RITA MEDICAL SYSTEMS INC
Form 10-Q
November 14, 2002
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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 September 30, 2002

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 ¨

As of November 8, 2002, there were 15,143,708 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, except per share amounts, unaudited)

	September 30, 2002	December 31, 2001
Assets		
Current assets:		
Cash and cash equivalents	$ 9,484	$ 7,297
Marketable securities	5,766	11,887
Accounts and note receivable, net of allowance for doubtful accounts of $1,308 at September 30, 2002 and $629 at December 31, 2001	3,966	5,056
Inventories, net	3,096	3,645
Prepaid assets and other current assets	1,205	1,282
Total current assets	23,517	29,167
Long term securities		4,353
Long term note receivable, net	414	
Property and equipment, net	1,586	1,934
Intangibles and other assets	1,562	380
Total assets	$27,079	$ 35,834
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 955	$ 822
Accrued liabilities	2,737	2,675
Capital lease obligations	45	192
Total liabilities	3,737	3,689
Contingencies (Note 5)		
Stockholders equity		
Common stock, $0.001 par value	15	15
Additional paid-in capital	88,359	88,459
Deferred stock compensation	(159)	(1,905)
Receivable from stockholders	(49)	(99)
Accumulated other comprehensive income	16	70
Accumulated deficit	(64,840)	(54,395)
Total stockholders equity	23,342	32,145
Total liabilities and stockholders equity	$27,079	$ 35,834

See accompanying notes

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RITA MEDICAL SYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data, unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
Sales	$ 4,454	$ 3,707	$ 13,679	$ 10,780
Cost of goods sold	1,730	1,472	5,773	4,912
Gross profit	2,724	2,235	7,906	5,868
Operating expenses				
Research and development	1,218	1,627	3,882	4,837
Selling, general and administrative	4,311	4,016	14,837	11,539
Total operating expenses	5,529	5,643	18,719	16,376
Loss from operations	(2,805)	(3,408)	(10,813)	(10,508)
Interest income and other expense, net	85	324	368	1,309
Net loss	$ (2,720)	$ (3,084)	$ (10,445)	$ (9,199)
Net loss per share, basic and diluted	$ (0.18)	$ (0.21)	$ (0.70)	$ (0.64)
Shares used in computing basic and diluted net loss per share	14,996	14,406	14,816	14,299

See accompanying notes

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RITA MEDICAL SYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands, unaudited)

	Nine Months Ended September 30,	
	2002	**2001**
Operating activities:		
Net loss	$ (10,445)	$ (9,199)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,021	704
Stock-based compensation	308	1,417
Allowance for doubtful accounts	823	389
Allowance for inventory reserve	517	223
Changes in operating assets and liabilities		
Accounts and note receivable	(147)	(2,316)
Inventories	32	(1,090)
Prepaid and other current assets	77	(289)
Accounts payable and accrued liabilities	195	370
Net cash used in operating activities	(7,619)	(9,791)
Cash flows from investing activities:		
Purchase of property and equipment	(614)	(1,364)
Purchases of short term investments		(16,647)
Maturities of investments	10,420	27,499
Capitalization of patent litigation costs	(1,245)	(88)
Other assets	4	5
Net cash provided by investing activities	8,565	9,405
Cash flows from financing activities:		
Proceeds from issuance of common stock	1,389	682
Proceeds from revolving term loan		25
Payments on revolving term loan		(858)
Payments on capital lease obligations	(148)	(212)
Net cash provided by (used in) financing activities	1,241	(363)
Net increase (decrease) in cash and cash equivalents	2,187	(749)
Cash and cash equivalents at beginning of period	7,297	12,676
Cash and cash equivalents at end of period	$ 9,484	$ 11,927

See accompanying notes

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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, 2001 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 normal and recurring in 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, 2001 contained in the Company s annual report on Form 10-K.

2. Net loss per share

Basic earnings (loss) per share figures are calculated based on the weighted-average number of common shares outstanding during the period. Diluted earnings (loss) per share figures include the dilutive effect of common stock equivalents consisting of stock options, warrants and shares subject to repurchase, provided that the inclusion of such common stock equivalents is not antidilutive. For the three-month and nine-month periods ended September 30, 2002 and 2001 respectively, the Company has excluded the following period end potentially dilutive securities (in thousands) from earnings per share computations because their inclusion would have the effect of reducing our loss per share:

	Three and Nine Months Ended September 30,	
	2002	2001
Options and warrants	2,887	2,388
Common shares subject to repurchase	28	55
	2,915	2,443

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

	Three months ended September 30,		Nine months ended September 30,	
	2002	2001	2002	2001
Weighted average shares of common stock outstanding	15,027	14,467	14,851	14,368
Less: weighted-average shares subject to repurchase	31	61	35	69
Weighted average shares used in basic and diluted net loss per share	14,996	14,406	14,816	14,299

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3. Balance sheet components Note receivable and Inventories

During the third quarter of 2002, the Company converted the outstanding receivable from a major customer to a five-year unsecured note, bearing interest at the rate of 3% per year. Related balances as of September 30, 2002 are as follows (in thousands):

	September 30, 2002	
	Current	Long-term
Note receivable, net	$ 100	$ 414

The current portion of the note receivable has been included within accounts receivable for presentation on the Company s Condensed Consolidated Balance Sheet.

