RITA MEDICAL SYSTEMS INC
Form 10-Q
August 09, 2004
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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, 2004

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.)**

967 N. Shoreline Blvd.

Mountain View, CA 94043

(Address of principal executive offices, including zip code)

650-314-3400

(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, 2004, there were 18,039,158 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, unaudited)

	June 30, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 4,404	$ 4,580
Marketable securities	1,881	4,022
Accounts and note receivable, net	3,101	2,990
Inventories	1,664	2,192
Prepaid and other current assets	699	1,028
Total current assets	11,749	14,812
Long term marketable securities		933
Long term note receivable, net	316	338
Property and equipment, net	754	1,089
Intangible assets	5,967	4,814
Other assets	47	47
Total assets	$ 18,833	$ 22,033
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 1,178	$ 757
Accrued liabilities	2,445	2,169
Total current liabilities	3,623	2,926
Deferred maintenance revenue, less current portion	24	23
Total liabilities	3,647	2,949
Stockholders equity		
Common stock	18	18
Additional paid-in capital	98,317	98,037

Accumulated other comprehensive income	(3)	2
Accumulated deficit	(83,146)	(78,973)
Total stockholders equity	15,186	19,084
Total liabilities and stockholders equity	$ 18,833	$ 22,033

The accompanying notes are an integral part of the 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,	
	2004	2003	2004	2003
Sales	$ 4,659	$ 4,049	$ 9,303	$ 8,546
Cost of goods sold	1,670	1,702	3,285	3,276
Gross profit	2,989	2,347	6,018	5,270
Operating expenses:				
Research and development	981	1,061	1,824	2,419
Selling, general and administrative	4,018	4,736	8,384	9,300
Total operating expenses	4,999	5,797	10,208	11,719
Loss from operations	(2,010)	(3,450)	(4,190)	(6,449)
Interest income and other expense, net	7	50	17	125
Net loss	$ (2,003)	$ (3,400)	$ (4,173)	$ (6,324)
Net loss per common share, basic and diluted	$ (0.11)	$ (0.19)	$ (0.23)	$ (0.36)
Shares used in computing net loss per common share, basic and diluted	18,025	17,578	18,012	17,402

The accompanying notes are an integral part of the 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,	
	2004	**2003**
Cash flows from operating activities:		
Net loss	$ (4,173)	$ (6,324)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	792	784
Loss on disposal of property and equipment	23	
Revaluation of common stock warrants for services received		(42)
Amortization of stock-based compensation	101	
Allowance for doubtful accounts	(47)	55
Provision for obsolete inventories	39	247
Changes in operating assets and liabilities:		
Accounts and note receivable	(102)	(316)
Inventories	489	547
Prepaid and other current assets	329	332
Accounts payable and accrued liabilities	(349)	(1,450)
Deferred maintenance revenue	1	
Net cash used in operating activities	(2,897)	(6,167)
Cash flows from investing activities:		
Purchase of property and equipment	(198)	(409)
Purchase of marketable securities	(312)	(6,871)
Sales and maturities of marketable securities	3,381	4,367
Capitalization of patent litigation costs		(621)
Acquisition of intangibles		(2,650)
Capitalization of merger-related costs	(389)	
Note receivable and other assets	60	68
Net cash provided by (used in) investing activities	2,542	(6,116)
Cash flows from financing activities:		
Proceeds from issuance of common stock	179	9,152
Net cash provided by financing activities	179	9,152
Net decrease in cash and cash equivalents	(176)	(3,131)
Cash and cash equivalents at beginning of period	4,580	6,888

Cash and cash equivalents at end of period	$ 4,404	$ 3,757

The accompanying notes are an integral part of the 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, 2003 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 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, 2003 contained in the Company s annual report on Form 10-K.

2. Liquidity

As of June 30, 2004, the Company s total assets were $18.8 million, total liabilities were $3.6 million, working capital was $8.1 million and cash and cash equivalents totaled $4.4 million. Current and anticipated demand for the Company s products as well as procurement and production affect the need for capital. Also, the Company s merger with Horizon Medical Products will require significant cash payments over the last six months of 2004 and further require service of acquired debt, which totaled approximately $17.7 million as of the merger date, July 29, 2004. Approximately $6.5 million of this debt will come due in July of 2005. If the cash we expect to generate from operations is insufficient to satisfy our liquidity requirements, we may need to sell additional equity or debt securities or obtain an additional credit facility. 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 the Company and our stockholders. In addition, future equity financings could result in dilution to shareholders, and future debt financings could result in certain financial and operational restrictions.

3. 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 dilutive 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 reconciliation of total weighted average outstanding common shares to shares used in determining net loss per share is as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Weighted average shares of common stock outstanding	18,025	17,582	18,012	17,410
Less: weighted-average shares subject to repurchase		(4)		(8)
Weighted average shares used in basic and diluted net loss per common share	18,025	17,578	18,012	17,402

The following numbers of shares represented by options and warrants (prior to application of the treasury stock method) and shares subject to repurchase were excluded from the computation of diluted net loss per share as their effect was antidilutive (in thousands):

	June 30,	
	2004	2003
Effect of potentially dilutive securities:		
Options	2,743	2,182
Warrants	25	25
Total potentially dilutive securities excluded from the computation of net loss per common share as their effect was antidilutive	2,768	2,207

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4. Inventories

The components of the Company s inventories at June 30, 2004 and December 31, 2003, respectively, were as follows (in thousands):

