

RITA MEDICAL SYSTEMS INC
Form 10-Q
November 13, 2003
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2003

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)

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-Q

Delaware
(State or other jurisdiction of
incorporation or organization)

94-3199149
(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 No

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

As of October 31, 2003, there were 17,966,210 shares of the registrant's Common Stock outstanding.

Table of ContentsINDEX

	<u>Page</u>
PART I. FINANCIAL INFORMATION	
Item 1.	Financial Statements (unaudited)
	<u>Condensed Consolidated Balance Sheets September 30, 2003 and December 31, 2002</u>
	3
	<u>Condensed Consolidated Statements of Operations three and nine months ended September 30, 2003 and 2002</u>
	4
	<u>Condensed Consolidated Statements of Cash Flows nine months ended September 30, 2003 and 2002</u>
	5
	<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>
	6
Item 2.	<u>Management's Discussion and Analysis of Financial Conditions and Results of Operations</u>
	9
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
	19
Item 4.	<u>Controls and Procedures</u>
	19
PART II. OTHER INFORMATION	
Item 1.	<u>Legal Proceedings</u>
	20
Item 2.	<u>Changes in Securities and Use of Proceeds</u>
	20
Item 3.	<u>Defaults Upon Senior Securities</u>
	20
Item 4.	<u>Submission of Matters to a Vote of Security Holders</u>
	20
Item 5.	<u>Other Information</u>
	20
Item 6.	<u>Exhibits and Reports on Form 8-K</u>
	20
<u>SIGNATURES</u>	21
<u>EXHIBIT INDEX</u>	22

Table of Contents**PART 1. FINANCIAL INFORMATION****Item 1. Financial Statements****RITA MEDICAL SYSTEMS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(In thousands, unaudited)

	September 30,	December 31,
	2003	2002
	<u> </u>	<u> </u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,327	\$ 6,888
Marketable securities	6,132	5,427
Accounts and note receivable, net	2,565	2,798
Inventories, net	2,392	3,521
Prepaid assets and other current assets	1,097	995
	<u> </u>	<u> </u>
Total current assets	15,513	19,629
Long term marketable securities	1,106	520
Long term note receivable, net	372	381
Property and equipment, net	1,268	1,565
Intangibles and other assets	5,001	2,071
	<u> </u>	<u> </u>
Total assets	\$ 23,260	\$ 24,166
	<u> </u>	<u> </u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 702	\$ 1,053
Accrued liabilities	1,594	2,510
	<u> </u>	<u> </u>
Total liabilities	2,296	3,563
	<u> </u>	<u> </u>
Stockholders' equity		
Common stock	18	15
Additional paid-in capital	97,675	88,525
Stockholder notes receivable		(50)
Accumulated other comprehensive income	3	7
Accumulated deficit	(76,732)	(67,894)
	<u> </u>	<u> </u>
Total stockholders' equity	20,964	20,603
	<u> </u>	<u> </u>

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-Q

Total liabilities and stockholders' equity	\$ 23,260	\$ 24,166
--	-----------	-----------

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

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

(In thousands, except per share data, unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2003	2002	2003	2002
Sales	\$ 3,865	\$ 4,454	\$ 12,412	\$ 13,679
Cost of goods sold	1,253	1,730	4,530	5,773
Gross profit	2,612	2,724	7,882	7,906
Operating expenses:				
Research and development	976	1,218	3,395	3,882
Selling, general and administrative	4,182	4,311	13,482	14,837
Total operating expenses	5,158	5,529	16,877	18,719
Loss from operations	(2,546)	(2,805)	(8,995)	(10,813)
Interest income and other expense, net	32	85	157	368
Net loss	\$ (2,514)	\$ (2,720)	\$ (8,838)	\$ (10,445)
Net loss per share, basic and diluted	\$ (0.14)	\$ (0.18)	\$ (0.50)	\$ (0.70)
Shares used in computing net loss per share, basic and diluted	17,807	14,996	17,538	14,816

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

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

(In thousands, unaudited)

	Nine Months Ended	
	September 30,	
	2003	2002
Cash flows from operating activities:		
Net loss	\$ (8,838)	\$ (10,445)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,228	1,052
Disposal of property and equipment	158	
Revaluation of common stock warrants for services received	(101)	(31)
Amortization of stock-based compensation		308
Allowance for doubtful accounts	56	823
Provision for obsolete inventories	393	517
Changes in operating assets and liabilities:		
Accounts and note receivable	82	(147)
Inventories	736	32
Prepaid and other current assets	(102)	77
Accounts payable and accrued liabilities	(1,267)	195
Net cash used in operating activities	(7,655)	(7,619)
Cash flows from investing activities:		
Purchase of property and equipment	(720)	(614)
Purchase of investments	(7,855)	
Sales and maturities of investments	6,560	10,420
Capitalization of patent litigation costs	(621)	(1,245)
Acquisition of intangibles	(2,650)	
Note receivable and other assets	106	4
Net cash provided by (used in) investing activities	(5,180)	8,565
Cash flows from financing activities:		
Proceeds from issuance of common stock	9,274	1,389
Payments on capital lease obligations		(148)
Net cash provided by financing activities	9,274	1,241
Net increase (decrease) in cash and cash equivalents	(3,561)	2,187
Cash and cash equivalents at beginning of period	6,888	7,297
Cash and cash equivalents at end of period	\$ 3,327	\$ 9,484

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-Q

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

-5-

Table of Contents**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, 2002 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, 2002 contained in the Company's annual report on Form 10-K.