The components of the Company s inventories at September 30, 2002 and December 31, 2001 respectively were as follows (in thousands):

	September 30, 2002	December 31, 2001
Raw materials	$ 1,087	$ 1,017
Work-in-process	291	377
Finished goods	1,718	2,251
	$ 3,096	$ 3,645

4. Recent Accounting Pronouncements

In July 2002, The Financial Accounting Standards Board (FASB) issued Statements of Financial Accounting Standards No. 146 (SFAS 146), Accounting for Costs Associated with Exit or Disposal Activities, which is effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. The standard nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity including Certain Costs Incurred in a Restructuring). SFAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. Examples of costs covered by the standard include lease termination costs and certain employee severance costs that are associated with a restructuring, discontinued operation, plant closing or other exit or disposal activity. The Company does not believe adoption of this statement will materially impact its financial position or results of operations.

5. Contingencies

In July 1999, the United States Patent and Trademark Office (USPTO) declared an interference involving us, which was provoked by RadioTherapeutics Corporation, a competitor of ours and now a wholly owned subsidiary of Boston Scientific Corporation, in which the validity of a patent claim previously issued to us was called into question. The claims at issue in the interference covered a radiofrequency ablation device having an array of deployable electrodes effective, in a deployed state, to define a tissue ablation volume. In February 2001, the USPTO issued a decision on preliminary motions filed in the patent interference proceeding. The decision found that one of the claims in our United States Patent No. 5,536,267 (claim no. 32) is invalid. On September 27, 2002, the USPTO Board of Patent Appeals and Interferences (the Board) issued a final decision finding that RadioTherapeutics had failed to establish priority of invention over the Company s established invention date and, therefore, were not themselves entitled to any patent claims in the interference. The Board also affirmed the earlier preliminary decision, described above, regarding claim 32. On October 16, 2002, RadioTherapeutics filed an action in the United States District Court for the Northern District of California seeking to reverse the Board s priority decision, affirm the Board s decision

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regarding claim 32, and to initiate a new interference between certain issued patent claims licensed to RadioTherapeutics and certain of the Company s patent claims. Final determination of these patent interference proceedings may take several years. If the United States District Court reverses the decision of the Board as to RadioTherapeutics entitlement to priority, and we were found to infringe RadioTherapeutics patent claims and were unable to obtain a license to use the relevant patent or successfully modify our disposable device, we could be unable to sell our system and our business could suffer. If the District Court affirms the Board s decision regarding claim 32 or if RadioTherapeutics prevails on its new interference, the Company could lose one or more of its issued patent claims.

In March 2000, RadioTherapeutics filed an opposition to our European Patent No. 0777445 before the European Patent Office. This patent also covers the curvature of the array at the tip of our disposable devices. In this opposition, the validity of our issued patent is being questioned. In February 2002, the European Patent Office determined that we were entitled to European Patent No. 0777445. Both parties have appealed this ruling and a final decision is not expected in this proceeding for several years. If we do not prevail in the opposition proceeding, we could lose our only currently issued patent in Europe.

In August 2001, the Company filed a complaint in the United States District Court for the Northern District of California against RadioTherapeutics. This complaint alleges that RadioTherapeutics radiofrequency ablation products infringe six different patents held by the Company. As of September 30, 2002, the Company has capitalized approximately $1,577,000 in litigation costs incurred in defense of its patent positions.

In April 2002, a patent infringement suit against the Company was filed in the United States District Court for the Northern District of California by RadioTherapeutics and SciMed Life Systems, Inc. (two wholly-owned subsidiaries of Boston Scientific Corporation), the Board of Regents of the University of Nebraska and UneMed Corporation. The suit alleges that certain of the Company s products infringe a patent assigned to the University of Nebraska and licensed by UneMed and RadioTherapeutics and a patent owned by Scimed. RadioTherapeutics filed a first amended complaint in October 2002 adding to the complaint a second patent assigned to the University of Nebraska and licensed to RadioTherapeutics.

In July 2002, a patent infringement suit against the Company was filed in the United States District Court for the Northern District of California by Boston Scientific Corporation, the University of Kansas and the University of Kansas Medical Center Research Institute. The suit alleges that certain of the Company s products infringe a patent assigned to the University of Kansas and licensed by Boston Scientific Corporation.

We believe that the outcome of our outstanding legal proceedings, claims and litigation will not have a material adverse effect on our business, results of operations or financial condition. However, such matters involve complex questions of fact and law and could involve significant costs and the diversion of resources to defend. Additionally, the results of litigation are inherently uncertain, and an adverse outcome is at least reasonably possible. We are unable to estimate the range of possible loss from outstanding litigation and other legal proceedings and no amounts have been provided for such matters in the accompanying Consolidated Financial Statements. If we are not successful in defending these claims, our business, financial condition and results of operations could be materially adversely affected.