	June 30, 2004	December 31, 2003
Raw materials	$ 622	$ 719
Work-in-process	150	214
Finished goods	892	1,259
	$ 1,664	$ 2,192

5. Intangible assets and related amortization

The Company s intangible assets and related accumulated amortization at June 30, 2004 and December 31, 2003, respectively, were as follows (in thousands):

	June 30, 2004		December 31, 2003	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Capitalized patent defense litigation costs	$ 2,755	$ (472)	$ 2,755	$ (351)
Capitalized patent license agreements	2,650	(401)	2,650	(240)
Capitalized merger-related costs	1,435			
	$ 6,840	$ (873)	$ 5,405	$ (591)

Aggregate amortization expense for the six months ended June 30, 2004, and estimated amortization expense for the six months ended December 31, 2004 and each of the five years ended December 31, 2005 through 2009 is as follows (in thousands):

Aggregate amortization expense:

For the six months ended June 30, 2004	$ 282

Estimated amortization expense:

For the six months ended December 31, 2004	$ 281
For the twelve months ended December 31, 2005	$ 563
For the twelve months ended December 31, 2006	$ 563
For the twelve months ended December 31, 2007	$ 563
For the twelve months ended December 31, 2008	$ 563
For the twelve months ended December 31, 2009	$ 563

6. Deferred maintenance revenue

Revenue for maintenance contracts is recognized on a pro-rata basis over the period of the applicable maintenance contract, ranging from 12 to 36 months. Costs are recognized as incurred. The Company had no deferred maintenance revenue during the three and six months ended June 30, 2003. Changes in the Company s deferred maintenance revenue during the three and six months ended June 30, 2004, were as follows (in thousands):

	Three months ended June 30, 2004	Six months ended June 30, 2004
Balance at beginning of period	$ 48	$ 45
Add: maintenance contract billings	5	14
Less: revenue recognized	(8)	(14)
Balance at end of period	45	45
Less: current portion	(21)	(21)
Deferred maintenance revenue, less current portion	$ 24	$ 24

7. Comprehensive loss

Comprehensive 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.

8. Recent accounting pronouncements

In April 2004, the Emerging Issues Task Force issued Statement No. 03-06, Participating Securities and the Two-Class Method Under FASB Statement No. 128, Earnings per Share, (EITF 03-06). EITF 03-06 addresses a number of questions regarding the computation of earnings per share by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the company when, and if, it declares dividends on its common stock. EITF 03-06 also provides further guidance in applying the two-class method of calculating earnings per share, clarifying what constitutes a participating security and how to apply the two-class method of

computing earnings per share once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. EITF 03-06 is effective for fiscal periods beginning after March 31, 2004. The adoption of EITF 03-06 is not expected to have a material effect on the Company s results of operations or financial position.

9. 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.

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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, 2004 and 2003, respectively, if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation granted under all of the stock option plans and the Employee Stock Purchase Plan (in thousands, except per share amounts):

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Net loss, as reported	$ (2,003)	$ (3,400)	$ (4,173)	$ (6,324)
Deduct: Total stock-based employee compensation determined under the fair value based method for all awards	(367)	(408)	(1,176)	(1,088)
Net loss, pro-forma	$ (2,370)	$ (3,808)	$ (5,349)	$ (7,412)
Basic and diluted net loss per common share:				
As reported	$ (0.11)	$ (0.19)	$ (0.23)	$ (0.36)
Pro-forma	$ (0.13)	$ (0.22)	$ (0.30)	$ (0.43)

The determination of stock-based employee compensation, as relating to 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,	
	2004	2003	2004	2003
Volatility	76%	76%	76%	76%
Risk-free interest rate	3.49%	2.69%	3.14%	2.73%
Expected life	5 years	5 years	5 years	5 years
Expected dividends	0%	0%	0%	0%

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

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Volatility	60%	70%	60%	70%
Risk-free interest rate	1.01%	3.15%	1.01%	3.15%
Expected life	0.5 years	1.3 years	0.5 years	1.3 years
Expected dividends	0%	0%	0%	0%

10. Subsequent event

On July 29, 2004, the Company merged with Horizon Medical Products, Inc. in a transaction accounted for under the purchase method of accounting. The combined companies will continue to operate under the name RITA Medical Systems, Inc. The merger was pursued and

completed because the management groups and stockholders of each company believe the combined entity will achieve higher sales and profitability than either or both of the pre-merger companies on a stand-alone basis.

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 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 are estimated to be approximately $2.4 million. The total purchase price was approximately $109.4 million. The fair value of assets acquired, net of liabilities assumed, was $21.2 million, resulting in goodwill of $88.2 million.

The preliminary allocation of purchase price is as follows (in thousands):

Current assets	$ 13,296
Property and equipment	1,325
Intangible assets	27,563
Goodwill	88,197
Other assets	374
Current liabilities	(4,802)
Debt	(16,487)
Other liabilities	(83)
Net assets	$ 109,383

The final determination of the purchase price allocation will be based on the fair values of the assets and liabilities assumed at July 29, 2004, the date the merger closed. The purchase price will remain preliminary until the Company is able to complete a third party valuation of significant intangible assets acquired and evaluate the fair value of the other assets and liabilities acquired. The final determination of the purchase price will be completed as soon as practicable. The final amounts allocated to assets and liabilities acquired could differ significantly from the amounts presented in the unaudited pro forma condensed consolidated financial information above.