2. Net loss per share

Basic earnings per share figures are calculated based on the weighted-average number of common shares outstanding during the period less the weighted-average number of any common shares subject to repurchase by the Company. Diluted earnings per share further includes the dilutive effect of potentially dilutive securities consisting of stock options and warrants provided that the inclusion of such securities is not antidilutive; the Company has reported net losses and therefore has excluded such potentially dilutive securities from its calculation of diluted earnings per share.

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2003	2002	2003	2002
Weighted average shares of common stock outstanding	17,807	15,027	17,543	14,851
Less: weighted-average shares subject to repurchase		(31)	(5)	(35)
Weighted average shares used in basic and diluted net loss per share	17,807	14,996	17,538	14,816

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-Q

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

	September 30,	
	2003	2002
	—	—
Effect of potentially dilutive securities:		
Unvested common stock subject to repurchase		28
Options	2,307	2,862
Warrants	25	25
	—	—
Total potentially dilutive securities excluded from the computation of net loss per share as their effect was antidilutive	2,332	2,915
	—	—

Table of Contents

3. Balance sheet components Inventories

The components of the Company's inventories at September 30, 2003 and December 31, 2002, respectively, were as follows (in thousands):

	September 30, 2003	December 31, 2002
Raw materials	\$ 853	\$ 1,039
Work-in-process	10	341
Finished goods	1,529	2,141
	<u>\$ 2,392</u>	<u>\$ 3,521</u>

4. Accounting for stock-based compensation

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

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

The following table illustrates the effect on net loss and net loss per share for the three and nine month periods ended September 30, 2003 and 2002, respectively, if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation granted under all of the stock option plans and the Employee Stock Purchase Plan (in thousands, except per share amounts):

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2003	2002	2003	2002
Net loss, as reported	\$ (2,514)	\$ (2,720)	\$ (8,838)	\$ (10,445)
Add: Stock-based employee compensation expense included in reported net loss	(349)	56	(1,436)	338
	<u>(2,863)</u>	<u>(2,664)</u>	<u>(10,274)</u>	<u>(10,107)</u>

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-Q

Deduct: Total stock-based employee compensation determined under fair value based method for all awards

	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Pro-forma net loss	\$ (2,863)	\$ (3,453)	\$ (10,274)	\$ (12,204)
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Basic and diluted net loss per share:				
As reported	\$ (0.14)	\$ (0.18)	\$ (0.50)	\$ (0.70)
Pro-forma	\$ (0.16)	\$ (0.23)	\$ (0.59)	\$ (0.82)

The determination of stock-based employee compensation under the fair value based method used the following weighted average assumptions:

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2003	2002	2003	2002
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Volatility	76%	79%	76%	79%
Risk-free interest rate	3.21%	3.45%	2.74%	3.94%
Expected life	5 years	5 years	5 years	5 years
Expected dividends	0%	0%	0%	0%

Table of Contents

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2003	2002	2003	2002
Volatility	70%	79%	70%	79%
Risk-free interest rate	2.50%	3.16%	2.95%	3.29%
Expected life	1.4 years	0.9 years	1.3 years	0.7 years
Expected dividends	0%	0%	0%	0%

5. Comprehensive loss

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

6. Private placement of securities

In January 2003, the Company issued to SF Capital Partners Ltd., Riverview Group, LLC, Baystar Capital II, L.P., and Baystar International II, L.P., 2,045,453 shares of unregistered common stock at a price of \$4.40 per share, netting approximately \$8.3 million after issuance fees and expenses. Wells Fargo Securities, LLC served as the lead placement agent for the transaction. The issuance was deemed to be exempt from registration under the Securities Act in reliance upon Section 4(2) thereof as transactions by an issuer not involving any public offering. On February 14, 2003, the Company's Registration Statement on Form S-3, which registered the shares of common stock sold to the purchasers in the private placement transaction, was declared effective by the SEC.

7. Intangible assets and related amortization

The Company's intangible assets and related accumulated amortization at September 30, 2003 and December 31, 2002, respectively, were as follows (in thousands):

September 30, 2003		December 31, 2002	
Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-Q

Capitalized patent defense litigation costs	\$ 2,755	\$ (290)	\$ 2,134	\$ (111)
Capitalized patent license agreements	2,650	(160)		
	\$ 5,405	\$ (450)	\$ 2,134	\$ (111)

Aggregate amortization expense for the nine months ended September 30, 2003, and estimated amortization expense for the three months ended December 31, 2003 and each of the five years ended December 31, 2004 through 2008 is as follows (in thousands):

Aggregate amortization expense:

For the nine months ended September 30, 2003 \$ 339

Estimated amortization expense:

For the three months ended December 31, 2003 \$ 141
 For the twelve months ended December 31, 2004 \$ 563
 For the twelve months ended December 31, 2005 \$ 563
 For the twelve months ended December 31, 2006 \$ 563
 For the twelve months ended December 31, 2007 \$ 563
 For the twelve months ended December 31, 2008 \$ 563

8. Recent accounting pronouncements

In November 2002, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. Adoption of this statement has had no material impact on the Company's financial position or results of operations.

