger will enable us to increase the effectiveness of our selling effort in the future.

Our manufacturing costs consist of raw materials, including generators and ancillary hardware components produced for us by third-party suppliers, labor to produce our disposable devices and to inspect incoming, in-process and finished goods, sterilization performed by an outside service provider and general overhead expenses. Our manufacturing costs are volume-dependent, and our unit costs should decrease as our production volumes increase. The integration of our manufacturing operations in our Manchester, Georgia location, completed during the second quarter of 2005, should result in lower costs in the future from the use of less expensive labor and economies of scale. We also believe we have the opportunity to reduce the cost of our vendor-supplied hardware products through higher order volumes or product redesign. Besides manufacturing costs, our cost of goods sold reflects amortization of intangible assets relating to product technology. We expect these amortization charges to continue through 2016. Our cost of goods sold also includes provisions to our reserve for obsolete inventory. Technology in our marketplace has evolved rapidly and we have, from time to time, recognized relatively high expenses related to obsolete inventory as our product line has changed. We may experience similar product changes and related obsolete inventory provisions in the future.

Our gross margins reflect our selling prices, our domestic / international mix percentages, our product mix percentages, our production volumes, the prices we pay for vendor manufactured product and our provisions for obsolete inventory. Our gross margin for the quarter ended June 30, 2005 was 61%, compared to a gross margin of 64% for the quarter ended June 30, 2004. We believe that the 61% gross margin in the second quarter of 2005 reflects costs associated with the integration of our manufacturing operations and is therefore lower than our long-term expectations for the business. However, historically, the gross margin rate for our specialty

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access catheter products has been lower than that of our radiofrequency ablation products. Also, amortization of our product technology related intangible assets will negatively impact cost of goods sold. Future gross margins may, therefore, be lower than our historical gross margin rates because of inclusion of these products and expenses in our results.

In addition to the selling statistics discussed above, management relies on certain measurements to assess the effectiveness of our operations. The following tables sets forth some of these measurements, derived from our Unaudited Condensed Consolidated Statements of Operations for the three and six month periods ended June 30, 2005 and 2004, our Consolidated Statements of Operations for the years ended December 31, 2004, 2003 and 2002, our Unaudited Condensed Consolidated Balance Sheets as of June 30, 2005 and March 31, 2005, and our Consolidated Balance Sheets as of December 31, 2004, 2003 and 2002 (in thousands):

	Three months ended June 30,		Six months ended June 30,		Years ended December 31,		
	2005	2004	2005	2004	2004	2003	2002
Research and development expense	$ 999	$ 981	$ 2,038	$ 1,824	$ 3,787	$ 4,294	$ 5,052
Selling, general and administrative expense	7,415	4,018	14,183	8,384	20,637	17,418	19,366
Restructuring charges			60		1,309		
Total operating expenses	$ 8,414	$ 4,999	$ 16,281	$ 10,208	$ 25,733	$ 21,712	$ 24,418

	June 30, 2005	March 31, 2005	December 31, 2004	2003	2002
Cash and cash equivalents	$ 4,262	$ 5,906	$ 12,978	$ 3,780	$ 4,438
Marketable securities, current and long term		251	880	5,755	8,397
Total cash and marketable securities	$ 4,262	$ 6,157	$ 13,858	$ 9,535	$ 12,835

If we are to become profitable, we must continue to manage our operating expenses. Our operating expenses consist of product development costs, clinical trial expenses, patent litigation expenses, sales and marketing expenses related to our selling efforts in the United States, Europe and Asia, and administrative expenses, including the costs associated with our status as a public company, professional service expenses and our provisions for uncollectible accounts. Changes in these expenses are determined by the breadth of our new product development portfolio, the number of headcount we maintain in our selling and administrative functions, the scope of our marketing efforts, the costs we incur in defense of our patents and intellectual property rights and the extent to which credit issues and economic conditions constrain our ability to collect our receivables.

Research spending in the quarter ended June 30, 2005 was $1.0 million, compared to $1.0 million in the quarter ended June 30, 2004. Research spending in 2005 is expected to increase modestly, driven by programs aimed at technical innovation of our radiofrequency ablation products and the introduction of new implantable ports and access catheters.

Selling, general and administrative expense in the quarter ended June 30, 2005 was $7.4 million, compared to $4.0 million in the quarter ended June 30, 2004. The primary reasons for the increase were the consolidation of Horizon results and expenses incurred in the integration of the two companies. We believe our integration efforts are now complete. Also, the merger resulted in recognition of intangible assets relating to trademarks, customer relationships and our distribution contract with Medtronic, amortization of which will result in charges to selling, general and administrative expense of $1.4 million to $1.6 million per year through 2014. Further, during the quarter ended June 30, 2005 we continued to incur significant public company costs, particularly expenses related to compliance with the Sarbanes-Oxley Act of 2002. We incurred restructuring expenses of $60,000 during the six months ended June 30, 2005, consisting of severance related to termination of employees to eliminate duplicative activities. The total of such restructuring charges since the merger is $1,369,000, and we believe our restructuring is now complete.