Because the merger was effected subsequent to June 30, 2004, none of Horizon s results of operations are included in the Company s condensed consolidated statements of operations for the three or six month periods ended June 30, 2004 and

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Horizon s assets and liabilities are not included in the Company s condensed consolidated balance sheet as of June 30, 2004. 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 had been completed on January 1, 2004. That information is as follows (in thousands, except per share amounts):

	Three months ended June 30, 2004				Six months ended June 30, 2004			
	RITA	Horizon	Amortization expense arising from the merger	Total	RITA	Horizon	Amortization expense arising from the merger	Total
Sales	$ 4,659	$ 7,423	$	$ 12,082	$ 9,303	$ 14,509	$	$ 23,812
Net income / (loss)	$ (2,003)	$ 78	$ (365)	$ (2,290)	$ (4,173)	$ (917)	$ (730)	$ (5,820)
Net income / (loss) per common share, basic and diluted	$ (0.11)	$		$ (0.06)	$ (0.23)	$ (0.02)		$ (0.16)

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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 , 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, 2003. 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 minimally invasive products that use radiofrequency energy to treat patients with solid cancerous or benign tumors. 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. On July 29, 2004, we completed a merger with Horizon Medical Products, Inc. (Horizon). We believe the merger will lead to higher sales and profitability due to a larger, more effective sales group, consolidation of manufacturing operations that will result in lower product costs, and reduced administrative expenses.

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 months ended June 30, 2004 and 2003, and for the years ended December 31, 2003, 2002 and 2001, sets forth some of these measurements:

	Three months ended June 30,		Six months ended June 30,		Years ended December 31,		
	2004	2003	2004	2003	2003	2002	2001
Total sales (in thousands)	$ 4,659	$ 4,049	$ 9,303	$ 8,546	$ 16,607	$ 17,393	$ 14,791
Percentage of sales: United States	80%	81%	79%	76%	80%	74%	54%
Percentage of sales: International	20%	19%	21%	24%	20%	26%	46%
Percentage of sales: Disposable products	93%	87%	93%	87%	88%	75%	78%
Percentage of sales: Hardware products	7%	13%	7%	13%	12%	25%	22%
Gross margin	64%	58%	65%	62%	63%	60%	59%

Consolidation of Horizon s results will not begin until the closing date of the merger, July 29, 2004. However, Horizon s sales for the three and six months ended June 30, 2004 were $7.4 million and $14.5 million, respectively. Horizon s gross margins for the three and six months ended June 30, 2004 were 64% and 62%, respectively.

Our products are sold in the United States through our direct sales force and internationally through distribution partners. 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 have, to date, introduced our premium-priced Starburst Xli and Xlie families of disposable needles only in this region. These actions have resulted in a growing percentage of sales derived from the domestic market. In contrast, our international markets in Europe and Japan have more restrictive reimbursement conditions than those in the United States, which combined with our distributor discounts, limit our average selling prices in these markets. Further, some of our distributors in Europe and Japan have been reducing their inventory levels. These factors have resulted in slow growth or even declining volume in some of our international markets. Going forward, we expect 2004 sales growth for radiofrequency ablation products in the United States to continue to outpace international growth,

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because we believe our international markets, particularly Japan, will continue to reduce inventory levels, and because we believe the introduction of premium products to our international distributors will have a relatively small impact on growth due to pricing limitations. However, we note that the Japanese Ministry of Health, Labor and Welfare approved reimbursement for our procedure for treatment of liver cancer, effective April 1, 2004. As a result, we believe that Japan will be a growing source of international revenue beginning in 2005.

Through June 30, 2004, essentially all of our revenue has come from the sale of our disposable devices and radiofrequency generators used in the treatment of cancerous liver tumors. As the number of customers using these products grows, we expect that the percentage of sales related to disposable products will grow relative to that of hardware products, although we have, in the past, seen temporary deviations from this trend as a result of large hardware shipments to international distributors. Since our disposable products are self-manufactured and more profitable than our vendor-sourced hardware products, a growing percentage of disposable product sales is favorable to the Company. In 2004, our strategy for radiofrequency ablation products will continue to focus on expanding our base of customers and on increasing usage of our disposable products in our established accounts. As a result, we expect revenue from the sale of our higher-margin disposable devices to grow faster than revenue from the sale of our generators. Further, the merger with Horizon will expand our product offering beginning in the third quarter of 2004 and generate additional revenue for the Company, primarily from the sale of implantable vascular ports used in cancer treatment protocols. The integration of two sales groups and the two companies product lines will require training that may limit sales growth over the balance of 2004. However, we believe that the inclusion of the additional product lines made available by the merger will ultimately increase the efficiency of our selling effort, resulting in 2005 sales greater than the two companies would have achieved if they continued operating on a standalone basis.

In 2002, we began to see some additional nominal revenue from the use of the RITA system sold for the treatment of patients with metastatic bone tumors. Our sales from devices used in bone tumor procedures remained small in 2003 and the first half of 2004, but we expect that the American Medical Association s January 2004 approval of a reimbursement code for bone procedures will eventually have a favorable impact going forward. We are conducting research and clinical trials in other organs that may lead to additional sources of revenue in future years, although there can be no assurances that such additional revenue will materialize.