Table of Contents

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations and other parts of this quarterly report on Form 10-Q contain forward-looking statements that involve risks and uncertainties. Words such as "anticipates", "expects", "intends", "plans", "believes", "estimates", and similar expressions identify such forward-looking statements. These statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or forecasted. Factors that might cause such a difference include, but are not limited to, those discussed in the section entitled "Factors That May Affect Future Results" and those appearing elsewhere in this quarterly report on Form 10-Q and in our annual report on Form 10-K for the fiscal year ended December 31, 2002. Readers are cautioned not to place undue reliance on these forward-looking statements that reflect management's analysis only as of the date hereof. We assume no obligation to update these forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements.

Overview

We develop, manufacture and market minimally invasive products that use radiofrequency energy to treat patients with solid cancerous or benign tumors. In 2001, we commercially launched our StarBurst XLI family of disposable devices and expanded our direct domestic sales organization and our international distribution network. In 2002, the XLI family of disposable devices gained acceptance in the United States. Also in 2002, we received regulatory approval from the FDA to use our products to treat pain associated with bone tumors, increasing the potential market for our products.

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, 2003, sales in the United States accounted for 86% of our total sales, compared to 77% in the prior year period, while sales in our international markets accounted for 14% of our total sales compared to 23% in the prior year period. We continue to expect domestic sales to account for the majority of total sales in future periods. Also, we expect that inventory reductions, particularly by our distributor in Japan, coupled with ongoing reimbursement issues in both Japan and Europe, to limit sales growth in these regions for at least the remainder of 2003. We believe that over the next several years, as reimbursement issues are resolved and customer inventories are reduced, growth in international markets should resume. We expect our international operations to continue to represent a material portion of our revenue 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, 2003, 91% of our sales were derived from our disposable devices and 9% were derived from the sale of our generators. Disposable product revenue for the quarter was flat compared to the prior year period reflecting reduced sales to international customers offset by higher average selling prices for disposable products in our domestic market. Generator revenue decreased by 62% compared to the third quarter of 2002, as the prior year period included large generator shipments to our Japanese distributor. Going forward, 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, we expect revenue from the sale of our higher-margin disposable devices to grow faster than revenue from the sale of our generators.

To date, essentially all of our revenue has come from products sold in the treatment of cancerous liver tumors. In 2002, however, we began to see nominal revenue from the use of the RITA system sold for the treatment of patients with metastatic bone tumors. We are conducting research and clinical trials in other organs that may lead to additional sources of revenue in future years, although there can be no assurances that such additional revenue will materialize.

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-Q

Our manufacturing costs consist of raw materials, including generators and ancillary hardware components produced for us by third-party suppliers, labor to produce our disposable devices and to inspect incoming, in-process and finished goods, sterilization performed by an outside service provider and general overhead expenses. 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 distributor discounts. Our gross margin for the three months ended September 30, 2003 was 68%, compared to a 61% margin rate in the prior year period, and compared to a 58% margin rate in the three months ended June 30, 2003. This margin improvement reflects the impact of the growing percentages of higher-margin domestic and disposable products in our sales mix. Improvement compared to the three months ended June 30, 2003 is also partially due to the end of temporary cost increases on vendor-sourced hardware that constrained margins during that period. However, margins in the current three-month period were limited by \$0.1 million in amortization of capitalized license fees associated with the settlement of our patent litigation dispute with Boston Scientific Corporation, described below. We expect such amortization charges to continue through 2015. Charges to cost of goods sold during the three months ended September 30, 2003 also included \$0.1 million in provision to our reserve for obsolete inventory, compared to only a very modest expense in the prior year period and a \$0.2 million expense in the three months ended June 30, 2003. We have, from time to time, recognized relatively high expenses related to obsolete inventory provisions as our product line has undergone several changes, and we may experience pressure on margins in the future due to similar product changes. Despite this possibility, we generally expect stable gross margins over the balance of 2003, reflecting a relatively constant sales mix and stable manufacturing costs, with no immediate expectation of significant additional provisions to our reserve for obsolete inventory.

