RITA MEDICAL SYSTEMS INC
Form 10-Q
November 14, 2001

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, 2001

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 October 31, 2001, there were 14,532,954 shares of the registrant's Common Stock outstanding.

INDEX

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

RITA MEDICAL SYSTEMS, INC.

CONDENSED BALANCE SHEETS

(In thousands, unaudited)

	September 30, 2001
Assets	

Current assets:	
Cash and cash equivalents	$ 11,927
Marketable securities	15,027
Accounts receivable, net	4,364
Inventories, net	2,504
Prepaid assets and other current assets	1,111
Total current assets	34,933
Long term securities	1,579
Property and equipment, net	1,923
Intangibles and other assets	144
Total assets	$ 38,579
Liabilities and Stockholders' Equity	
Current liabilities:	
Accounts payable	$ 711
Accrued liabilities	1,979
Current portion of long term obligations	224
Total current liabilities	2,914
Long term obligations	42
Total liabilities	2,956
Contingencies (Note 5)	
Stockholders' equity	
Common stock, $0.001 par value	15
Additional paid-in capital	88,458
Deferred stock compensation	(2,208)
Receivable from stockholders	(97)
Accumulated other comprehensive income	89
Accumulated deficit	(50,634)
Total stockholders' equity	35,623
Total liabilities and stockholders' equity	$ 38,579

See accompanying notes

RITA MEDICAL SYSTEMS, INC.

CONDENSED STATEMENTS OF OPERATIONS

(In thousands, except per share data, unaudited)

	Three Months Ended September 30,	
	2001	2000

Sales	$ 3,707	$ 2,712	$
Cost of goods sold	1,472	1,622	
Gross profit	2,235	1,090	
Operating expenses			
Research and development	1,627	1,262	
Selling, general and administrative	4,016	3,023	
Total operating expenses	5,643	4,285	
Loss from operations	(3,408)	(3,195)	
Interest income and other expense, net	324	239	
Net loss	$ (3,084)	$ (2,956)	$
Net loss per share, basic and diluted	$ (0.21)	$ (0.31)	$
Shares used in computing basic and diluted net loss per share	14,406	9,607	

See accompanying notes

RITA MEDICAL SYSTEMS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(In thousands, unaudited)

Operating activities:
Net loss
Adjustments to reconcile net loss to net cash used in operating activities:
Depreciation and amortization
Amortization of stock-based compensation
Allowance for doubtful accounts
Allowance for inventory reserve
Changes in operating assets and liabilities
Accounts receivable
Inventory
Prepaid and other current assets

Accounts payable and accrued liabilities	
Net cash used in operating activities	
Cash flows from investing activities:	
Purchase of property and equipment	
Purchases of short term investments	
Maturities of short term investments	
Purchases of long term investments	
Capitalization of patent litigation costs	
Other assets	
Net cash provided by (used in) investing activities	
Cash flows from financing activities:	
Proceeds from issuance of common stock	
Proceeds from borrowings of long term debt	
Payments on long term debt	
Proceeds from revolving term loan	
Payments on revolving term loan	
Payments on capital lease obligations	
Net cash provided by (used in) financing activities	
Net increase (decrease) in cash and cash equivalents	
Cash and cash equivalents at beginning of period	
Cash and cash equivalents at end of period	

See accompanying notes

RITA MEDICAL SYSTEMS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(unaudited)

1. Basis of Presentation

The accompanying unaudited condensed 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, 2000 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 financial statements contain all adjustments (all of which are normal and recurring in nature) 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 condensed financial statements should be read in conjunction with the financial statements and footnotes thereto for the year ended December 31, 2000 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, shares subject to repurchase and shares issuable upon conversion of preferred stock provided that the inclusion of such common stock equivalents is not antidilutive. For the three and nine month periods ended September 30, 2001 and September 30, 2000, the Company has excluded potentially dilutive securities from earnings per share computations as they have an antidilutive effect due to the Company's net losses. The following weighted options and warrants (prior to application of the treasury stock method), convertible preferred shares (on an as-if-converted method) and common shares subject to repurchase were so excluded (in thousands):

	Three months ende September 30,	
	2001	200
Options and warrants	2,438	2,13
Convertible preferred stock	-	3,01
Common shares subject to repurchase	61	9
	2,499	5,24

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

	Three months ende September 30,	
	2001	200
Weighted average shares of common stock outstanding	14,467	9,70
Less: weighted-average shares subject to repurchase	61	9
Weighted average shares used in basic and diluted net loss per share	14,406	9,60

3. Inventories (in thousands)

	September 30, 2001	December 31, 2000
Raw materials	$ 538	$ 404
Work-in-process	283	203
Finished goods	1,683	1,031
	$2,504	$1,638

4. Recent Accounting Pronouncements

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS No. 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. This Statement supersedes FASB Statement No. 121 and APB 30, however, this Statement retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. This Statement addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Management does not expect the adoption of SFAS No. 144 to have a material impact on the Company's financial position and results of operations.