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. We also 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 for 2003 and the six months ended June 30, 2004 reflects amortization of capitalized license fees associated with the April 2003 settlement of our patent litigation dispute with Boston Scientific Corporation. We expect these amortization charges to continue through 2015. Further, 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, although we generally expect only modest impacts from such provisions. However, we also note that completion of the merger with Horizon will permit us, by year-end 2004, to consolidate our manufacturing operations in Horizon s relatively low-cost Georgia location. This should result in lower product costs through the use of less expensive labor and economies of scale.

Our gross margins reflect our selling prices, our domestic / international mix percentages, our product mix percentages, our production volumes, the costs we pay for vendor manufactured product and our provisions for obsolete inventory. Our gross margin for the three months ended June 30, 2004 was 64%, compared to a gross margin of 58% for the three months ended June 30, 2003. Over the balance of 2004, we expect modest improvement in our gross margin rate for radiofrequency ablation products, based on projected improvements in domestic / international and product sales mix, lower manufacturing costs and relatively modest provisions for obsolete inventory. However, the gross margin rate for Horizon products has historically been somewhat less than that of our radiofrequency ablation products, so overall company margins may, on average, be reduced by inclusion of these products in our results, at least until we can fully integrate our manufacturing operations and lower our product costs.

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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 months ended June 30, 2004 and 2003, our Consolidated Statements of Operations for the years ended December 31, 2003, 2002 and 2001, our Unaudited Condensed Consolidated Balance Sheets as of March 31 and June 30, 2004, and our Consolidated Balance Sheets as of December 31, 2003, 2002 and 2001:

	Three months ended June 30,		Six months ended June 30,		Years ended December 31,		
	2004	2003	2004	2003	2003	2002	2001
Research and development expense	$ 981	$ 1,061	$ 1,824	$ 2,419	$ 4,294	$ 5,052	$ 6,489
Selling, general and administrative expense	4,018	4,736	8,384	9,300	17,418	19,366	16,646
Total operating expenses	$ 4,999	$ 5,797	$ 10,208	$ 11,719	$ 21,712	$ 24,418	$ 23,135

	June 30,	March 31,	December 31,		
	2004	2004	2003	2002	2001
Cash and cash equivalents	$ 4,404	$ 6,122	$ 4,580	$ 6,888	$ 7,297
Marketable securities, current and long term	1,881	1,990	4,955	5,947	16,240
Total cash and marketable securities	$ 6,285	$ 8,112	$ 9,535	$ 12,835	$ 23,537

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 legal expenses, sales and marketing expenses related to our selling efforts in the United States and Europe, 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, among other factors, 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 maintenance of our patent portfolio and intellectual property rights and the extent to which credit issues and economic conditions constrain our ability to collect our receivables. For the three months ended June 30, 2004, research and development expense was 8% lower than in the three months ended June 30, 2003, as a result of a $0.2 million reduction in clinical trial activity, partially offset by a $0.1 million increase in product research spending. Over the balance of 2004 and in 2005, research spending is expected to increase, driven by programs aimed at improving and extending our technologies into additional clinical applications. Selling, general and administrative expense for the three months ended June 30, 2004 was 15%, or $0.7 million, lower than in the three months ended June 30, 2003. This decrease reflected $0.9 million in lower expenses, due to lower headcount, in our domestic sales group, offset by a $0.2 million increase in marketing and administrative expenses. Beginning in the third quarter of 2004, the merger with Horizon will result in operating expenses that are much higher that the $5.0 million reported by the Company for the second quarter of 2004, simply reflecting the combination of the two companies. However, headcount reductions, particularly in the domestic sales groups, will be effected throughout the third and fourth quarters of 2004, and should result in expense levels for the combined company that are lower than the sum of expenses for the two companies prior to the merger.

Our combined total of cash, cash equivalents and marketable securities was $6.3 million as of June 30, 2004, down from $9.5 million as of December 31, 2003. Our net cash used in operating activities for the six months ended June 30, 2004 was $2.2 million. We must continue to strictly manage our use of cash and may need to raise additional cash through borrowing or the sale of securities in order to support operations over the next twelve months.

We incurred a net loss of $2.0 million for the three months ended June 30, 2004 compared to $3.4 million for the three months ended June 30, 2003. Due to the costs associated with research and development programs and our sales and marketing efforts, we expect to incur net losses throughout 2004. Profitability depends on our success in expanding product usage in our current markets and in developing new markets, as well as the successful integration of Horizon s operations. To the extent current or new markets do not materialize in accordance with our expectations, or the integration of operations does not proceed as we expect, our sales and profitability could be lower than expected and we may be unable to achieve or sustain profitability.

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, 2003. No changes in these policies and estimates have occurred during the three months ended June 30, 2004.

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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 current quarter ended June 30, 2004 and the four preceding fiscal quarters:

	Q2 2004	Q1 2004	Q4 2003	Q3 2003	Q2 2003
Domestic sales	80%	79%	83%	86%	81%
International sales	20%	21%	17%	14%	19%
Total sales	100%	100%	100%	100%	100%
Cost of goods sold	36%	35%	39%	32%	42%
Gross profit	64%	65%	61%	68%	58%
Operating expenses:					
Research and development	21%	18%	21%	25%	26%
Selling, general and administrative	86%	94%	94%	109%	117%
Total operating expenses	107%	112%	115%	134%	143%
Loss from operations	(43)%	(47)%	(54)%	(66)%	(85)%
Interest income and other expense, net	0%	0%	0%	1%	1%
Net loss	(43)%	(47)%	(54)%	(65)%	(84)%