Table of Contents

Our operating expenses consist of product development costs, clinical trial expenses, patent litigation expenses, sales and marketing expense related to our selling efforts in the United States and Europe, and administrative expenses, including the costs associated with our status as a public company, professional service expenses and our provisions for uncollectible accounts. Growth in these areas is determined by the breadth of our new product development portfolio, the number of headcount we maintain in our selling and administrative functions, the scope of our marketing efforts, the costs we incur in defense of our patents and intellectual property and the extent to which credit issues and economic conditions constrain our ability to collect our receivables. For the three months ended September 30, 2003, \$1.0 million of our operating expenses were related to research and development activities, including \$0.2 million associated with patent litigation expenses. For the prior year period, we had \$1.2 million in research and development expense, including \$0.2 million for litigation costs, so expenses for product development and clinical trials were lower for the three months ended September 30, 2003 than such expenses for the same period last year. We expect expenses for product development and clinical trials to remain stable for the remainder of 2003. We believe that ongoing legal expenses associated with patent litigation should be similar to 2003 third quarter results. Total selling, general and administrative costs for the three months ended September 30, 2003, were \$4.2 million compared with \$4.3 million in the prior year period. This reduction reflects \$0.2 million in reduced expenses associated with provisions to our allowance for uncollectible accounts, with no additional charges in the current period. Although the deterioration we experienced in international collections in 2002 has stabilized in 2003, we may encounter new difficulties with international collections that require further increases in our allowance for uncollectible accounts in the future, and we may require specific accounts to post letters of credit or pay in advance to minimize credit risk to the Company. Selling expenses for the current quarter were also \$0.2 million lower, on lower headcount. However, recruiting and compensation expenses related to additions to our management team were \$0.3 million higher during the three months ended September 20, 2003 than during the prior year period. We expect flat or modestly reduced levels of selling, general and administrative expense for the remainder of 2003.

From 1999 until April 2003, we were involved in patent related disputes before the United States Patent and Trademark Office, the European Patent Office and several patent infringement suits filed in the United States District Court for the Northern District of California. The principal parties in these matters were ourselves, Boston Scientific Corporation, two of its operating divisions and two of its licensors. In April 2003, we signed a definitive agreement with Boston Scientific, its affiliates and its licensors to settle all outstanding patent disputes. Under the terms of the agreement, litigation in the United States, including Boston Scientific's appeal of a United States Patent and Trademark Office ruling, has been dismissed with prejudice and Boston Scientific has withdrawn its opposition before the European Patent Office. We made one-time payments of \$1,325,000 to the University of Kansas and \$1,325,000 to the University of Nebraska, the licensors of several of the disputed patents. These amounts were capitalized in April 2003 and are being amortized over the related assets' useful lives, which range from six to twelve years. The agreement includes a series of licenses and sub-licenses, none of which include our proprietary temperature control technology. We agreed to license to Boston Scientific, on a royalty-bearing basis, our infusion technology for future products. However, Boston Scientific will not market or sell products utilizing licensed infusion technology before October 5, 2004.

Our working capital decreased to \$13.2 million at September 30, 2003, from \$16.1 million at December 31, 2002. Since December 31, 2002, we have used \$7.7 million in cash for operations, \$0.7 million in capital expenditures and \$0.6 million in capitalized legal costs related to defense of our patent rights. We also paid \$2.65 million for licenses acquired in settlement of our patent litigation disputes with Boston Scientific Corporation. Offsetting these amounts were cash inflows of approximately \$9.3 million from financing activities. Our January 2003 issuance of 2,045,453 shares of unregistered common stock at \$4.40 per share netted approximately \$8.3 million after associated fees and expenses, and the balance of the cash inflows from financing resulted from exercise of stock options. We do not expect significantly increased capital expenditures for the remainder of 2003.

We incurred net losses of \$2.5 million for the three months ended September 30, 2003. As of September 30, 2003, we had an accumulated deficit of \$76.7 million. Due to the costs associated with continued research and development programs, clinical research programs and sales and marketing efforts, we expect to continue to incur net losses for the balance of 2003 and 2004. Profitability depends 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.

Table of Contents**Critical Accounting Policies and Estimates**

Our critical accounting policies and estimates were discussed in our annual report on Form 10-K for the fiscal year ended December 31, 2002. No changes in these policies and estimates have occurred during the nine months ended September 30, 2003.

Results of Operations

The following table sets forth the percentage of net revenue represented by certain items in our Condensed Consolidated Statements of Operations for the current quarter ended September 30, 2003 and the four preceding fiscal quarters:

	<u>Q3 2003</u>	<u>Q2 2003</u>	<u>Q1 2003</u>	<u>Q4 2002</u>	<u>Q3 2002</u>
Domestic sales	86%	81%	71%	76%	77%
International sales	14%	19%	29%	24%	23%
Total sales	100%	100%	100%	100%	100%
Cost of goods sold	32%	42%	35%	31%	39%
Gross profit	68%	58%	65%	69%	61%
Operating expenses:					
Research and development	25%	26%	30%	32%	27%
Selling, general and administrative	109%	117%	102%	122%	97%
Total operating expenses	134%	143%	132%	154%	124%
Loss from operations	(66)%	(85)%	(67)%	(85)%	(63)%
Interest income and other expense, net	1%	1%	2%	3%	2%
Net loss	(65)%	(84)%	(65)%	(82)%	(61)%

Three months ended September 30, 2003 and 2002

Sales decreased 13% to \$3.9 million for the quarter ended September 30, 2003, down from \$4.5 million for the quarter ended September 30, 2002. Domestic sales decreased by 3% and international sales, principally due to large generator shipments to our distributor in Japan in the prior year period, decreased by 46% from the three months ended September 30, 2002. Sales of our disposable products totaled \$3.5 million for the quarter, equal to the comparable prior year period, reflecting higher average selling prices in the domestic market, as unit shipments of disposable products decreased 18%. Generator sales for the quarter were 62% lower than sales in the third quarter of 2002, due again to the large generator shipments to our distributor in Japan in the prior year period.