In addition to management of our operating expenses, we must continue to conserve our cash. Our combined total of cash, cash equivalents was $4.3 million as of June 30, 2005, compared to $13.9 million at December 31, 2004. Our net cash used in operating activities for the six month period ended June 30, 2005 was $2.6 million. We had approximately $10.0 million in short term and long term debt as of June 30, 2005. We may in the future need to raise additional cash through borrowing or sale of equity securities or to renegotiate the payment terms of our debt.

We incurred a net loss of $1.4 million for the quarter ended June 30, 2005 compared to $2.0 million for the quarter ended June 30, 2004. Future profitability depends on, among other things, our success in expanding product usage in our current markets and in developing new markets, as well as our ability to improve our gross margins and control our expenses. To the extent current or new markets do not materialize in accordance with our expectations, our sales could be lower than expected and we may be unable to achieve or sustain profitability.

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In the first quarter of 2006, we expect to implement SFAS No. 123R. We have not yet been able to determine the impact of SFAS No. 123R on our results in 2006, or in subsequent years, but we expect to incur significant charges as a result of adoption of the standard.

Critical Accounting Policies and Estimates

Our critical accounting policies and estimates were discussed in our annual report on Form 10-K for the fiscal year ended December 31, 2004, as amended. All of the policies and estimates discussed at that time remain unchanged.

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 June 30, 2005 and the four preceding fiscal quarters:

	Q2 2005	Q1 2005	Q4 2004	Q3 2004	Q2 2004
Domestic sales	81%	86%	86%	86%	80%
International sales	19%	14%	14%	14%	20%
Total sales	100%	100%	100%	100%	100%
Cost of goods sold	39%	43%	47%	35%	36%
Gross profit	61%	57%	53%	65%	64%
Operating expenses:					
Research and development	8%	9%	9%	11%	21%
Selling, general and administrative	62%	60%	56%	78%	86%
Restructuring charges	0%	1%	2%	14%	0%
Total operating expenses	70%	70%	67%	103%	107%
Loss from operations	(9)%	(13)%	(14)%	(38)%	(43)%
Interest expense	(2)%	(3)%	(3)%	(3)%	0%
Interest income and other expense, net	(1)%	1%	0%	0%	0%
Net loss	(12)%	(15)%	(17)%	(41)%	(43)%

Three months ended June 30, 2005 and 2004

The following table, which sets forth key comparisons of our sales results for the second quarter of 2005 compared to the second quarter of 2004, provides additional information on the impact of the consolidation of our acquired vascular access products upon our results (in

thousands):

	Three months ended June 30,			
	2005	2004	Growth	%
Domestic sales:				
Radiofrequency ablation products	$ 3,892	$ 3,710	$ 182	5%
Specialty access catheter products	5,846		5,846	
Total domestic sales	$ 9,738	$ 3,710	$ 6,028	162%
International sales:				
Radiofrequency ablation products	$ 1,270	$ 949	$ 321	34%
Specialty access catheter products	947		947	
Total international sales	$ 2,217	$ 949	$ 1,268	134%
Total radiofrequency ablation sales	$ 5,162	$ 4,659	$ 503	11%
Total specialty access catheter products	6,793		6,793	
Total sales	$ 11,955	$ 4,659	$ 7,296	157%

For the quarter ended June 30, 2005, sales totaled $12.0 million, an increase of 157% or $7.3 million from $4.7 million in the second quarter of 2004. Sales of specialty access catheter products acquired in the merger with Horizon explained most of this increase, adding $6.8 million to our sales, while sales of our radiofrequency ablation products increased $0.5 million or 11% compared to the quarter ended June 30, 2004. Domestic sales of radiofrequency ablation products were 5% higher in the 2005 quarter

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than in the 2004 quarter. International sales of radiofrequency ablation products were 34% higher in the 2005 quarter than in the 2004 quarter. For the quarter ended June 30, 2005, domestic sales represented 81% of total sales, compared to 80% in the second quarter of 2004.

Cost of goods sold for the quarter ended June 30, 2005 was $4.6 million, up from $1.7 million for the quarter ended June 30, 2004, primarily reflecting inclusion of $2.8 million in cost associated with SAC product sales. Cost of goods sold for the quarter ended June 30, 2005 also reflects a $0.1 million increase in patent-related amortization and $0.2 million in net costs associated with integration of our manufacturing operations following the Horizon merger, but these factors were offset by a $0.2 million decrease in our provision for obsolete inventory compared to the prior period. Our gross margin rate was 61% in the second quarter of 2005, compared to 64% in the quarter ended June 30, 2004. We believe that the 61% gross margin in the second quarter of 2005 reflects costs associated with the integration of our manufacturing operations and is therefore lower than our long-term expectations for the business. However, historically, the gross margin rate for our specialty access catheter products has been lower than that of our radiofrequency ablation products. Also, amortization of our product technology related intangible assets will negatively impact cost of goods sold. Future gross margins may, therefore, be lower than our historical gross margin rates because of inclusion of these products and expenses in our results.