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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 Form 10-Q contain forward-looking statements that involve risks and uncertainties. Words such as anticipates , expects , intends , plans , believes , seeks , estim 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 Form 10-Q. 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. From inception in 1994 through 1996, our operations consisted primarily of various start-up activities, including development of technologies central to our business, recruiting personnel and raising capital. In 1997, we began commercial product shipments. 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.

Our products are sold in the United States through our direct sales force and internationally through distribution partners. For the three months ended September 30, 2002, sales in the United States accounted for 77% of our total sales while sales in our international markets accounted for 23% of our total sales. We expect domestic sales to account for a majority of sales in future periods due to our significant investment in and the efforts of our domestic sales force. Conversely, we expect reimbursement issues in Europe and Japan to limit sales growth in these regions for the next several years. However, our international operations will continue to represent a significant, if decreasing, portion of our revenue at least in part because of the high incidence of primary liver cancer in certain Asian and European markets.

All of our revenue is derived from the sale of our disposable devices and radiofrequency generators. For the three months ended September 30, 2002, 79% of our revenue was derived from the sale of our disposable devices and 21% was derived from the sale of our generators. We will continue to focus on expanding our base of customer accounts and on increasing usage of our disposable products in our established accounts. As a result, revenue from our higher-margin disposable devices should continue to predominate our sales. During the third quarter of 2002, we were affected by a disruption in the supply of an accessory device used with our Starburst XLi line of disposable devices. This disruption had a modest impact on sales for the period and is likely to have a more significant impact on sales in the fourth quarter. We expect to resolve these supply issues by year-end and return towards our historical rates of growth.

To date, essentially all of our revenue has come from products sold in the treatment of cancerous liver tumors. In 2002, we expect nominal revenue in the fourth quarter to come from the use of the RITA system sold for the treatment of patients with metastatic bone tumors. In 2003, we expect additional revenue from the treatment of bone tumors and nominal revenue from the treatment of unresectable lung tumors in overseas markets. We are conducting research and clinical trials in other organs that may lead to additional sources of revenue in the years beyond 2003.

Our manufacturing costs consist of raw materials, including generators and ancillary devices produced for us by third-party suppliers, labor to produce our disposable devices and to inspect incoming materials and in-process and finished goods, sterilization performed by an outside service provider and general overhead expenses. Gross margins are affected by production volumes, average selling prices, the sales mix of higher-margin disposable devices versus generators and the mix of domestic direct sales versus international sales, which provide for standard distributor discounts. Our gross margin for the three months ended September 30, 2002 was 61%, approximately 1% higher than our margin in the third quarter ended September 30, 2001, and about 3% higher than our margin in the preceding quarter ended June 30, 2002, which bore unusually heavy charges relating to our provision for obsolete inventory. We expect gross

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margins to further improve in the fourth quarter primarily as a result of continued improvements in sales mix and cost factors.

For the three months ended September 30, 2002, 22% of our operating expenses were related to research and development activities, compared with 20% in each of the two preceding quarters, but in terms of dollars expended, our investment in research has remained essentially constant since the beginning of 2002. We expect our research and development activities to account for a similar percentage of our operating expense in the fourth quarter of 2002, with dollars expended about equal to third quarter levels. Selling, general and administrative activities represented 78% of our operating expenses for the third quarter, down from 80% in the first and second quarters of 2002, but still higher than in recent preceding 2001 quarters, reflecting our investments in our domestic sales force, international distribution activities, physician training and patient awareness programs. In dollar terms, however, selling and administrative expense for the third quarter was approximately one million dollars less than in the second quarter, due to lower sales compensation expense and general expense management efforts. Also, our provision to our allowance for uncollectible accounts was lower in the third quarter than in the second, because while we continue to experience relatively long collection periods with many of our European distributors, our allowance has now grown to the point where we believe it adequately reflects this change in business conditions. We expect charges for selling and administrative expense in the fourth quarter to increase modestly in response to higher levels of marketing activity.

In connection with grants of stock options to employees and non-employees, we record deferred stock-based compensation as a component of stockholders equity. This stock-based compensation is amortized as charges to operations over the vesting periods of the options. We recorded amortization of deferred compensation of approximately $57,000 for the three months ended September 30, 2002. We expect to record additional amortization expense for deferred compensation in diminishing amounts through 2004, at which point our existing deferred stock-based compensation will be fully amortized.

We incurred net losses of $2.7 million for the three months ended September 30, 2002. As of September 30, 2002, we had an accumulated deficit of $64.8 million. Because we expect to continue to incur high costs associated with our research and development programs, clinical research programs and sales and marketing efforts, we expect to continue to incur net losses through 2002 and most or all of 2003. We currently expect to become modestly profitable around the end of 2003, which would be the final quarter of 2003 or the first quarter of 2004. Profitability will depend on our success in expanding product usage in our current market and in developing new markets. To the extent current or new markets do not materialize in accordance with our expectations, our sales and profitability could be lower than expected and we may be unable to achieve or sustain profitability.

We are currently involved in patent proceedings and may become a party to additional patent or product liability proceedings. The costs of such lawsuits or proceedings may be material and could affect our earnings and financial position and the point at which we achieve profitability; to date, we have capitalized certain costs related to patent proceedings. An adverse outcome in a patent lawsuit could require us to cease sales of affected products or to pay royalties and/or fees, which could harm our results of operations.