5. Contingencies

The Company is involved in a patent interference proceeding with RadioTherapeutics Corporation in which the validity of a patent issued to the Company has been called into question. Although the Company believes it has meritorious defenses, if it does not prevail in this interference, it could be prevented from selling the RITA system or be required to pay license fees and / or royalties on past and future product sales.

Also, in August 2001 the Company filed a complaint in the United States District Court for the Northern District of California against RadioTherapeutics Corporation. This complaint, which is distinct from the patent interference proceeding described above, alleges that RadioTherapeutics' radiofrequency ablation products infringe six different patents held by the Company. The Company has to date capitalized approximately $88,000 in litigation costs incurred in this defense of its patent positions.

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", "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 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 2000, we commercially launched our Model 1500 generator and StarBurst 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, 2001, sales in the United States accounted for 56% of our total sales while sales in our international markets accounted for 44% of our total sales. The percentage of our revenues from international markets has decreased in 2001 as reimbursement concerns in Europe and Japan have slowed the growth of our business in these markets and as our revenue in the United States has responded to continued investment. We expect this trend to continue through the balance of 2001 and 2002. Longer term, we expect that a significant portion of our revenue will continue to come from international operations because of the high incidence of primary liver cancer in 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, 2001, 80% of our sales were derived from our disposable devices and 20% were derived from the sale of our generators. Placement of generators at hospitals is necessary for customers to use our disposable devices, and we continue to focus on expanding our base of customer accounts. We are also continuing to focus on increasing usage of our disposable products at our established accounts, and we expect that a significant proportion of our revenues will continue to be derived from the sale of our higher-margin disposable devices.

Our manufacturing costs consist of raw materials, including generators 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. Gross margins are affected by production volumes and average selling prices. In addition, margins are affected by the sales mix of disposable devices versus generators, the mix of domestic direct sales versus international sales, which provide for standard distributor discounts, and our regular provisions for obsolete or excess inventory.

For the three months ended September 30, 2001, 29% of our operating expenses were related to research and development activities, while 71% of our operating expenses were related to selling, general and administrative activities. We expect to continue to devote significant resources to product development and clinical research programs. We also expect to continue to devote the majority of our operating expenses to selling, general and administrative activities, particularly to our sales and marketing efforts. These efforts include the selective expansion of our domestic sales force and our international distribution support activities as well as physician training and patient awareness programs.

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 $0.4 million for the three months ended September 30, 2001. We expect to record additional amortization expense for deferred compensation in future periods.

We incurred net losses of $3.1 million for the three months ended September 30, 2001. As of September 30, 2001, we had an accumulated deficit of $50.6 million. Due to the high costs associated with continued research and development programs, expanded clinical research programs and increased sales and marketing efforts, we expect to continue to incur net losses for the balance of 2001 and for the year 2002.

Our future growth depends on expanding product usage in our current market and finding new large markets in which we can leverage our core technologies of applying radiofrequency energy to treat cancerous and benign tumors. To the extent our current or new markets do not materialize in accordance with our expectations, our sales could be lower than expected.

On August 15, 2001 we filed a complaint against RadioTherapeutics Corporation which alleges that the sale by RadioTherapeutics of its radiofrequency ablation products infringes six of our patents. In addition, we are currently involved in other patent disputes with RadioTherapeutics and may become a party to additional patent or product liability proceedings in the ordinary course of business. The costs of such lawsuits or proceedings may be material and could affect our earnings and financial position. An adverse outcome in a patent lawsuit could require us to cease sales of affected products or to pay royalties and/or license fees, which could harm our results of operations.