Research and development expenses for the second quarter ended June 30, 2005 were $1.0 million, equal to the $1.0 million of research and development expense we incurred in the second quarter of 2004. Inclusion of research and development expenses for specialty access products that totaled $0.1 million for the quarter ended June 30, 2005, but the impact of these new expenses was offset by reduced legal expenses relating to our patents and by reduced expenses for RFA product development. Expenses associated with clinical trial work, specifically investigations into the use of our technology in the fields of kidney and breast cancer, increased modestly.

Selling, general and administrative expenses for the quarter ended June 30, 2005 were $7.4 million, compared to $4.0 million in the second quarter of 2004. Increased sales and marketing expenses reflecting headcount increases and programs after the Horizon merger totaled $1.4 million for the second quarter of 2005. Similarly, corporate expenses in our administrative functions following the Horizon merger, including payroll, insurance, rent and public company costs, increased $1.3 million over the prior period. Another $0.4 million of the increase for the 2005 period resulted from amortization of merger-related intangible assets. Expenses associated with management turnover increased $0.2 million in the 2005 second quarter, compared to the second quarter of 2004. Our bad debt expense was about $0.1 million higher in the second quarter of 2005, compared to the second quarter of 2004.

Interest expense, net of interest and other income, for the second quarter ended June 30, 2005 was $0.3 million. We had no net interest expense in the prior year period.

Six months ended June 30, 2005 and 2004

The following table, which sets forth key comparisons of our sales results for the first six months of 2005 compared to the first six months of 2004, provides additional information on the impact of the consolidation of our acquired vascular access products upon our results (in thousands):

	Six months ended June 30,			
	2005	2004	Growth	%

Domestic sales:				
Radiofrequency ablation products	$ 7,493	$ 7,381	$ 112	2%
Vascular access products	11,894		11,894	
Total domestic sales	$ 19,387	$ 7,381	$ 12,006	163%
International sales:				
Radiofrequency ablation products	$ 2,197	$ 1,922	$ 275	14%
Vascular access products	1,576		1,576	
Total international sales	$ 3,773	$ 1,922	$ 1,851	96%
Total radiofrequency ablation sales	$ 9,690	$ 9,303	$ 387	4%
Total vascular access product sales	13,470		13,470	
Total sales	$ 23,160	$ 9,303	$ 13,857	149%

For the six months ended June 30, 2005, sales totaled $23.2 million, an increase of 149%, or $13.9 million, from $9.3 million in the first six months of 2004. Sales of specialty access catheter products acquired in the merger with Horizon explained most of this increase, adding $13.5 million to our sales, while sales of our radiofrequency ablation products increased $0.4 million or 4%

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compared to the six months ended June 30, 2004. Domestic sales of radiofrequency ablation products were 2% higher in the first half of 2005 than in the first half of 2004. International sales of radiofrequency ablation products were 14% higher in the first half of 2005 than in the first half of 2004. For the six months ended June 30, 2005, domestic sales represented 84% of total sales, compared to 79% in the first six months of 2004.

Cost of goods sold for the six months ended June 30, 2005 was $9.4 million, up from $3.3 million for the first six months ended June 30, 2004, primarily reflecting inclusion of $5.4 million in cost associated with SAC product sales. Cost of goods sold for the six months ended June 30, 2005 also reflects a $0.3 million increase in patent-related amortization and $0.8 million in net costs associated with integration of our manufacturing operations following the Horizon merger, but these factors were offset by a $0.4 million decrease in our provision for obsolete inventory compared to the prior period. Our gross margin rate was 59% in the first six months of 2005, compared to 65% in the prior period. We believe that the 59% gross margin in the first six months of 2005 reflects unusual costs associated with the integration of our manufacturing operations and is therefore lower than our long-term expectations for the business. However, historically, the gross margin rate for our specialty access catheter products has been lower than that of our radiofrequency ablation products. Also, amortization of our product technology related intangible assets will negatively impact cost of goods sold. Future gross margins may, therefore, be lower than our historical gross margin rates because of inclusion of these products and expenses in our results.

Research and development expense for the six months ended June 30, 2005 was $2.0 million, $0.2 million higher than the $1.8 million of research and development expense we incurred in the first six months of 2004. Inclusion of research and development expenses for specialty access products added $0.2 million to our research and development expense for the first half of 2005, compared to the prior period, and expenses associated with clinical trial work, specifically investigations into the use of our technology in the fields of kidney and breast cancer, also increased by $0.2 million. The impact of these new expenses was offset by $0.1 million in reduced legal expense relating to our patents and by a $0.1 million reduction in expense for RFA product development.