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-Q

Cost of goods sold for the quarter ended September 30, 2003 was \$1.3 million, resulting in a gross margin rate of 68% for the period. This compares to cost of goods sold of \$1.7 million for the quarter ended September 30, 2002, and a gross margin rate of 61% for that period. This improvement was primarily due to higher percentages of relatively high-margin domestic and disposable sales in our current period sales compared to prior period sales. However, margins in the current period were limited by \$0.1 million in amortization of capitalized license fees associated with the settlement of our patent litigation dispute with Boston Scientific Corporation. We expect such amortization charges to continue through 2015. Charges to cost during the three months ended September 30, 2003 also included \$0.1 million in provision to our reserve for obsolete inventory, compared to only a very modest provision in the prior year period. We have, from time to time, recognized relatively high expenses related to obsolete inventory provisions as our product line has undergone several changes, and we may experience pressure on margins in the future due to similar product changes. Despite this possibility, we generally expect stable gross margins over the balance of 2003, reflecting a relatively constant sales mix and stable manufacturing costs, with no immediate expectation of significant additional provisions to our reserve for obsolete inventory.

For the three months ended September 30, 2003, \$1.0 million of our operating expenses were related to research and development activities, compared to \$1.2 million in the three months ended September 30, 2002, primarily because of reduced expenses for product development and clinical trials. We expect expenses for product development and clinical trials to remain stable for the remainder of 2003.

Table of Contents

Total selling, general and administrative costs for the three months ended September 30, 2003, were \$4.2 million compared with \$4.3 million in the prior year period. Selling expenses for the current quarter were \$0.2 million lower, reflecting organizational changes made during 2003 in our domestic sales group, including headcount reductions. Also, we made no additional provisions to our allowance for uncollectible accounts, compared to \$0.2 million in the prior year period, but recruiting and compensation expenses related to additions to our management team offset this savings. Although the deterioration we experienced in international collections in 2002 has stabilized in 2003, we may encounter new difficulties with international collections that require further increases in our allowance for uncollectible accounts in the future, and we may require specific accounts to post letters of credit or pay in advance to minimize credit risk to the Company. We expect stable or modestly reduced levels of selling, general and administrative expense for the remainder of 2003.

Interest income, net of interest and other expenses, was \$32,000 for the quarter ended September 30, 2003, down from \$85,000 in the corresponding period of 2002. 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.

Nine months ended September 30, 2003 and 2002

Sales decreased 9% to \$12.4 million for the nine months ended September 30, 2003, down from \$13.7 million for the nine months ended September 30, 2002. For the nine months ended September 30, 2003, domestic sales decreased by 3% and international sales, due to large generator shipments to our distributor in Japan in the prior year period, decreased by 27% from the nine months ended September 30, 2002. Sales of our disposable products totaled \$11.0 million for the year to date period, an increase of 8% over the prior year. This increase reflects higher average selling prices in the domestic market and higher shipments of disposable products to our international distributors. Unit shipments of disposable products in the domestic market decreased 4%. Generator sales for the nine months ended September 30, 2003 were 59% lower than sales in the same period last year, due again to the large generator shipments to our distributor in Japan in the prior year period.

Cost of goods sold for the nine months ended September 30, 2003 was \$4.5 million compared to \$5.8 million for the nine months ended September 30, 2002, resulting in a 64% margin rate for the current year to date period, compared with a 58% rate in the comparable prior year period. This improvement was primarily due to higher percentages of domestic and disposable sales in our current period sales mix compared to prior period sales. However, in the current nine-month period, these trends were partially offset by \$0.2 million in amortization of capitalized license fees associated with the settlement of our patent litigation dispute with Boston Scientific Corporation. We expect such amortization charges to continue through 2015. Also, margins were limited by temporary cost increases, effective through June 2003, on some of our vendor-sourced hardware products. For the nine months ended September 30, 2003, cost of goods sold also included \$0.4 million in provision for obsolete inventory, compared with \$0.5 million in the comparable prior period. We have, from time to time, recognized relatively high expenses related to obsolete inventory provisions as our product line has undergone several changes, and we may experience pressure on margins in the future due to similar product changes. Despite this possibility, we generally expect stable gross margins over the balance of 2003, reflecting a relatively constant sales mix and stable manufacturing costs, with no immediate expectation of significant additional provisions to our reserve for obsolete inventory.

For the nine months ended September 30, 2003, \$3.4 million of our operating expenses were related to research and development activities, compared to \$3.9 million in the nine months ended September 30, 2002, primarily because of reduced expenses for product development and clinical trials. We expect expenses for product development and clinical trials to remain stable for the remainder of 2003.