Results of Operations

The following table sets forth the percentage of net revenue represented by certain items in our Statements of Operations for the current quarter ended September 30, 2002 and the four preceding fiscal quarters:

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	Q3 2002	Q2 2002	Q1 2002	Q4 2001	Q3 2001
Domestic sales	77%	73%	72%	65%	56%
International sales	23%	27%	28%	35%	44%
Total sales	100%	100%	100%	100%	100%
Cost of goods sold	(39%)	(42%)	(45%)	(30%)	(40%)
Gross profit	61%	58%	55%	70%	60%
Operating Expenses:					
Research and development	(27%)	(28%)	(30%)	(41%)	(44%)
Selling, general and administrative	(97%)	(110%)	(118%)	(128%)	(108%)
Total operating expenses	(124%)	(138%)	(148%)	(169%)	(152%)
Loss from operations	(63%)	(80%)	(93%)	(99%)	(92%)
Other income, net	2%	2%	3%	5%	9%
Net loss	(61%)	(78%)	(90%)	(94%)	(83%)

Three months ended September 30, 2002 and 2001

Sales increased 20% to $4.5 million for the quarter ended September 30, 2002 from $3.7 million for the quarter ended September 30, 2001. Domestic sales increased by 64% over the comparable prior year period, although international sales decreased by 36%. Sales of our disposable products totaled $3.5 million for the quarter, an increase of 18% over the comparable prior year period. Domestically, higher unit shipments of disposable products resulted from increased physician awareness of our technology and the efforts of our expanded sales force. However, our international shipment volumes were lower due to reimbursement pressures in Europe and Japan as well as the timing of shipments to distributors. Average selling prices of disposable products benefited from the increasing proportion of domestic business in our sales mix as well as the acceptance of our premium-priced StarBurst XLi line of disposable devices. Generator sales for the quarter were 27% higher than sales in the third quarter of 2001, reflecting higher unit placements.

Cost of goods sold for the quarter ended September 30, 2002 was $1.7 million compared to $1.5 million for the quarter ended September 30, 2001, primarily as a result of higher unit placements of generators and ancillary hardware devices. Charges to cost of goods sold for amortization of deferred stock-based compensation were essentially zero for the quarter, compared to $142,000 in the prior year period. With sales up 20% and cost of goods sold increasing 18%, the company s gross margin rate improved to 61% for the quarter ended September 30, 2002, compared to 60% for the quarter ended September 30, 2001.

Research and development expenses for the quarter ended September 30, 2002 were $1.2 million compared to $1.6 million for the corresponding period in 2001. This decrease was primarily attributable to reduced new product development charges. Our investment in clinical programs investigating new applications for our technology has remained relatively constant. Charges to research and development expense for amortization of deferred stock-based compensation were $28,000 for the quarter, down from $96,000 in the corresponding period in 2001.

Selling, general and administrative expenses for the quarter ended September 30, 2002 were $4.3 million as compared to $4.0 million in the corresponding period in 2001. The increase was primarily due to expansion of our domestic sales organization and increased customer training costs, modestly offset by small reductions in marketing, business development and administrative expenses. Charges to selling, general and administrative expense for amortization of deferred stock-based compensation were $32,000 for the quarter compared to $159,000 for the corresponding period in 2001.

Interest income, net of interest expense, was $0.1 million for the quarter ended September 30, 2002 compared to $0.3 million in the corresponding period of 2001. The change was primarily attributable to a

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smaller portfolio of interest bearing securities, reflecting our use of cash over the past year, and lower interest rates.

Nine months ended September 30, 2002 and 2001

Sales increased 27% to $13.7 million for the nine months ended September 30, 2002 from $10.8 million for the nine months ended September 30, 2001. Domestic sales increased by 86% over the comparable prior year period, although international sales decreased by 33%. Sales of our disposable products totaled $10.2 million for the nine months ended September 30, 2002, an increase of 22% over the comparable prior year period. Domestically, higher unit shipments of disposable products resulted from increased physician awareness of our technology and the efforts of our expanded sales force, although our international shipment volumes were lower. Average selling prices of disposable products benefited from the increasing proportion of domestic business in our sales mix as well as the acceptance of our premium-priced StarBurst XLi line of disposable devices. Generator sales for the nine months ended September 30, 2002 were 43% higher than sales in the comparable period of 2001, reflecting higher unit placements.

Cost of goods sold for the nine months ended September 30, 2002 was $5.8 million compared to $4.9 million for the nine months ended September 30, 2001. The cost of product shipments rose about $0.9 million. Other manufacturing costs, principally increases in our reserve for obsolete inventory, were $0.5 million higher, totaling $0.9 million for the nine months ended September 30, 2002, compared to $0.4 million in the prior year period. These reserve provisions relate to older generation disposable devices that have been largely replaced in the market by our Starburst and Starburst Xli devices; such reserve provisions are now essentially complete. These increases were offset by a reduction in the charge to cost of goods sold for amortization of deferred stock-based compensation, which fell to $52,000 for the nine months, compared to $518,000 in the prior year period. With sales up 27% and cost of goods sold increasing 18%, the company s gross margin rate improved to 58% for the nine months ended September 30, 2002, compared to 54% for the nine months ended September 30, 2001.