Results of Operations

Three months ended September 30, 2001 and 2000

Sales increased 37% to $3.7 million for the quarter ended September 30, 2001 from $2.7 million for the quarter ended September 30, 2000. We saw growth in both domestic and international markets, with domestic sales increasing by 60% and international sales up by 15% over the comparable prior year period. Sales of our disposable products totaled $3.0 million for the quarter, an increase of 59% over the comparable prior year period. Higher unit shipments of disposable products resulted from increased physician awareness of our technology, expansion of our domestic sales force and increased geographical representation through the appointment of new international distributors. Also, average selling prices of disposable products benefited from the increasing proportion of domestic business in our sales mix. Generator sales for the quarter were 13% lower than sales in the third quarter of 2000.

Cost of goods sold for the quarter ended September 30, 2001 was $1.5 million compared to $1.6 million for the quarter ended September 30, 2000, a 9% reduction. This reduction in cost of goods sold reflects a significant change in our sales mix, from relatively high cost generators to relatively low cost disposable products. Also, charges for amortization of deferred stock-based compensation totaled $0.1 million for the third quarter of 2001, down from $0.2 million in the corresponding period of 2000. With sales up 37% and cost of goods sold down 9%, the company's gross margin rate improved to 60% for the quarter ended September 30, 2001 compared to 40% for the quarter ended September 30, 2000.

Research and development expenses for the quarter ended September 30, 2001

were $1.6 million compared to $1.3 million for the corresponding period in 2000. This increase was attributable to new product development charges and increased activity in clinical programs investigating new applications for our technology. Charges to research and development expense for amortization of deferred stock-based compensation were $0.1 million for the period compared to $0.2 million for the corresponding period in 2000.

Selling, general and administrative expenses for the quarter ended September 30, 2001 were $4.0 million as compared to $3.0 million in the corresponding period in 2000. The increase resulted from the major expansion of our domestic sales organization and increased administrative expenses due to added personnel to support our growth in operations. Charges to selling, general and administrative expense for amortization of deferred stock-based compensation were $0.2 million for the period compared to $0.6 million for the corresponding period in 2000.

Interest income, net of interest expense, was $0.3 million for the quarter ended September 30, 2001 compared to $0.2 million of net expense in the corresponding period of 2000. The change was primarily attributable to earnings on short-term investments made with cash received from our initial public offering of common shares, completed in the third quarter of 2000.

Nine months ended September 30, 2001 and 2000

Sales increased 54% to $10.8 million for the nine months ended September 30, 2001 from $7.0 million for the nine months ended September 30, 2000. We saw growth in both domestic and international markets, with domestic sales increasing by 95% and international sales up by 28% over the comparable prior year period. Sales of our disposable products totaled $8.3 million for the first nine months of 2001, an increase of 85% over the comparable prior year period, while generator sales were flat. Higher unit shipments of disposable products resulted from increased physician awareness of our technology, expansion of our domestic sales force and increased geographical representation through the appointment of new international distributors. Also, average selling prices of disposable products benefited from the increasing proportion of domestic business in our sales mix.

Cost of goods sold for the nine months ended September 30, 2001 was $4.9 million compared to $4.3 million for the nine months ended September 30, 2000, an increase of 14%. The growth in cost of goods sold was attributable primarily to higher material, labor, and overhead costs associated with increased unit shipments. Charges to cost of goods sold for amortization of deferred stock-based compensation were $0.5 million for the period compared to $0.7 million for the corresponding period in

2000. With sales increasing by 54% and cost of goods sold increasing by only 14%, the company's gross margin rate improved to 54% for the nine months ended September 30, 2001 compared to 38% for the nine months ended September 30, 2000.

Research and development expenses for the nine months ended September 30, 2001 were $4.8 million compared to $4.3 million for the corresponding period in 2000. This increase was attributable to new product development charges and increased activity in clinical programs investigating new applications for our technology. Charges to research and development expense for amortization of deferred stock-based compensation were $0.3 million for the period compared to $0.8 million for the corresponding period in 2000.

Selling, general and administrative expenses for the nine months ended

September 30, 2001 were $11.5 million compared to $8.3 million in the corresponding period in 2000. The increase resulted from the major expansion of our domestic sales organization, increased administrative expenses due to added personnel to support our growth in operations and additional costs associated with our operation as a public company. Charges to selling, general and administrative expense for amortization of deferred stock-based compensation were $0.6 million for the period compared to $2.5 million for the corresponding period in 2000.