Total selling, general and administrative costs for the nine months ended September 30, 2003, were \$13.5 million compared with \$14.8 million in the prior year period. Selling expenses for the current period were \$0.5 million lower, on lower headcount, reflecting recent organizational changes in our domestic sales group. Also, we have made essentially no additional provisions to our allowance for uncollectible accounts during the nine months ended September 30, 2003, compared to \$0.8 million in the prior year period. Although the deterioration we experienced in

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-Q

international collections in 2002 has stabilized in 2003, we may encounter new difficulties with collections that require further increases in our allowance for uncollectible accounts in the future, and we may require specific accounts to post letters of credit or pay in advance to minimize credit risk to the Company. We expect stable or modestly reduced levels of selling, general and administrative expense for the remainder of 2003.

Interest income, net of interest expense and other expenses, was \$157,000 for the nine months ended September 30, 2003, down from \$368,000 in the corresponding period of 2002. 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.

Table of Contents**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. In January 2003, we completed a private placement of 2,045,453 common shares at a price of \$4.40 per share, raising approximately \$8.3 million net of expenses. As of September 30, 2003, we had \$3.3 million of cash and cash equivalents, \$7.2 million of short and long-term marketable securities and \$13.2 million of working capital.

For the nine months ended September 30, 2003, net cash used in operating activities was \$7.7 million principally due to our net loss of \$8.8 million offset by non-cash charges, including depreciation, amortization and provisions to reserves for uncollectible accounts and inventory, of \$1.7 million. Approximately \$0.6 million in cash was used by changes in working capital accounts, principally a \$1.3 million reduction in accounts payable and accrued liabilities. Our investing activities for the nine months ended September 30, 2003, were limited to the purchase of property and equipment in the amount of \$0.7 million, capitalization of certain patent defense litigation costs in the amount of \$0.6 million, and capitalization of intangibles associated with settlement of our patent litigation in the amount of \$2.65 million. During the nine months ended September 30, 2003, we invested, net of sales and maturities, approximately \$1.3 million in short and long-term marketable debt securities. Financing activities for the nine months ended September 30, 2003, provided \$9.3 million in cash, all related to issuance of common shares through our January private placement or exercise of stock options.

As of September 30, 2003, future minimum payments due under operating leases were as follows (in thousands):

2003	\$ 133
2004	356
	<hr/>
Total of future minimum operating lease payments	\$ 489
	<hr/>

Our capital requirements depend on numerous factors including our sales, research and development expenditures, expenses related to selling, general and administrative operations and working capital to support business growth. Our net cash used in operating activities was \$7.7 million for the nine months ended September 30, 2003, an average of approximately \$0.9 million per month, and recently implemented expense reduction programs reduced that rate during the current quarter. Although it is difficult for us to predict future liquidity requirements with certainty, we believe that our reduced rate of cash used in operating activities means our current balances of cash, cash equivalents and marketable securities will satisfy our cash requirements for approximately 18 months. During or after this period, if cash generated by operations is insufficient to satisfy our cash requirements, we may need to sell additional equity or debt securities or obtain an additional credit facility. There can be no assurance that additional financing will be available to us or, if available, that such financing will be available on terms favorable to the Company and our stockholders.

Recent Accounting Pronouncements

In November 2002, the EITF reached a consensus on Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. Adoption of this statement has had no material impact on the Company's financial position or results of operations.

Factors That May Affect Future Results

In addition to the other information in this quarterly report on Form 10-Q and in our annual report on form 10-K for the fiscal year ended December 31, 2002, the following factors should be considered carefully in evaluating our 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 have a history of losses and may never achieve profitability.

Although operating expenses during the quarter ended September 30, 2003 were lower than in the two preceding quarters, and although we believe that our quarterly operating expenses will stabilize at or below this level for the remainder of 2003 and throughout 2004, to become profitable we must increase our sales and continue to manage our operating expenses. If our sales do not grow, we may not be able to achieve or maintain profitability in the future. In particular, we incurred net losses of \$8.8 million in the nine months ended September 30, 2003, \$13.5 million in 2002, \$13.0 million in 2001, \$12.8 million in 2000 and \$7.5 million in 1999. At September 30, 2003, we had an accumulated deficit of approximately \$76.7 million.

Table of Contents

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

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

We compete directly with two companies in the domestic and international markets: RadioTherapeutics Corporation, a division of Boston Scientific Corporation, and Radionics, Inc., a division of Tyco Healthcare, which is a division of Tyco International. Boston Scientific Corporation and Tyco International are publicly traded companies with substantially greater resources than we have. Both RadioTherapeutics and Radionics sell products that use radiofrequency energy to ablate soft tissue. Furthermore, in April 2003, we entered into a license agreement with Boston Scientific, its affiliates and licensors, pursuant to which we granted Boston Scientific rights to manufacture and sell products using our infusion technology after October 5, 2004. As a result, Boston Scientific may develop and sell some competing products that would, in the absence of this license agreement, infringe our patents.

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

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 perceived to be 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.

Our products are supported by clinical follow-up data in published clinical reports or scientific presentations covering periods from five months to five years after radiofrequency ablation. If additional studies in liver cancer or in other applications fail to confirm or demonstrate the effectiveness of our products, our sales could decline. If longer-term patient follow-up or clinical studies indicate that our procedures cause unexpected, serious complications or other unforeseen negative effects, we could be subject to significant liability. Further, because some of our data has been produced in studies that were retrospective, not randomized or included small patient populations and because, in certain circumstances, we rely on clinical data developed by independent third party physicians, our clinical data may not be reproduced in wider patient populations.