Three months ended June 30, 2004 and 2003

For the three months ended June 30, 2004, sales totaled $4.7 million, an increase of 15% over sales of $4.0 million in the three months ended June 30, 2003. Our domestic sales for the second quarter of 2004 grew 12%, or $0.4 million, to $3.7 million, compared to $3.3 million in the prior period. The increase in domestic sales reflects increases in our installed customer base and in higher product utilization by our customers. Our international sales for the second quarter of 2004 increased 20%, or $153,000, to $936,000, compared to $783,000 in the prior period. Our international sales results were due to higher sales to our international distributors in Europe and Asia, with only negligible sales to our Japanese distributor. For the quarter ended June 30, 2004, domestic sales represented 80% of total sales, compared to 81% in second quarter of 2003. Sales of our disposable products in the second quarter of 2004 grew by 23% compared with 2003 results, although hardware sales decreased 38%.

Cost of goods sold for each of the quarters ended June 30, 2004 and June 30, 2003 was $1.7 million. Our gross margin rate was 64% in the current quarter, compared to 58% in the prior period, reflecting a greater percentage of relatively high-margin disposable sales, and the fact that the prior period ended June 30, 2003 was burdened by both very low production levels and unusual and temporary cost increases on some of our vendor-sourced hardware products.

Research and development expenses for the quarter ended June 30, 2004 were $1.0 million, compared to $1.1 million in the second quarter of 2003. This decrease was due to a $0.2 million reduction in clinical trial activity, partially offset by a $0.1 million increase in product research spending aimed at technical innovation of our radiofrequency ablation products. Spending on new and more innovative radiofrequency products will continue to grow in the third and fourth quarters of 2004, and in 2005.

Selling, general and administrative expenses for the quarter ended June 30, 2004 were $4.0 million, compared to $4.7 million in the second quarter of 2003. Our domestic selling expenses decreased by $0.9 million, reflecting lower headcount in our U.S. based sales force. However, marketing and administrative expenses increased $0.2 million, reflecting higher headcount and program activity, including reimbursement expenses and expenses related to the Horizon merger. Prior to the Horizon merger, we expected our selling, general and administrative expense to show little or no growth in 2004, compared to 2003, reflecting the full-year impact of our 2003 organizational changes. With the completion of the merger, expenses will increase sharply in the third quarter of 2004, simply reflecting the combination of the two companies. However, headcount reductions, particularly in the domestic sales groups, will be effected throughout the third and fourth quarters of 2004, and should result in expense levels for the combined company that are lower than the sum of expenses for the two companies prior to the merger.

Interest income was negligible for the second quarter of 2004, down from $0.1 million in the second quarter of 2003, because average daily cash balances fell over the intervening twelve months as we utilized cash for operations. We had no interest expense in either period. However, the terms of the Horizon merger include the assumption of Horizon s debt, which totaled $17.7 million as of the merger date, July 29, 2004. Horizon s interest expense was $0.5 million for the three months ended June 30, 2004.

Six months ended June 30, 2004 and 2003

For the six months ended June 30, 2004, sales totaled $9.3 million, an increase of 9% over sales of $8.5 million in the six months ended June 30, 2003. Our domestic sales for the first half of 2004 grew 14%, or $0.9 million, to $7.4 million, compared

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to $6.5 million in the prior period. The increase in domestic sales reflects increases in our installed customer base and in higher product utilization by our customers. Our international sales for the first half of 2004 decreased 8%, or $0.1 million, to $1.9 million, compared to $2.0 million in the prior period. Our international sales results for the first half of 2004 reflect higher sales to our international distributors in Europe and Asia, but only negligible sales to our Japanese distributor in 2004, while the prior period included $0.5 million in Japanese sales. For the first six months ended June 30, 2004, domestic sales represented 79% of total sales, compared to 76% in first half of 2003. Sales of our disposable products in the first half of 2004 grew by 16% compared with 2003 results, although hardware sales decreased 42%.

Cost of goods sold for each of the six month periods ended June 30, 2004 and June 30, 2003 was $3.3 million. Our gross margin rate was 65% in the first half of 2004, compared to 62% in the prior period, reflecting a greater percentage of relatively high-margin disposable sales, and the fact that the prior period ended June 30, 2003 was burdened by both very low production levels and unusual and temporary cost increases on some of our vendor-sourced hardware products.

Research and development expenses for the six months ended June 30, 2004 were $1.8 million, compared to $2.4 million in the six months ended June 30, 2003. This decrease was due to a $0.3 million reduction in patent legal expenses and another $0.4 million reduction in clinical trial activity, with product research spending up $0.1 million. Spending on new and more innovative radiofrequency products will continue to grow in the third and fourth quarters of 2004, and in 2005.

Selling, general and administrative expenses for the six months ended June 30, 2004 were $8.4 million, compared to $9.3 million in the six months ended June 30, 2003. Our domestic selling expenses decreased by $1.6 million, reflecting lower headcount in our U.S. based sales force. However, marketing and administrative expenses increased $0.7 million, reflecting higher headcount and program activity, including reimbursement expenses and expenses related to the Horizon merger. Prior to the Horizon merger, we expected our selling, general and administrative expense to show little or no growth in 2004, compared to 2003, reflecting the full-year impact of our 2003 organizational changes. With the completion of the merger, expenses will increase sharply in the third quarter of 2004, simply reflecting the combination of the two companies. However, headcount reductions, particularly in the domestic sales groups, will be effected throughout the third and fourth quarters of 2004, and should result in expense levels for the combined company that are lower than the sum of expenses for the two companies prior to the merger.