Selling, general and administrative expenses for the six months ended June 30, 2005 were $14.2 million, compared to $8.4 million in the first six months of 2004. Increased sales and marketing expenses reflecting headcount increases and programs after the Horizon merger totaled $2.4 million for the first six months of 2005. Similarly, following the Horizon merger, corporate expenses in our administrative functions, including payroll, insurance, rent and public company costs, increased $2.5 million over the six months ended June 30, 2004. Another $0.8 million of the increase for the period resulted from amortization of merger-related intangible assets. Expenses associated with management turnover increased $0.2 million in the first six months of 2005, compared to the first six months of 2004. Our bad debt expense was about $0.1 million lower in the first six months of 2005, compared to the first six months of 2004.

Interest expense, net of interest and other income, for the six months ended June 30, 2005 was $0.5 million. We had essentially no net interest expense in the prior year period.

Liquidity and Capital Resources

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 and warrants to purchase our common shares. As of June 30, 2005, we had $4.3 million of cash and cash equivalents and $12.2 million of working capital.

For the six months ended June 30, 2005, net cash used in operating activities was $2.6 million principally due to our net loss of $3.1 million, offset by non-cash charges of $1.9 million, including depreciation and amortization, stock-based compensation and provisions to reserves for uncollectible accounts receivable and inventory. Stock-based compensation for the six months ended June 30, 2005 was essentially zero, resulting from the impact of decreases in our stock price on the revaluation of consultant options. Approximately $1.4 million in cash was used in the six month period by changes in working capital accounts, including a $0.4 million increase in accounts and notes receivable, a $0.7 million increase in inventory and a $0.2 million increase in prepaid expenses. Accounts payable and accrued liabilities, in aggregate, decreased by $0.1 million. For the six months ended June 30, 2005, $0.4 million was provided by investing activities, with net sales of marketable securities providing $0.9 million offset by $0.4 million used in purchase of property and equipment and $50,000 used in the acquisition of a patent license from EMcision Limited Incorporated (EMcision). The acquisition of the EMcision license further required the Company to commit to payment of an additional $500,000 in the future and to issue 150,000 of its common shares valued at $403,500. Financing activities for the six months ended June 30, 2005 used $6.5 million in cash, reflecting $6.8 million in debt payments made during the period offset by $0.3 million raised by the issuance of common stock in conjunction with the exercise of stock options.

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We have, from time to time, financed equipment through capital and operating leases. Also, in the course of the Horizon merger, we acquired debt, the balance of which was $10.0 million as of June 30, 2005. As of June 30, 2005, we had no future minimum payments due under capital leases. Future minimum payments due under our operating leases and debt agreements were as follows (in thousands):

	Operating Leases	Debt	Total
Six months ending December 31, 2005	$ 213	$ 354	$ 567
Year ending December 31, 2006	404	382	786
Year ending December 31, 2007	383	988	1,371
Year ending December 31, 2008	350	8,262	8,612
Year ending December 31, 2009	355		355
Year ending December 31, 2010 and thereafter	116		116
Total of future minimum operating lease payments	$ 1,821	$ 9,986	$ 11,807

Our 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. Our net cash used in operating activities was $2.6 million for the six month period ended June 30, 2005. Our balance of cash and cash equivalents at June 30, 2005 was $4.3 million. Subsequent to June 30, 2005, the Company completed a private placement of Senior Convertible Notes (the New Notes , see Private Placement of Convertible Debt). The terms of the New Notes require the Company to pay the unpaid balances of the Senior Notes and such payment will reduce the Company s interest expense by approximately $600,000 on an annualized basis. Additionally, the Securities Purchase Agreement pursuant to which the New Notes were issued (the Purchase Agreement) allows for subordination of the New Notes to certain working capital indebtedness. As a result, the Company is currently negotiating for a working capital line of credit to support its working capital needs. Although it is difficult for us to predict future liquidity requirements with certainty, we believe that our current balances of cash and cash equivalents and the successful negotiation and execution of a working capital line of credit will satisfy our cash requirements for at least the next 12 months. During or after this period, if cash generated by operations is insufficient to satisfy our liquidity requirements and/or we are unsuccessful in entering into a working capital line of credit, we may need to sell additional equity or debt securities, 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.