Research and development expenses for the nine months ended September 30, 2002 were $3.9 million compared to $4.8 million for the corresponding period in 2001. This decrease was primarily attributable to reduced new product development charges. Our investment in clinical programs investigating new applications for our technology has remained relatively constant. Charges to research and development expense for amortization of deferred stock-based compensation were $182,000 for the nine months, down from $340,000 in the corresponding period in 2001.

Selling, general and administrative expenses for the nine months ended September 30, 2002 were $14.8 million as compared to $11.5 million in the corresponding period in 2001. The increase was primarily due to the major expansion of our domestic sales organization and increased customer training costs. Also, provisions to our reserve for uncollectible accounts resulted in $0.5 million in increased expenses. Charges to selling, general and administrative expense for amortization of deferred stock-based compensation were approximately $104,000 for the nine months compared to $559,000 for the corresponding period in 2001.

Interest income, net of interest expense, was $0.4 million for the nine months ended September 30, 2002 compared to $1.3 million in the corresponding period of 2001. The change was primarily attributable to a smaller portfolio of interest bearing securities, reflecting our use of cash over the past year, and lower interest rates.

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, of which there was less than $0.1 million in principal outstanding at September 30, 2002. Also as of September 30, 2002, we had $9.5 million of cash and cash equivalents, $5.8 million of short-term marketable securities and $19.8 million of working capital.

For the nine months ended September 30, 2002, net cash used in operating activities was $7.1 million, principally due to our net loss. Our investing activities for this period were limited to the purchase of

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property and equipment in the amount of $0.6 million and net purchases or sales of both short-term and long-term investment instruments. Also, we capitalized $1.2 million in costs associated with legal action we initiated in 2001 in defense of our patent rights (see Part II, Legal Proceedings for discussion of this and other legal proceedings). Net cash provided by financing activities was $1.2 million, principally from the issuance of common shares.

We have, from time to time, financed equipment through capital and operating leases. As of September 30, 2002, our future minimum payments due under capital and operating leases are as follows (in thousands):

Future minimum capital lease payments

Payments due in the remainder of 2002	$ 46
Less imputed interest (including warrants)	(1)
Present value of future minimum capital lease payments	$ 45

Future minimum operating lease payments

Remainder of 2002	$ 135
2003	539
2004	360
Total of future minimum operating lease payments	$1,034

Our capital requirements depend on numerous factors including our research and development expenditures, including certain legal expenses, expenses related to selling, marketing and administration as well as working capital to support business growth. Although it is difficult for us to predict future liquidity requirements with certainty, we believe that our current cash and cash equivalents will satisfy our cash requirements for at least the next 15 months. During or after this period, if cash generated by 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 us and our stockholders.

Recent Accounting Pronouncements

In July 2002, The Financial Accounting Standards Board (FASB) issued Statements of Financial Accounting Standards No. 146 (SFAS 146), Accounting for Costs Associated with Exit or Disposal Activities, which is effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. The standard nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity including Certain Costs Incurred in a Restructuring). SFAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. Examples of costs covered by the standard include lease termination costs and certain employee severance costs that are associated with a restructuring, discontinued operation, plant closing or other exit or disposal activity. The Company does not believe adoption of this statement will materially impact its financial position or results of operations.

Factors That May Affect Future Results

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

Due to our dependence on the RITA system, failure to achieve market acceptance in a timely manner could harm our business.

Because all of our revenue comes from the sale of the RITA system, our financial performance will depend upon physician adoption and patient awareness of this system. If we are unable to convince

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physicians to use the RITA system, we may not be able to generate revenues because we do not have alternative products.

We are currently involved in a patent interference action and a patent opposition action involving RadioTherapeutics Corporation, and if we do not prevail in these actions, we may be unable to sell the RITA system.

In July 1999, the United States Patent and Trademark Office declared an interference involving us, which was provoked by RadioTherapeutics Corporation, a competitor of ours and now a wholly owned subsidiary of Boston Scientific Corporation, in which the validity of a patent claim previously issued to us was called into question. The claims at issue in the interference cover a radiofrequency ablation device having an array of deployable electrodes effective, in a deployed state, to define a tissue ablation volume. In February 2001, the Patent and Trademark Office issued a decision on preliminary motions filed in the patent interference proceeding. The decision found that one of the claims in our United States Patent No. 5,536,267 (claim no. 32) is invalid. On September 27, 2002, the Patent and Trademark Office Board of Patent Appeals and Interferences issued a final decision finding that RadioTherapeutics had failed to establish priority of invention over RITA s established invention date and, therefore, were not themselves entitled to any patent claims in the interference. It also affirmed the earlier preliminary decision, described above, regarding claim 32. On October 16, 2002, RadioTherapeutics filed an action in the United States District Court for the Northern District of California seeking to reverse the Patent and Trademark Office Board of Patent Appeals priority decision, affirm its decision regarding claim 32, and to initiate a new interference between certain issued patent claims licensed to RadioTherapeutics and certain of the RITA s patent claims. Final determination of these patent interference proceedings may take several years. If the United States District Court reverses the decision of the Patent and Trademark Office Board of Patent Appeals as to RadioTherapeutics entitlement to priority, and we were found to infringe RadioTherapeutics patent claims and were unable to obtain a license to use the relevant patent or successfully modify our disposable device, we could be unable to sell our system and our business could suffer. If the District Court affirms the Patent and Trademark Board s decision regarding claim 32 or if RadioTherapeutics prevails on its new interference, we could lose one or more of our issued patent claims.