Interest income, net of interest expense, was $1.3 million for the nine months ended September 30, 2001 compared to $0.3 million in the corresponding period of 2000. The change was primarily attributable to earnings on short-term investments made with cash received from our initial public offering of common shares, completed in the third quarter of 2000.

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 $0.3 million in principal outstanding at September 30, 2001. As of September 30, 2001, we had $11.9 million of cash and cash equivalents, $15.0 million of short term marketable securities, $1.6 million of long term securities and $32.0 million of working capital.

For the nine months ended September 30, 2001, net cash used in operating activities was $9.8 million, principally due to our net loss and increases in accounts receivable. Our investing activities for this period were limited to the purchase of property and equipment in the amount of $1.4 million and net purchases or sales of both short-term and long-term investment instruments. Net cash used by financing activities was $0.4 million in the first nine months of 2001 with $1.1 million in debt reduction offset by proceeds from the issuance of common shares.

Our capital requirements depend on numerous factors including our research and development expenditures, 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 18 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 Company and our stockholders.

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 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 patent infringement, priority and validity disputes with RadioTherapeutics Corporation, and if we do not prevail in these disputes, we may be unable to sell the RITA system.

In August 2001, we filed a complaint against RadioTherapeutics Corporation alleging that RadioTherapeutics' radiofrequency ablation products infringe six of our patents. Our complaint seeks damages against RadioTherapeutics for its sale of radiofrequency ablation products, including the LeVeen CoAccess Electrode System and preliminary and permanent injunctive relief enjoining RadioTherapeutics from further infringement 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. While we believe that our complaint has merit and that we have strong defenses against the counterclaims made by RadioTherapeutics, we expect this litigation to be expensive and time consuming and the outcome cannot be predicted.

In July 1999, the United States Patent and Trademark Office declared an interference involving us, which was provoked by RadioTherapeutics, in which the validity of a patent claim previously issued to us is being called into question. The claim being questioned is one of a number of issued patent claims that cover the curvature of the array at the tip of our disposable devices. 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. We expect to receive the final confirmation of that decision in 2002. In the event that the decision is confirmed, we plan to file a motion in a United States District Court or the Court of Appeals for the Federal Circuit requesting review of the decision. Final determination of both the patent infringement and the patent interference proceedings may take several years. If the final determination in either patent dispute results in our patents being declared invalid and the issuance of the disputed patent rights to RadioTherapeutics and we were unable to obtain a license to use the relevant patent or modify our disposable devices, we could be unable to sell the RITA system and our business would suffer.

In March 2000, RadioTherapeutics filed an opposition to our European Patent No. 0777445. 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. 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 a history of losses, anticipate significant increases in our operating expenses over the next several years and may never achieve profitability.

We anticipate that our operating expenses will increase substantially in absolute dollars for the foreseeable future as we expand our sales and marketing, manufacturing, clinical research and product development efforts. 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. Historically, we have never shown a profit for any year or quarterly reporting period, and our accumulated deficit stands at $50.6 million as of September 30, 2001.

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 privately held company, and Radionics, Inc., a division of Tyco Healthcare LP, a publicly traded company with substantial resources. Both RadioTherapeutics and Radionics sell products that use radiofrequency energy to ablate soft tissue. Boston Scientific Corporation, a publicly traded company with substantially greater resources than we have, has recently announced plans to acquire RadioTherapeutics.

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.

Our products are supported by an average clinical follow-up of between five and 14 months in published clinical reports. If longer-term studies fail to confirm 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 not randomized and/or included small patient populations, our clinical data may not be reproduced in wider patient populations.

If we are unable to protect our intellectual property rights, we may lose market share to a competitor 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. Our pending United States and foreign patent applications may not issue or may issue and be subsequently successfully challenged by others and invalidated. 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 upon 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 extensive and time consuming and could divert our 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 a competitor and our business could suffer.

If we are sued for patent infringement, we could be prevented from selling our products and our business could suffer.

We are aware of the existence of patents held by competitors in our market, which could result in a patent lawsuit against us. In the event that we are subject to a patent infringement lawsuit and if the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be prevented from selling our products unless we could obtain a license or were able to redesign the product to avoid infringement. If we were unable to obtain a license or successfully redesign our system, we may be prevented from selling our system 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 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 34 percent of our international revenues for the nine months ended September 30, 2001 and 48 percent of our international revenues in 2000. M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, accounted for 18 percent of our international revenues for the nine months ended September 30, 2001 and 17 percent of our international revenues for 2000. Because international revenues accounted for 50 percent of our total revenues for the nine months ended September 30, 2001 and these two distributors represented 52 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.