Private Placement of Convertible Debt

On August 5, 2005, the Company completed a private placement of subordinated Senior Convertible Notes with an aggregate principal amount of $9.7 million. The New Notes were issued pursuant to a Securities 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 expenses. The New Notes are convertible into shares of common stock of the Company at an initial conversion price of $4.03 per share of common stock. The conversion price is subject to adjustment in certain circumstances. 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 securities sold pursuant to the Purchase Agreement have not yet been registered under the Securities Act of 1933 and may not be offered or sold in the United States in the absence of an effective registration statement or exemption from registration requirements. Pursuant to the Purchase Agreement, the Company is required to file a registration statement on Form S-3 within 30 days after the closing of the transaction for

purposes of registering the resale of the shares of Common Stock issuable upon conversion of the Notes. If (i) the registration statement is not declared effective within 60 days after the filing in the event that the SEC does not undertake a review of the registration statement, or (ii) such registration statement is not declared effective within 120 days after the filing in the event that the SEC does undertake a review of the registration statement, then the Company has agreed to make pro-rata payments to each of the Investors in an amount equal to 1% of the aggregate purchase price paid by each Purchaser for the New Notes for each 30-day period following the applicable deadline or during any period in which sales cannot be made (the Default Fee), provided that in no event shall the aggregate amount of cash to be paid as Default Fees exceed 12% of the aggregate purchase price paid by each Purchaser for the New Notes.

The consummation of the Purchase Agreement and the issuance of the New Notes triggered an event of default under the note purchase agreement governing the Company s Senior Notes held by Medtronic and ComVest (the Note Purchase Agreement). Accordingly, as of August 5, 2005, ComVest and Medtronic may, by written notice to the Company, declare the unpaid principal amount of the Senior Notes to be immediately due and payable, together with the interest accrued thereon and all fees, costs, expenses, indemnities and other obligations (as defined in the Note Purchase Agreement). The Company is not currently aware of any material fees, costs or expenses. Alternatively, Medtronic and ComVest may convert any portion of the principal amount of the Senior Debt into shares of the Company s common stock at a price equal to 90% of the five day average of the closing price of the Company s common stock before the date of the notice. As of August 9, 2005, the aggregate unpaid principal amount of the Senior Notes is $8,262,000, and the aggregate amount of accrued interest payable on the 2002 Senior Notes is $115,894.

Pursuant to the terms of the New Notes, the Company must repay the Senior Notes within 21 days of the issuance of the New Notes, or August 26, 2005. Failure to repay the Senior Notes will result in an Event of Default (as defined in the Notes). ComVest and Medtronic were sent notice of the Company s intent to prepay the Senior Notes on August 5, 2005. Unless ComVest and / or Medtronic elect to convert their debt into shares of the Company s common stock, the Company will use the proceeds from the private placement to retire the Senior Notes on or about August 9, 2005. Further, the Company plans to use the proceeds from the private placement to retire its Junior Note held by Bank of America prior to August 12, 2005.

Recent Accounting Pronouncements

In March 2004, the Financial Accounting Standards Board (FASB) issued EITF Issue No. 03-1 (EITF 03-1), The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments which provides new guidance for assessing impairment losses on investments. Additionally, EITF 03-1 includes new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB delayed the accounting provisions of EITF 03-1; however, the disclosure requirements remain effective for annual periods ending after June 15, 2004. The Company will evaluate the impact of EITF 03-1 once the final guidance is issued.

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Effective April 1, 2004, the SEC adopted Staff Accounting Bulletin No. 105, Application of Accounting Principles to Loan Commitments (SAB 105). SAB 105 clarifies the requirements for the valuation of loan commitments that are accounted for as derivatives in accordance with SFAS 133. Management does not expect the implementation of this new bulletin to have any impact on our financial position, results of operations and cash flows. The Company does not have any loan commitments.

In July 2004, the EITF issued a draft abstract for EITF Issue No. 04-08, The Effect of Contingently Convertible Debt on Diluted Earnings per Share (EITF 04-08). EITF 04-08 reflects the Task Force s conclusion that contingently convertible debt should be included in diluted earnings per share computations regardless of whether the market price trigger has been met. EITF 04-08 is effective for reporting periods ending after December 15, 2004. Prior period earnings per share amounts presented for comparative purposes are required to be restated to conform to this consensus and the Company is required to include the shares issuable upon the conversion of the Notes in the diluted earnings per share computation for all periods during which contingently convertible notes are outstanding. In August 2005, the Company issued contingently convertible debt (see Note 16, Subsequent Event: Convertible Debt Financing). Although the Company has not yet quantified the impact of this standard on its financial statements, it is likely that adoption of this standard will have a material impact on the Company s results of operations.

In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning in the second quarter of fiscal 2006. The Company does not believe the adoption of SFAS No. 151 will have a material effect on its consolidated financial position, results of operations or cash flows.

In December 2004, the FASB issued Statement of Accounting Standards (SFAS) No. 123R, Share-Based Payment , which replaces SFAS No. 123. SFAS No. 123R 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. 123R 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. In April 2005, the SEC amended the compliance dates for SFAS 123(R), to allow companies to implement the standard at the beginning of their next fiscal year, instead of the next reporting period beginning after June 15, 2005. SFAS No. 123R is effective for the Company in the quarter ending March 31, 2006. Upon adoption of SFAS 123R, companies are allowed to select one of three alternative transition methods, each of which has different financial reporting implications. Management is currently evaluating the transition methods, valuation methodologies and other assumptions for employee stock options in light of SFAS No. 123R. Current estimates of option values using the Black-Scholes method may not be indicative of results from valuation methodologies ultimately implemented by the Company upon adoption of SFAS No. 123R. Although the Company has not yet fully quantified the impact this standard will have on its financial statements, it is likely that the adoption of SFAS No. 123R will have a material impact on the Company s financial position and results of operations.