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

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-Q

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

In the event a competitor infringes on our patent or other intellectual property rights, enforcing those rights may be difficult and time consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time consuming and could divert management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against a challenge. In addition, confidentiality agreements executed by our employees, consultants and advisors may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure. If we are unable to protect our intellectual property rights we could lose market share to our competitors and our business could suffer.

Table of Contents

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 increase product sales in international markets, we are exposed to risks specific to business operations outside the United States. These risks include:

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

the risk of inventory build-up by our distributors which could negatively impact sales in future periods (for example, our distributor in Japan has built up a significant inventory of product in anticipation of the receipt of product and reimbursement approvals);

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 its product demand, our international and total revenues could decline.

We are substantially dependent on a limited number of significant distributors in our international markets, and if we lose these distributors and fail to attract additional distributors, our international revenues could decline. ITX Corporation, formerly known as Nissho Iwai Corporation, is our primary distributor in Asia. It accounted for 24% of our international revenues in the nine months ended September 30, 2003 and 55% of our international revenues in 2002. M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, accounted for 24% of our international revenues in the nine months ended September 30, 2003 and 17% of our international revenues for 2002. Because international revenues accounted for 21% of our total revenues for the nine months ended September 30, 2003 and these two distributors represented 48% of that total, the loss of either distributor or a significant decrease in unit purchases by either distributor could cause our revenues to decline substantially. If we are unable to attract additional international distributors, our international revenues may not grow.

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

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-Q

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

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

In 2002, we significantly increased our allowance for uncollectible accounts to address the risk associated with longer collection periods that have arisen principally with our European distributors. Although the deterioration we experienced in international collections in 2002 has stabilized in 2003, we may encounter new difficulties with collections that require further increases in our allowance for uncollectible accounts in the future, and we may require specific accounts to post letters of credit or pay in advance to minimize credit risk to the Company. Additional future increases in our allowance for uncollectible accounts would reduce our profits.

Table of Contents

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 Corporation, 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 in foreign markets 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 coverage or adequate reimbursement for the cost of procedures using our products from third-party payors, such as Medicare, Medicaid and private health insurance plans. If physicians believe that using our system will add cost to a procedure but will not add sufficient offsetting economic or clinical benefits, physician adoption of our products could be delayed. Even though in February 2002 we were successful in establishing a new liver CPT code assigned by the American Medical Association, some third-party payors still may not cover or reimburse adequately for procedure using our products. We are aware of liver procedures using our system where the patient's insurance has denied coverage. In addition, there are no assigned CPT codes for radiofrequency ablation of tumors in other organs. Further, we believe the advent of the Medicare fixed payment schedules has made it difficult to receive adequate liver reimbursement for procedures using our products in the outpatient setting. Medicare reimbursement levels for procedures using our products are highest when our products are used in an in-patient setting. If there is a trend toward the use of our products on an outpatient basis or if coverage continues to be denied or reimbursement levels continue to be inadequate, physician use of our products could decline which would cause our revenues to decline.

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

We are highly dependent on the principal members of our management team, including our Chief Executive Officer and Chief Financial Officer, as well as key staff in the areas of finance, operations and research and development. Our future success will depend in part on the continued service of our staff and our ability to identify, hire and retain additional personnel. The market for qualified management personnel in Northern California, where our offices are located, is competitive and is expected to remain so. Because the environment for good personnel is so competitive, costs related to compensation may increase significantly. If we are unable to attract and retain both the management team and key personnel we need to support and grow our business, our business will suffer.

We may be subject to costly and time-consuming product liability actions.

We manufacture medical devices that are used on patients in both minimally invasive and open surgical procedures and, as a result, we may be subject to product liability lawsuits. To date, we have not been subject to a product liability claim; however, any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, we could have to pay any amount awarded by a court in excess of policy limits. Finally, even a meritless or unsuccessful product liability claim could be time consuming and expensive to defend and could result in the diversion of management's attention from

managing our core business.

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

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

Table of Contents

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 or our 2003 private placement transaction;

our ability to successfully commercialize our products;

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

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.

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

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

our products, our business could suffer.

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

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

We are dependent on two suppliers as our only sources 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.

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

Table of Contents

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 requirements. For example, some of our newer products have not received approval in Japan. Any failure to obtain necessary regulatory approvals for our new products in foreign countries could negatively affect revenues.