In March 2000, RadioTherapeutics filed an opposition to our European Patent No. 0777445 before the European Patent Office. This patent also covers the curvature of the array at the tip of our disposable devices. In this opposition, the validity of our issued patent is being questioned. In February 2002, the European Patent Office determined that we were entitled to European Patent No. 0777445. Both parties have appealed this ruling and a final decision is not expected in this proceeding for several years. If we do not prevail in the opposition proceeding, we could lose our only currently issued patent in Europe.

We have been sued for patent infringement by two Boston Scientific Corporation entities, UneMed Corporation and their licensors and if we do not prevail in this lawsuit, we could be prevented from selling our products and our business could suffer.

On April 11, 2002, RadioTherapeutics Corporation and SciMed Life Systems, Inc., (two wholly-owned subsidiaries of Boston Scientific Corporation), the Board of Regents of the University of Nebraska, and UneMed Corporation filed a complaint against us alleging that certain of our products infringe a patent assigned to the University of Nebraska and licensed by UneMed and RadioTherapeutics and a patent owned by SciMed. RadioTherapeutics filed a first amended complaint on October 30, 2002 adding to the litigation a second patent assigned to the University of Nebraska and licensed to RadioTherapeutics. Also, in a separate action initiated on July 9, 2002, Boston Scientific Corporation and the University of Kansas filed a complaint against us alleging that certain of our products infringe a patent assigned to the University of Kansas and licensed by Boston Scientific. In addition, we are aware of the existence of patents held by competitors in our market, which could result in additional patent lawsuits against us. In the event that we do not prevail in the Boston Scientific lawsuits or if we are subject to additional patent litigation and we are found to infringe, we could be prevented from selling our products unless we could obtain a license or were able to redesign our products to avoid infringement. If we were unable to obtain a license or successfully redesign our products, we may be prevented from selling our products and our business could suffer.

We have a history of losses, anticipate significant increases in our operating expenses over the next several years and may never achieve profitability.

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Although we anticipate that our operating expenses will begin to stabilize in absolute dollars over the next several quarters, to become profitable we must continue to increase our sales. If sales do not continue to grow, we may not be able to achieve or maintain profitability in the future. In particular, we incurred net losses of $10.4 million in the first nine months of 2002, $13.0 million in 2001, $12.8 million in 2000 and $7.5 million in 1999. At September 30, 2002, we had an accumulated deficit of approximately $64.8 million.

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.

We are also aware of several small companies in international markets which sell products that compete directly with ours. These companies could erode our international market share in the future.

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 both cancerous and benign tumors. If these alternative therapies prove to offer treatment options that are superior to 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.

In the area of liver cancer, our products are supported by clinical follow-up data in published clinical reports or scientific presentations covering periods from five months to three 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. That could result in additional 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

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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 revenues, could harm our business.

Because our future profitability will depend in part on our ability to grow 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 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 two distributors in our international markets, and if we lose either distributor or if either distributor significantly reduces their 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. It accounted for 50 percent of our international revenues for the nine months ended September 30, 2002 and 31 percent of our international revenues in 2001. M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, accounted for 20 percent of our international revenues for the nine months ended September 30, 2002 and 17 percent of our international revenues for 2001. Because international revenues accounted for 26 percent of our total revenues for the nine months ended September 30, 2002 and these two distributors represented 70 percent of that total, the loss of either distributor or a significant decrease in unit purchases by either distributor could cause revenues to decline substantially. If we are unable to attract additional international distributors, our international revenues may not grow.

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. If our distributors or we terminate our existing agreements, finding companies to replace them could be an expensive and time-consuming process and sales could decrease during any 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

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negatively impacted. 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.

In recent quarters we have significantly increased our reserve for uncollectible accounts to address the risk associated with longer collection periods that have arisen principally with our European distributors. If difficult economic conditions persist, and our collection experience worsens as a result, we may need to further adjust our reserve for uncollectible accounts in future periods, thereby reducing 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. For example, ITX, our distributor in Japan, is seeking to obtain reimbursement coverage in Japan, but to date has not yet received this approval. If we are unable to either obtain the required reimbursement codes or develop an effective strategy to resolve the reimbursement issue, physicians may be unwilling to purchase our products which could negatively impact our international revenues.