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standard (SFAS) No. 153, Exchanges of Nonmonetary Assets - an amendment of APB Opinion No. 29, which amends Opinion 29 by eliminating the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for fiscal years beginning after June 15, 2005, and implementation is done prospectively. Management does not expect the implementation of this new standard to have a material impact on the Company s financial position, results of operations and cash flows.

In December 2004, the FASB issued and made effective two Staff Positions (FSP) that provide accounting guidance on how companies should account for the effect of the American Jobs Creation Act of 2004 that was signed into law on October 22, 2004. In FSP FAS 109-1, Application of FASB Statement No. 109, Accounting for Income Taxes, to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004, the FASB concluded that the special tax deduction for domestic manufacturing, created by the new legislation, should be accounted for as a special deduction instead of a tax rate reduction. As such, the special tax deduction for domestic manufacturing is

recognized no earlier than the year in which the deduction is taken on the tax return. FSP FAS 109-2, Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004, allows additional time to evaluate the effects of the new legislation on any plan for reinvestment or repatriation of foreign earnings for purposes of applying FASB Statement No. 109. The Company does not anticipate that this legislation will impact its results of operations or financial condition.

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 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 the Company s consolidated financial statements.

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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. The Company does not believe the adoption of SFAS No. 154 will have a material effect on its consolidated financial position, results of operations or cash flows.

Factors That May Affect Future Results

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

We have limited experience manufacturing our RFA 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.

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 system 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.

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 to our Manchester, Georgia location. We have incurred low product yields in our initial production runs of RFA products in Georgia. If we become unable to meet customer demand for our products, or if the high initial costs associated with manufacture of our RFA products in Georgia do not abate, our business could suffer.

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We have identified material weaknesses in our internal control over financial reporting. Failure to remediate these weaknesses could impact the reliability of our financial reporting.

To date, we have identified material weaknesses in our procurement process which did, prior to adjustment, or could otherwise, result in a material misstatement of our annual or interim financial statements. As a result of these material weaknesses, we have determined that we did not maintain effective internal control over financial reporting as of December 31, 2004. See our disclosure in Status of Management s Report on Internal Control over Financial Reporting included in our annual report on Form 10-K, as amended, for the year ended December 31, 2004 for further discussion of these material weaknesses.

We may be unable to realize all of the anticipated benefits of our merger with Horizon Medical Products.

Our merger with Horizon involved the integration of two companies that previously have operated independently, a complex, costly and time-consuming process. The difficulties of combining the companies operations have included, among other things:

- Coordinating geographically disparate organizations, systems and facilities;
- Integrating personnel with diverse business backgrounds;
- Consolidating corporate and administrative functions;
- Consolidating research and development, and manufacturing operations;
- Coordinating sales and marketing functions;
- Retaining key employees; and
- Preserving research and development, collaboration, distribution, marketing, promotion and other important relationships of the companies.

We believe the integration of the two companies to be essentially complete as of June 30, 2005. However, as of June 30, 2005, we have less than a full year of combined operations, and we may, in the future, encounter again any or all of the difficulties in operational integration we have faced in the period since the merger. These difficulties could include an interruption of, or loss of momentum in, the activities of the combined company s business and the loss of key personnel. Further, the diversion of our management s attention and any delays or difficulties encountered in connection with the operation of our geographically disparate organization could harm our business, results of operations, financial condition or prospects.

We will be heavily dependent on the RITA system and our line of specialty access catheters in order to achieve our sales goals and our profitability targets. Failure to achieve and grow market acceptance for either product line could harm our business.

The majority of our sales will come from the sale of the RITA system and our line of specialty access catheters. Our financial performance will depend upon physician adoption and patient awareness of these products. If we are unable to convince physicians to use these products, we may not be able to generate sales because we do not have alternative products.

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

We incurred net losses of $3.1 million during the first six months of 2005, $9.3 million in 2004, $11.1 million in 2003, $13.5 million in 2002, $13.0 million in 2001, $12.8 million in 2000 and $7.5 million in 1999. At June 30, 2005, we had an accumulated deficit of $91.4 million. To become profitable we must increase our sales and continue to 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.

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

The market for our products is 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 after October 5, 2004. 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. C.R. Bard is a publicly traded company with substantially greater resources than we have.

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 radiofrequency ablation system 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 radiofrequency ablation 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 radiofrequency ablation products in various applications. If the safety or efficacy of our radiofrequency ablation products is questioned, our sales could decline.