Interest income was negligible for the first half of 2004, down from $0.1 million in the first half of 2003, because average daily cash balances fell over the intervening twelve months as we utilized cash for operations. We had no interest expense in either period. However, the terms of the Horizon merger include the assumption of Horizon s debt, which totaled $17.7 million as of the merger date, July 29, 2004. Horizon s interest expense was $1.1 million for the six months ended June 30, 2004.

Liquidity and Capital Resources

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, which 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. As of June 30, 2004, we had $4.4 million of cash and cash equivalents, $1.9 million of marketable securities and $8.5 million of working capital.

For the six months ended June 30, 2004, net cash used in operating activities was $2.9 million principally due to our net loss of $4.2 million, offset by non-cash charges of $0.9 million, including depreciation and amortization, provisions to reserves for uncollectible accounts and

inventory, and expenses associated with options granted to consultants. There was also a $0.5 million reduction in inventory and a $0.3 million reduction in prepaid and other current assets. The inventory decrease resulted from management s efforts to reduce the Company s investment in raw materials and finished goods on-hand. The reduction in prepaid and other current assets was primarily related to amortization of prepaid insurance. Accounts payable and accrued liabilities increased $0.7 million, but this was due to $1.0 million of costs incurred, but not yet paid, in conjunction with the Horizon merger. Therefore, there was a $0.3 million use of cash in operating activities relating to changes in accounts payable and accrued liabilities. In addition to the $1.0 million of costs incurred, but not yet paid, in conjunction with the Horizon merger, there were $0.4 million in such costs that have been paid as of June 30, 2004, and the $1.4 million total of such costs has been included in intangible assets on our balance sheet as of June 30, 2004. The $0.4 million in costs already paid as of June 30, 2004 was a component of cash used in investing activity for the six months ended June 30, 2004. Other investing activities were limited to the purchase of property and equipment in the amount of $0.2 million. Maturities and (net) sales of investment instruments provided $3.1 million in cash in support of operations. Financing activities for the year provided $0.2 million in cash, generally through 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. As of June 30, 2004, we had no future minimum payments due under capital leases. In March 2004, we extended the lease on our primary facility through January 2005, affecting our future minimum payments due under operating lease, which are now as follows (in thousands):

Payments due in 2004	$ 171
Payments due in 2005	24
Total future minimum operating lease payments	$ 195

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 averaged $0.5 million per month for the six months ended June 30, 2004, compared to $0.4 million of average monthly net cash used in operating activities for the six months ended December 31, 2003.

Prior to the merger with Horizon, we believed that our current balances of cash and cash equivalents, and the sale of marketable securities as necessary, would satisfy our cash requirements for at least the next 12 months. The merger, however, will require significant cash payments relating to the integration of the two companies over the last six months of 2004. Also, as of the merger date, the Company assumed approximately $17.7 million of Horizon s debt, of which $6.5 million will come due in July of 2005. If the cash we expect to generate from operations is insufficient to satisfy our liquidity requirements, we may need to sell additional equity or debt securities or obtain an additional credit facility. 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 the Company and our stockholders.

Recent Accounting Pronouncements

In April 2004, the Emerging Issues Task Force issued Statement No. 03-06, Participating Securities and the Two-Class Method Under FASB Statement No. 128, Earnings per Share, (EITF 03-06). EITF 03-06 addresses a number of questions regarding the computation of earnings per share by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the company when, and if, it declares dividends on its common stock. EITF 03-06 also provides further guidance in applying the two-class method of calculating earnings per share, clarifying what constitutes a participating security and how to apply the two-class method of computing earnings per share once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. EITF 03-06 is effective for fiscal periods beginning after March 31, 2004. The adoption of EITF 03-06 is not expected to have a material effect on the Company s results of operations or financial position.

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 may be unable to integrate our operations successfully and realize all of the anticipated benefits of our merger with Horizon Medical Products.

Our merger with Horizon Medical Products involves the integration of two companies that previously have operated independently, which is a complex, costly and time-consuming process. The difficulties of combining the companies operations include, 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.

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The process of integrating our operations with those of Horizon Medical Products could cause an interruption of, or loss of momentum in, the activities of the combined company s business and the loss of key personnel. The diversion of our management s attention and any delays or difficulties encountered in connection with the integration of our operations with those of Horizon Medical Products could harm our business, results of operations, financial condition or prospects after the merger.

If our independent auditor is unable to provide us with an unqualified report as to the adequacy of our internal controls over financial reporting as of December 31, 2004 and future year-ends as required by Section 404 of the Sarbanes-Oxley Act of 2002, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the company s internal controls over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of such company s internal controls over financial reporting. In addition, the public accounting firm auditing our financial statements must attest to and report on management s assessment of the effectiveness of our internal controls over financial reporting. We are expending significant resources in developing the necessary documentation and testing procedures required by Section 404. Compliance with all of the requirements imposed by Section 404 will be very difficult due at least in part to the changes in processes we expect to make in conjunction with the merger with Horizon Medical Products. If we fail to implement required new or improved controls, or if our independent auditors are not satisfied with our internal controls over financial reporting or with the level at which these controls are documented, operated or reviewed, they may decline to attest to management s assessment or may issued a qualified report. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements, which could cause the market price of our shares to decline.