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. ITX, our distributor in Japan, is conducting studies that are necessary 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. Hospitals using our products are currently reimbursed based on established general reimbursement codes. Because there is no specific reimbursement code for physicians performing procedures using the RITA system, physicians need to submit a patient case history and data supporting the applicability of our system to the patient's condition in order to obtain reimbursement. Each payor then determines whether and to what extent to reimburse for a medical procedure or product. Payors may refuse to provide reimbursement for procedures covered by general codes because the applicability of the code must be determined on a case-by-case basis. Although we have been notified by the American Medical Association Coding Committee that specific reimbursement codes for radiofrequency ablation of liver tumors will be established in 2002, they reserve the right to reverse this decision. In this case, we would be required to reapply for a specific code.

This process is time consuming and costly and may require us to provide extensive supporting scientific, clinical and cost-effectiveness data for our products to the American Medical Association. Even if we were successful in establishing a new code, a payor still may not reimburse adequately for the procedure or product. In addition, 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.

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 twelve months and plan to continue to increase the domestic direct sales force in the future. 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 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 extremely competitive and is expected to continue to be highly 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 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.

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 increase our quality assurance staff for both our generators and our disposable

devices and expand our manufacturing staff and facility for our disposable devices. Our systems, procedures and controls may not be adequate to support our expected growth in operations.

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.

Because there is only one supplier that provides us with a component that we include in our disposable devices, a disruption in the supply of this component could negatively affect revenues. This supplier is the only source of this component. 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 third-party contractors for the supply of our generators, and any failure to deliver generators to us could result in lower than expected revenues.

One third-party supplier currently manufactures, to our specifications, one of the generators we sell. There is only one other third-party contractor who we have used who could readily assume this manufacturing function. Two third-party suppliers produce the other generator we sell. 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 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, bone 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 28 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 27, 2001.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

On August 27, 2001 we filed a complaint against RadioTherapeutics Corporation 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 dispute 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. RadioTherapeutics has also moved to stay the litigation pending the outcome of the patent interference proceeding described below. 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 interference proceeding before the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office. On July 16, 1999 the United States Patent and Trademark Office declared an interference between a claim of one of our issued patents and claims of a patent application controlled by RadioTherapeutics. The principal parties in the proceeding are RadioTherapeutics and RITA. The factual basis underlying the claim is the determination by the commissioner of the United States Patent and Trademark Office that our patent and the RadioTherapeutics patent application interfere. In the interference proceeding, 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. The European opposition is pending before the European Patent Office and was instituted on March 2, 2000. The principal parties are RadioTherapeutics and

RITA. The factual basis underlying the claim is the allegation by RadioTherapeutics that our European patent is not valid. In the opposition, RadioTherapeutics seeks to have our patent declared invalid and to have our patent cancelled. We are defending our patent and seek to defend it as issued.

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

On August 1, 2000, we completed our initial public offering of 3,600,000 common shares at a price of $12.00 per share, raising approximately $39.0 million net of underwriting discounts, commissions and other offering costs. The managing underwriters were Salomon Smith Barney and Robertson Stephens. We intend to use the proceeds of the offering to expand sales, marketing, physician and patient awareness programs, to continue product development and clinical research programs, to repay debt and to fund general corporate purposes including working capital. Additionally, we may use the proceeds of the offering to fund the acquisition of complementary businesses, products or technologies, although there are no current agreements or negotiations with respect to any specific transaction.

As of September 30, 2001, we had applied $31.9 million of the $39.0 million in net proceeds from our offering as follows:

Use	Approximate Dollar Amount (in millions)
Permanent working capital	$ 5.0
Repayment of term loans and other debt	$ 4.6
Sales, marketing, research and clinical programs and general corporate purposes	$22.3
TOTAL:	$31.9

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: ** Exhibit 10.3: 2000 Stock Plan, as amended, and form of option agreement
** Exhibit 10.4: 2000 Director's Stock Option Plan, as amended, and form of option agreement

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

** Supersedes previously filed exhibit.

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, 2001

EXHIBIT INDEX

** Exhibit 10.3: 2000 Stock Plan, as amended, and form of option agreement.
** Exhibit 10.4: 2000 Director's Stock Option Plan, as amended, and form of option agreement

**Supersedes previously filed exhibit.