Our radiofrequency ablation products are supported by clinical follow-up data in published clinical reports or scientific presentations covering periods from five months to five years after radiofrequency ablation. If additional studies in liver cancer or in other applications fail to confirm or demonstrate the effectiveness of our radiofrequency ablation products, our sales could decline. If

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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 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 market, 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 may be difficult and time consuming. 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 revenues, which account for a significant portion of our total revenues, 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 challenge of managing international sales 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;

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 18% of our international sales in the first six months of 2005 and 19% of our international sales for the year ended December 31, 2004. International sales accounted for 16% of our total sales in the first six months of 2005 and 16% of our total sales for the year ended December 31, 2004. The loss of this distributor, or a significant decrease in demand from this distributor, could cause our sales to decline substantially.

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

We sell our products in international markets and selected domestic markets 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 that lasted approximately nine months. If our

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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.

In 2002, we significantly increased our allowance for doubtful accounts to address the risk associated with longer collection periods that have arisen principally with our European distributors. Although the deterioration we experienced in international collections in 2002 stabilized in 2003, and has remained stable in 2004 and 2005, 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. 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.

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 revenues.

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, or CMS. 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.

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, operations and research and development. During our second quarter ended June 30, 2005, our Chief Financial Officer announced his resignation effective as of October 2005, and a search is being conducted for a replacement. 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 are primary operating facilities are located, are competitive and expected to remain so. 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.

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. Any product liability 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

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addition, we could have to pay any amount awarded by a court in excess of policy limits. Finally, even a meritless or unsuccessful product liability 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 understanding 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 integrate the operations of Horizon 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;

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.

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

Until 2003, there was only one supplier available to provide us with a component that we include in our disposable devices. During the quarter ended September 30, 2003, we qualified a second supplier. However, a disruption in the supply of this component is still possible and could negatively affect revenues. If we were unable to remedy a disruption in supply of this component within twelve months, we could be required to redesign the handle of our RFA disposable devices, which could divert engineering resources from other projects or add to product costs. In addition, a new or supplemental filing with applicable regulatory authorities may require clearance prior to our marketing a product containing new materials. This clearance process may take a substantial period of time, and we may be unable to obtain necessary regulatory approvals for any new material to be used in our products on a timely basis, if at all.

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

In the past, we have experienced shortages in the supply of accessory infusion pumps used in conjunction with our Starburst Xli and Starburst Xlie lines of disposable radiofrequency devices. We currently have one supplier for our accessory infusion pumps and, although we believe this supplier to be reliable, future disruptions in supply are possible. In that event, our business could suffer due to lower sales or higher costs.

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

We are dependent on two third-party suppliers to produce our RFA generators. While we have agreements with both of these suppliers, any delay in shipments of generators to us could result in our failure to ship generators to customers and could negatively affect sales.

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 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 RFA 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. 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, uterus and breast, 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

assumption of liabilities of the acquired company.

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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.

We may need to raise additional capital in the future resulting in dilution to our stockholders.

We may need to raise additional funds for our business operations and to execute our business strategy. We may seek to sell additional equity or debt securities or to obtain an additional 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 may not be available in amounts or on terms acceptable to us, if 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.

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 4.6% of our outstanding common stock as of June 30, 2005. 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 3. Quantitative and Qualitative Disclosures About Market Risk

We assumed fixed rate borrowings in conjunction with our merger with Horizon Medical Products. These borrowings have increased our interest expense. Also, changes in interest rates will affect the fair market value of these borrowings. As of June, 2005 the Company s borrowings and related interest rates were as follows:

	Balance Oustanding	Interest Rate
Senior subordinated convertible notes	$ 8,262,000	8.0%
Junior promissory note	1,392,500	6.0%
Note payable	331,450	8.0%
Total borrowings outstanding and weighted average interest rate	$ 9,985,950	7.7%

On July 29, 2005, the interest rate on the Senior Subordinated Convertible Notes increased to 14%. Except for these factors, 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 annual report on Form 10-K for the year ended December 31, 2004, as amended.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures that are 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.

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of Company management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to the Securities Exchange Act of 1934 Rules 13a-15(b) and 15d-15(b). Based upon, and as of the date of this evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were not effective, because the material weaknesses discussed in the Company s annual report on Form 10-K for the year ended December 31, 2004, as amended, have not yet been fully remediated. In light of these material weaknesses, the Company performed additional analysis and other post-closing procedures to ensure that the consolidated financial statements were prepared in accordance with generally accepted accounting principles. Accordingly, management believes that the financial statements included in this report fairly present in all material respects our financial condition, results of operations and cash flows for the periods presented.