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 substantial reimbursement for the cost of the procedures using our products from third-party payors, such as Medicare, Medicaid and private health insurance plans. Even though in February of 2002 we were successful in establishing a new CPT code related to liver procedures with the American Medical Association, a payor still may not reimburse adequately for the procedure or product. In addition, there is no specific reimbursement code for radiofrequency ablation of tumors in other organs. Further, we believe the advent of fixed payment schedules has made it difficult to receive reimbursement for disposable products, even if the use of these products improves clinical outcomes. Fixed payment schedules typically permit reimbursement for a procedure rather than a device. If physicians believe that our system will add cost to a procedure but will not add sufficient offsetting economic or clinical benefits, physician adoption could be slowed.

You may have a difficult time evaluating our company as an investment because we have a limited operating history.

You can only evaluate our business based on a limited operating history because we began selling the RITA system in 1997. This short history may not be adequate to enable you to fully assess our ability to achieve market acceptance of our products and respond to competition.

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, operations and research and development staff. Our future success will depend in part on the continued service of these individuals and our ability to identify, hire and retain additional personnel, including sales and marketing staff. The market for qualified management personnel in Northern California, where our offices are located, is competitive and is expected to continue to be competitive. Because the environment for good personnel is so competitive, costs related to compensation may increase significantly. If we are unable to attract and retain the 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

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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. This may result in unsatisfactory patient outcomes, patient injury and related liability or negative publicity that could have an adverse effect on our product sales.

Any failure to build and manage our direct sales organization may negatively affect our revenues.

We have significantly expanded our direct sales force in the United States over the past eighteen months. There is intense competition for skilled sales and marketing employees, especially for people who have experience selling disposable devices and generators to the physicians in our target market, and we may be unable to hire skilled individuals to sell our products. Any inability to build and effectively manage our direct sales force could negatively impact our growth.

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

Our stock price may fluctuate for a number of reasons including:

- failure of the public market to support the valuation established in our initial public offering;
- our ability to successfully commercialize our products;
- 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;
- 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.

If we fail to support our anticipated growth in operations, our business could suffer.

If we fail to execute our sales strategy and develop further our products, our business could suffer. To manage anticipated growth in operations, we must, over time, increase our operations staff and expand our manufacturing facilities. Our systems, procedures and controls may not be adequate to support our expected growth in operations.

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We have limited experience manufacturing our disposable devices in substantial quantities, and if we are unable to hire sufficient additional personnel, 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. 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 our manufacturing operations or are otherwise unable to meet customer demand for our products, our business could suffer.

We are dependent on one supplier as the only source of a component that we use in our disposable devices, and any disruption in the supply of this component could negatively affect our revenues.

To date, there has been only one supplier available to provide us with a component that we include in our disposable devices. Recently, we have identified a second supplier, but we have not yet qualified them. 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.

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

During the quarter ended September 30, 2002, we experienced shortages in the supply of accessory infusion pumps for which we currently have no alternate supplier. If we are unable to remedy this supply disruption, if we suffer similar disruptions in the future, or if we are unable to identify an alternate supplier of accessory infusion pumps our business could suffer through lower revenues or higher costs.

We are dependent on 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 international 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 international 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

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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. This 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. 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.

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.

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

Because our executive officers and directors, and their respective affiliates, own approximately 26 percent 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 change in control.

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

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

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 filing dated March 28, 2002.

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Item 4. Controls and Procedures

RITA evaluated the design and operation of its disclosure controls and procedures to determine whether they are effective in ensuring that the disclosure of required information is timely made in accordance with the Exchange Act and the rules and forms of the Securities and Exchange Commission. This evaluation was made under the supervision and with the participation of management, including RITA s principal executive officer and principal financial officer within the 90-day period prior to the filing of this Quarterly Report on Form 10-Q. The principal executive officer and principal financial officer have concluded, based on their review, that RITA s disclosure controls and procedures, as defined at Exchange Act Rules 13a-14(c) and 15d-14(c), are effective to ensure that information required to be disclosed by RITA in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. No significant changes were made to RITA s internal controls or other factors that could significantly affect these controls subsequent to the date of their evaluation.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

On July 16, 1999, the United States Patent and Trademark Office declared an interference involving us, which was instituted by RadioTherapeutics Corporation, a competitor of ours and now a wholly owned subsidiary of Boston Scientific Corporation, in which the validity of a patent claim previously issued to us was called into question. The principal parties in the proceeding are RadioTherapeutics and RITA. The claims at issue in the interference cover a radiofrequency ablation device having an array of deployable electrodes effective, in a deployed state, to define a tissue ablation volume. In February 2001, the Patent and Trademark Office issued a decision on preliminary motions filed in the patent interference proceeding. The decision found that one of the claims in our United States Patent No. 5,536,267 (claim no. 32) is invalid. On September 27, 2002, the Patent and Trademark Office Board of Patent Appeals and Interferences issued a final decision finding that RadioTherapeutics had failed to establish priority of invention over RITA s established invention date and, therefore, were not themselves entitled to any patent claims in the interference. It also affirmed the earlier preliminary decision, described above, regarding claim 32. On October 16, 2002, RadioTherapeutics filed an action in the United States District Court for the Northern District of California seeking to reverse the Patent and Trademark Office Board of Patent Appeals priority decision, affirm its decision regarding claim 32, and to initiate a new interference between certain issued patent claims licensed to RadioTherapeutics and certain of the RITA s patent claims. The factual basis alleged to underlie the new interference proceeding is the claim that our patent and the patent licensed to RadioTherapeutics interfere. RadioTherapeutics seeks to invalidate our patent claims. Final determination of these patent interference proceedings may take several years. If the United States District Court reverses the decision of the Patent and Trademark Office Board of Patent Appeals as to RadioTherapeutics entitlement to priority, and we were found to infringe RadioTherapeutics patent claims and were unable to obtain a license to use the relevant patent or successfully modify our disposable device, we could be unable to sell our system and our business could suffer. If the District Court affirms the Patent and Trademark Office Board of Patent Appeals decision regarding claim 32 or if RadioTherapeutics prevails on its new interference, we could lose one or more of our issued patent claims.