We will be heavily dependent on the RITA system and Horizon s line of implantable vascular ports in order to achieve our sales goals. 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, after the date of the Horizon merger, Horizon s line of implantable vascular ports. 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 revenues because we do not have alternative products.

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

We incurred net losses of $4.2 million in the first six months of 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, 2004, we had an accumulated deficit of $83.1 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.

We compete directly with two companies in the domestic and international markets: RadioTherapeutics Corporation, a division of Boston Scientific Corporation, and Radionics, Inc., a division of Tyco Healthcare, which is a division of Tyco International. Boston Scientific Corporation 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.

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.

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Alternative therapies could prove to be superior to the RITA system, and physician adoption could be negatively affected.

In addition to competing against other companies offering products that use radiofrequency energy to ablate soft tissue, 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 system or to have less severe side effects than those resulting from our system, physician adoption of our products could be negatively affected and our revenues could decline.

We currently lack long-term data regarding the safety and efficacy of our 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 products in various applications. If the safety or efficacy of our products is questioned, our sales could decline.

Our 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 products, our sales could decline. If longer-term patient follow-up or clinical studies indicate that our procedures cause unexpected, serious complications or other unforeseen negative effects, we could be subject to significant liability. Further, because some of our data has been produced in studies that were 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. Under certain circumstances these 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;
- the risk of inventory build-up by our distributors which could negatively impact sales in future;
- 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.

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We are substantially dependent on two distributors in our international markets, and if we lose either distributor or if either distributor significantly reduces its product demand, our international and total revenues could decline.

We are substantially dependent on a limited number of significant distributors in our international markets, and if we lose these distributors and fail to attract additional distributors, our international revenues could decline. ITX Corporation, formerly known as Nissho Iwai Corporation, is our primary distributor in Asia. Although it accounted for only 2% of our revenue in the first half of 2004, it accounted for 21% of our international revenues in 2003. M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, accounted for 32% of our international revenue in the first half of 2004 and 22% of our international revenues in 2003. International revenues accounted for 21% of our total revenues for the six months ended June 30, 2004, and these two distributors represented 34% of that total. For the year ended December 31, 2003, international revenues accounted for 20% of our total revenues and these distributors represented 43% of that total. The loss of either distributor or a significant decrease in unit purchases by either distributor could cause our revenues to decline substantially. If we are unable to attract additional international distributors, our international revenues may not grow.

We may choose to change our business relationships with Horizon s domestic distributors, risking, for a period of time, lower sales and additional costs.

The integration of our sales efforts with those of Horizon Medical Products will result in re-assessment of the role of Horizon s domestic distributors. If we terminate our relationships with one or more of these distributors, we will incur costs associated with cancellation of our agreements and may experience lower sales while we transition this business to our direct sales force**.**

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

We sell our products in international markets through third-party distributors over whom we have limited control, and, if they fail to adequately support our products, our sales could decline. During the first quarter of 2003, we terminated our agreements with three of our international distributors and although we contracted with replacement distributors, we expended significant time and resources in doing so, and our sales in the three affected markets suffered during the transition period that we estimate ended September 30, 2003. If our distributors or we terminate other distributor agreements, we could incur similar or more burdensome expenses, we could expend significant time and resources in finding replacement distributors, and our sales could decrease during any related transition period.

We are aware that some of our international distributors have built up inventory of our products. As a result, future sales to these distributors could be negatively impacted. Sales to our Japanese distributor in 2003 and the first six months of 2004 were so affected. In addition, while these distributors have no price protection and no right of return relating to purchased products, if we permit the return of any of these products, we will have to adjust our revenues relating to these products which may also impact our revenue recognition policy on future distributor sales.

In 2002, we significantly increased our allowance for uncollectible 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 remained stable in the first six months of 2004, we may encounter new difficulties with collections that require further increases in our allowance for uncollectible accounts in the future, and we may require specific accounts to post letters of credit or pay in advance to minimize credit risk to the Company. Additional future increases in our allowance for uncollectible 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.

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If third-party payors do not reimburse health care providers for use of the RITA system, purchases could be delayed and our revenues could decline.

Physicians, hospitals and other health care providers may be reluctant to purchase our products if they do not receive coverage or adequate reimbursement for the cost of procedures using our products from third-party payors, such as Medicare, Medicaid and private health insurance plans. If physicians believe that using our system will add cost to a procedure but will not add sufficient offsetting economic or clinical benefits, physician adoption of our products could be delayed. Even though the American Medical Association has established CPT codes relating to liver procedures and bone tumor procedures, some third-party payors still may not cover or reimburse adequately for liver or bone tumor procedures using our products. We are aware of liver procedures using our system where the patient s insurance has denied coverage. In addition, there are no assigned CPT codes for radiofrequency ablation of tumors in organs other than liver or bone. Further, we believe the advent of the Medicare fixed payment schedules has made it difficult to receive adequate liver reimbursement for procedures using our products in the outpatient setting. Medicare reimbursement levels for procedures using our products are highest when our products are used in an in-patient setting. If there is a trend toward the use of our products on an outpatient basis or if coverage continues to be denied or reimbursement levels continue to be inadequate, physician use of our products could decline which would cause our revenues to decline.