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Changes in Internal Control Over Financial Reporting

The material weaknesses identified and discussed in the Company s annual report on Form 10-K for the year ended December 31, 2004, as amended, have resulted in changes in the Company s internal control over financial reporting during the quarter ended June 30, 2005, that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Although not yet complete, during the quarter ended June 30, 2005, we continued the following actions to remediate the material weaknesses we identified to be present as of December 31, 2004**:**

- Hiring of additional personnel, permitting enhanced segregation of duties and additional review;
- Additional training of staff;
- Identification of procedural improvements in our accounting processes;
- Enhancement of procedures for timely submission of invoices, particularly those received in California, to our Georgia-based accounting department.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings. Not applicable.

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

In May, 2005, the Company issued 150,000 shares of its commons stock to EMcision Limited pursuant to an exclusive worldwide license agreement for the Habib Sealer disposable radiofrequency resection device. In addition to the shares of common stock, the Company made a cash payment of $50,000 to EMcision and agreed to pay $500,000 upon the one year anniversary of the agreement. Further, the Company will pay EMcision an additional $200,000 upon the United States Food and Drug Administration s approval of EMcision s 510(K) application for use of the technology in the United States.

Item 3. Defaults Upon Senior Securities. Not applicable.

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

(a) On June 8, 2005, the Annual Meeting of Stockholders of RITA Medical Systems, Inc. was held in Menlo Park, California.

(b) An election of Class II directors was held with the following individuals being elected to our Board of Directors to serve until our Annual Meeting of Stockholders for the year ending December 31, 2008:

James E. Brands	(31,813,516 votes for, 3,428,433 votes withheld)
Thomas J. Dugan	(31,898,292 votes for, 3,343,657 votes withheld)
Wesley E. Johnson, Jr.	(31,903,231 votes for, 3,338,7181 votes withheld)

(c) Other matters voted upon and approved at the Annual Meeting and the number of affirmations, negative votes cast and abstentions with respect to each such matter were as follows:

Approval of the 2005 Stock and Incentive Plan (18,631,261 votes in favor, 4,347,056 votes opposed, 108,191 votes abstaining, 12,155,441 broker non-votes).

Approval of amendments to the 2000 Directors Stock Option Plan (the Directors Plan) to, among other things, (i) increase the number of shares of common stock issuable under the Directors Plan by an additional 500,000 shares, to an aggregate of 1,000,000 shares (approximately 2.4% of the outstanding shares as of April 11, 2005), (ii) increase the number of shares subject to options granted to nonemployee directors in connection with their initial appointment to the Board (from 25,000 shares) to 35,000 shares, (iii) increase the number of shares subject to options granted as of each annual meeting of stockholders to nonemployee directors in connection with their continued service on the Board (from 10,000 shares) to 20,000 shares, (iv) add new automatic annual option grants of 30,000 shares as of each annual meeting of stockholders to a nonemployee director who is serving as Chairman of the Board of the Company (in lieu of the 20,000-share annual option grant that other nonemployee directors will receive), (v) add new automatic annual option grants of 5,000 shares as of each annual meeting of stockholders to each nonemployee director who is at that time serving on a committee of the Board, (vi) add new automatic annual option grants of 2,000 shares as of each annual meeting of stockholders to each nonemployee director who is at that time serving as a chairperson of a committee of the Board (in addition to the 5,000-share option grant the director

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would be entitled to receive for serving on a committee as described above), (vii) provide that the number of shares to be granted subject to each automatic option grant as described above will automatically increase each year (beginning in 2006) by 3% of the number of shares subject to that type of automatic option grant for the previous year, (viii) provide that all options granted to nonemployee directors upon their initial appointment to the Board shall vest and become exercisable as to 1/36th of the total option shares each month following the grant date assuming continued service on the Board throughout such period (compared to 1/48th monthly vesting under the current terms of the Directors Plan), (ix) provide that all options granted to nonemployee directors as of the date of the Company s annual meeting of stockholders shall vest and become exercisable, assuming continued service on the Board throughout such period, as of the earlier of (a) the one year anniversary of the date of grant of the option and (b) the date immediately preceding the date of the annual meeting of the Company s stockholders for the year following the year of grant of the option, and (x) permit nonemployee directors eligible to receive any Board retainer payment to elect to receive such payment in the form of shares of our common stock issued under the Directors Plan (18,598,291 votes in favor, 4,383,448 votes opposed, 104,769 votes abstaining, 12,155,441 broker non-votes).

A proposal to re-appoint PricewaterhouseCoopers LLP as the Company s independent public accountants was not considered.

Item 5. Other Information. Not applicable.

Item 6. Exhibits.

(a) Exhibits:

4.12	Warrant dated December 13, 2001 between the Company and BEKL Corporation
10.4(1)	2000 Directors Stock Option Plan (as amended) and form of option agreement
10.90(1)	2005 Stock and Incentive Plan
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

(1) Incorporated by reference to our report on Form S-8 (File No. 333-126471) filed with the SEC on July 8, 2005.

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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: August 9, 2005

EXHIBIT INDEX

4.12	Warrant dated December 13, 2001 between the Company and BEKL Corporation
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