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

Unless we are exempt, we must obtain the appropriate FDA approval or clearance before we can sell a new medical device in the United States. Obtaining this approval or clearance can be a lengthy and time-consuming process. To date, all of our products have received clearances from the FDA through premarket notification under Section 510(k) of the Federal Food, Drug and Cosmetic Act. However, if the FDA requires us to submit a new premarket notification under Section 510(k) for modifications to our existing products, or if the FDA requires us to go through a lengthier, more rigorous examination than we now expect, our product introductions or modifications could be delayed or canceled which could cause our revenues to be below expectations. The FDA may determine that future products will require the more costly, lengthy and uncertain premarket approval process. In addition, modifications to medical device products cleared via the 510(k) process may require a new 510(k) submission. We have made minor modifications to our system. Using the guidelines established by the FDA, we have determined that some of these modifications do not require us to file new 510(k) submissions. If the FDA disagrees with our determinations, we may not be able to sell the RITA system until the FDA has cleared new 510(k) submissions for these modifications, or it may require us to recall previously sold products. In addition, we intend to request additional label indications, such as approvals or clearances for the ablation of tumors in additional organs, including lung, uterus and breast, for our current products. The FDA may either deny these requests outright, require additional extensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of approval or clearance. Therefore, obtaining necessary approvals or clearances for these additional applications could be an expensive and lengthy process. In addition, in the course of the FDA process leading to clearance or approval for a new indication, FDA may request an advisory panel meeting or meetings to discuss the clinical data, the appropriate study design or other criteria for clearance or approval. In the event that the advisory panel advises FDA that the clinical data are inadequate or the study design or other criteria are inappropriate, and FDA concurs, the FDA clearance or approval process could be lengthened and anticipated revenues from that new indication would be delayed.

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 10 percent of our outstanding common stock as of September 30, 2003, these stockholders may, as a practical matter, be able to exert significant influence over matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. This concentration of voting stock could have the effect of delaying or preventing a merger or acquisition or other change of control that a stockholder may consider favorable.

Table of Contents

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 or other change of control 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 for the year ended December 31, 2002, filed on March 28, 2003.

Item 4. Controls and Procedures

Within 90 days prior to the date of this report on Form 10-Q, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's principal executive officer and principal financial officer, of the effectiveness of the Company's disclosure controls and procedures, as defined in Rules 13a-14(c) and 15d-14(c) of the Securities Exchange Act of 1934. Based upon that evaluation, the principal executive officer and principal financial officer has concluded that the Company's disclosure controls and procedures are effective. The Company's disclosure controls and procedures are designed to provide a reasonable level of assurance of reaching its desired disclosure control objectives and are effective in doing so.

There were no significant changes in the Company's internal controls over financial reporting or in other factors that could significantly affect these internal controls subsequent to the date of their evaluation.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

From 1999 through March, 2003, the Company was involved in patent-related disputes that were settled in April 2003, and are more fully described in our report on Form 10-K filed on March 28, 2003, our report on Form 10-Q filed on May 15, 2003, and our report on Form 10-Q filed on August 13, 2003.

The Company may, from time to time, become a party to legal proceedings arising in the ordinary course of business. Such matters generally 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 such future litigation or other legal proceedings and no amounts have been provided for such matters in the accompanying unaudited condensed consolidated financial statements.

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:

- #10.37 Amended and Restated Consulting Agreement with Randy Lindholm dated August 5, 2003.
- #10.38 Form of Indemnification Agreement between the Company and Joseph DeVivo dated August 18, 2003, Wes Johnson dated August 5, 2003 and Stephen Pedroff dated September 2, 2003.
- #10.39 Form of Change of Control Agreement entered into between the Company and Joseph DeVivo dated August 18, 2003 and Stephen Pedroff dated September 2, 2003.
- #10.40 Offer letter between the Company and Joseph DeVivo dated July 23, 2003.
- #10.41 Offer letter between the Company and Stephen Pedroff dated August 22, 2003.

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-Q

- 31.1 Rule 13a-14(a) Section 302 Certification.
- 31.2 Rule 13a-14(a) Section 302 Certification.
- 32.1 Certification pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Management contract or compensatory plan or arrangement.

(b) Reports on Form 8-K:

A report on Form 8-K was filed with the SEC on July 7, 2003.
A report on Form 8-K was filed with the SEC on July 22, 2003.
A report on Form 8-K was filed with the SEC on July 31, 2003.
A report on Form 8-K was filed with the SEC on August 19, 2003.
A report on Form 8-K was filed with the SEC on September 10, 2003.
A report on Form 8-K was filed with the SEC on October 7, 2003.
A report on Form 8-K was filed with the SEC on October 23, 2003.
A report on Form 8-K was filed with the SEC on November 5, 2003.
A report on Form 8-K was filed with the SEC on November 13, 2003.

-20-

Table of Contents

EXHIBIT INDEX

- #10.37 Amended and Restated Consulting Agreement with Randy Lindholm dated August 5, 2003.
- #10.38 Form of Indemnification Agreement between the Company and Joseph DeVivo dated August 18, 2003, Wes Johnson dated August 5, 2003 and Stephen Pedroff dated September 2, 2003.
- #10.39 Form of Change of Control Agreement entered into between the Company and Joseph DeVivo dated August 18, 2003 and Stephen Pedroff dated September 2, 2003.
- #10.40 Offer letter between the Company and Joseph DeVivo dated July 23, 2003.
- #10.41 Offer letter between the Company and Stephen Pedroff dated August 22, 2003.
 - 31.1 Rule 13a-14(a) Section 302 Certification.
 - 31.2 Rule 13a-14(a) Section 302 Certification.
 - 32.1 Certification pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
 - 32.2 Certification pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Management contract or compensatory plan or arrangement.