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 and Chief Financial Officer, as well as key staff in the areas of finance, operations and research and development. 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 market for qualified management personnel in Northern California, where our offices are located, is competitive and is expected to remain so. Because the environment for good 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 may 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 may be subject to product liability lawsuits. To date, we have not been subject to a product liability claim; however, 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 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 due to market uncertainty about our ability to successfully integrate the operations of Horizon Medical Products and manage our cash during the process of integrations. Our stock price may also fluctuate for a number of other reasons including:

failure of the public market to support the valuation established in our initial public offering or our 2003 private placement transaction;

our ability to successfully commercialize our products;

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

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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 have limited experience manufacturing our 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.

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. In addition, we intend to consolidate our manufacturing operations with Horizon Medical Products over the balance of 2004. 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.

We may be required to relocate, or choose to relocate, to a new facility in 2005. If so, we will incur moving expenses, and our business will suffer.

The operating lease on our current facility was to expire in August of 2004, but we have negotiated an extension through January of 2005. We believe that during the third or fourth quarters of 2004 we will be able to either renew the lease on our existing facility, or lease alternative space, at commercially reasonable terms. If we choose to relocate to a new facility, we will incur normal and customary moving costs that will reduce our profitability.

We are dependent on two suppliers as the only sources of a component that we use in our 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 June 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 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. This could also create supply disruptions that could negatively affect our business.

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We are dependent on two suppliers as our only sources of an accessory device used in conjunction with our Starburst XLi and Xlie lines of disposable devices, and any disruption in the supply of these devices could negatively affect our revenues.

Until December 2002, we had only one supplier available to provide us with accessory infusion pumps used in conjunction with our Starburst XLi line of disposable devices. Our Starburst Xlie product line, introduced in 2003, also requires an accessory infusion pump. During the quarters ended September 30, 2002 and December 31, 2002, we experienced shortages in the supply of accessory infusion pumps. In December 2002, we qualified a new accessory infusion pump from our existing supplier for which we now have approval from UL and conditional approval from TUV for use in the United States and Europe. Also in December 2002, we qualified a second supplier of an accessory infusion pump, although we have not yet shipped this product to our customers commercially. Although we were able to remedy this supply disruption, future disruptions in the supply of this component are still possible and, in that event, our business could suffer through lower revenues or higher costs. Additionally, we have limited experience with both the primary and alternative pump and if either pump fails to perform as desired, revenues could be negatively affected.

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 revenues.

We are dependent on two third-party suppliers to produce our 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 revenues.

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 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 made minor modifications to our system. 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 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.

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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.

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 to execute on our business plan. If we are successful in raising capital through the sale of common stock, it will result in dilution of our existing stockholders, and if we are unsuccessful in raising additional capital, we may not be able to execute on our business plan and our results of operations may suffer.

We may seek to raise additional capital through the sale of our securities. It is expected that the offering proceeds, if raised, would be used, among other things, to retire debt assumed in the merger with Horizon Medical Products, including $14.7 million of outstanding senior subordinated notes of Horizon, and to execute our business plan. Any such sale of stock will reduce the proportionate ownership and voting power of our existing stockholders and may result in a reduction of the market price of our common stock. If we are unable to raise additional capital on acceptable terms, or at all, our liquidity may suffer as assumed debts mature and we may be limited in our ability to execute our business plan, negatively affecting both results of operations and our stock price.

Our executive officers and directors own a large percentage of our voting stock and could exert significant influence over matters requiring stockholder approval.

Our executive officers and directors, and their respective affiliates, owned approximately 10 percent of our outstanding common stock as of June 30, 2004. After completion of the merger on July 29, 2004, our executive officers and directors, and their respective affiliates, owned approximately 26% of our outstanding common stock. 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.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

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 Form 10-K for the year ended December 31, 2003, filed on March 15, 2004.

Item 4. Controls and Procedures

Based on our management s evaluation (with the participation of our principal executive officer and principal financial officer), as of the end of the period covered by this report, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)) are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

There was no change in the Company s internal control over financial reporting during the second quarter of fiscal 2004 that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings. Not applicable.

Item 2. Changes in Securities and Use of Proceeds. Not applicable.

Item 3. Defaults Upon Senior Securities. Not applicable.

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

Item 5. Other Information. Not applicable.

Item 6. Exhibits and Reports on Form 8-K.

(a) Exhibits:

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 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, of Chief Executive Officer

32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, of Chief Financial Officer

(b) Reports on Form 8-K:

On June 28, 2004, a Current Report on Form 8-K was filed with the SEC to announce the date of the Company s annual meeting of shareholders.

On June 9, 2004, a Current Report on Form 8-K was filed with the SEC regarding early results from a clinical trial showing a 92% survival rate in non-small cell lung cancer patients treated with radiofrequency ablation.

On June 3, 2004, a Current Report on Form 8-K was filed with the SEC to report an educational grant made by the Company to WebMD Medscape Health Network.

On May 14, 2004, a Current Report on Form 8-K was filed with the SEC to report the execution of an Agreement and Plan of Merger with Horizon Medical Products, Inc.

On May 10, 2004, a Current Report on Form 8-K was filed with the SEC to report the results of a clinical investigation, conducted by the University of Texas Southwestern Medical Center, and presented in a paper titled Laparoscopic Radiofrequency Ablation of Small Renal Tumors.

On April 29, 2004, a Current Report on Form 8-K was filed with the SEC to report the results of operations for the first quarter ended March 31, 2004.

On April 1, 2004, a Current Report on Form 8-K was filed with the SEC to report the results of a study into the use of radiofrequency ablation to treat breast cancer.

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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, 2004

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