On July 9, 2002, Boston Scientific Corporation, the University of Kansas and the University of Kansas Medical Center Research Institute filed a complaint against us in United States District Court for the Northern District of California. The principal parties in the dispute are Boston Scientific Corporation, the University of Kansas, the University of Kansas Medical Center Research Institute and RITA. The factual basis alleged to underlie the claim is that certain of our products infringe a patent licensed by Boston Scientific from the University of Kansas. The complaint seeks unspecified monetary damages and injunctive relief.

On April 11, 2002, RadioTherapeutics and SciMed Life Systems, Inc., (two wholly-owned subsidiaries of Boston Scientific Corporation), the Board of Regents of the University of Nebraska, and UneMed Corporation filed a complaint against us in United States District Court for the Northern District of California. The principal parties in the dispute are RadioTherapeutics, SciMed, the Board of Regents of the University of Nebraska, UneMed Corporation and RITA. The factual basis alleged to underlie the claim is that certain of our products infringe a patent licensed by UneMed and RadioTherapeutics and a patent owned by SciMed. The complaint seeks unspecified monetary damages and injunctive relief. RadioTherapeutics filed a first amended complaint on October 30, 2002 adding to the litigation a second patent assigned to the University of Nebraska and licensed to RadioTherapeutics.

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On August 27, 2001 we filed a complaint against RadioTherapeutics in the United States District Court for the Northern District of California. The principal parties in the proceeding are RadioTherapeutics and RITA. The factual basis underlying the proceeding is our claim that the sale by RadioTherapeutics of its radiofrequency ablation products infringes six of our patents. On October 17, 2001, RadioTherapeutics filed an answer and affirmative defenses to our complaint denying certain of the allegations in the complaint and asserting counterclaims requesting declaratory relief that RadioTherapeutics is not infringing our patents and that our asserted patents are invalid and unenforceable. Our complaint seeks treble damages against RadioTherapeutics for its sale of radiofrequency ablation products, as well as temporary and permanent injunctive relief enjoining RadioTherapeutics from further infringement of our patents.

We are also involved in a patent opposition pending before the European Patent Office. This opposition was instituted on March 2, 2000. The principal parties are RadioTherapeutics and RITA. This patent also covers the curvature of the array at the tip of our disposable devices. The factual basis alleged to underlie the claim is the allegation by RadioTherapeutics that our European patent is not valid. RadioTherapeutics seeks to invalidate our patent claim and to establish the patentability of the claims in their patent application. We seek to maintain the priority of our patent claim. On February 7, 2002, the European Patent Office determined that we are entitled to Patent No. 0777445 covering radiofrequency ablation technology, approving 27 claims. Both parties have appealed this rating.

In addition to these patent proceedings, we may from time to time become a party to various legal proceedings arising in the ordinary course of our business.

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:

10.28	Separation Agreement with Ronald Steckel effective July 31, 2002.
10.29	Separation Agreement with Daniel Balbierz dated July 30, 2002.
10.30	Change of Control Agreement entered into between the Company and Stephen J. Williams dated July 29, 2002.
10.31	Indemnification Agreement between the Company and Stephen J. Williams on July 29, 2002.
99.1	Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.2	Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K: Not applicable.

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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/ DONALD STEWART

Donald Stewart
Chief Financial Officer and Vice President, Finance and Administration

Date: November 14, 2002

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CERTIFICATION

Pursuant to 18 U.S.C. Section 1350,

as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Barry Cheskin, certify that:

1. I have reviewed this quarterly report on Form 10-Q of RITA Medical Systems, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

   c) disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

/s/ BARRY CHESKIN

Barry Cheskin
President and Chief Executive Officer

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CERTIFICATION

Pursuant to 18 U.S.C. Section 1350,

as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Donald Stewart, certify that:

1. I have reviewed this quarterly report on Form 10-Q of RITA Medical Systems, Inc.;

4. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

5. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

   c) disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

/s/ DONALD STEWART

Donald Stewart
Chief Financial Officer and
Vice President, Finance and Administration

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EXHIBIT INDEX

10.28	Separation Agreement with Ronald Steckel effective July 31, 2002.
10.29	Separation Agreement with Daniel Balbierz dated July 30, 2002.
10.30	Change of Control Agreement entered into between the Company and Stephen J. Williams dated July 29, 2002.
10.31	Indemnification Agreement between the Company and Stephen J. Williams on July 29, 2002.
99.1	Certificate pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.2	Certificate pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.