RITA MEDICAL SYSTEMS INC
Form 10-Q
May 15, 2002
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2002

OR

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

For the transition period from _____ to _____

Commission file number 000-30959

RITA MEDICAL SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

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

967 N. Shoreline Blvd.
Mountain View, CA 94043
(Address of principal executive offices, including zip code)

650-314-3400
(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ¨

As of April 30, 2002, there were 14,752,337 shares of the registrant s Common Stock outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

RITA MEDICAL SYSTEMS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share amounts, unaudited)

	March 31, 2002	December 31, 2001
Assets		
Current assets:		
Cash and cash equivalents	$ 5,494	$ 7,297
Marketable securities	13,939	11,887
Accounts receivable, net of allowance for doubtful accounts of $729 at March 31, 2002 and $629 at December 31, 2001	5,362	5,056
Inventories, net	3,622	3,645
Prepaid assets and other current assets	729	1,282
Total current assets	29,146	29,167
Long term securities		4,353
Property and equipment, net	2,012	1,934
Intangibles and other assets	665	380
Total assets	$ 31,823	$ 35,834
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 668	$ 822
Accrued liabilities	2,258	2,675
Current portion of capital lease obligations	120	192
Total liabilities	3,046	3,689
Contingencies (Note 5)		
Stockholders equity		
Common stock, $0.001 par value	15	15
Additional paid-in capital	88,604	88,459
Deferred stock compensation	(1,383)	(1,905)
Receivable from stockholders	(63)	(99)
Accumulated other comprehensive income (loss)	(8)	70
Accumulated deficit	(58,388)	(54,395)
Total stockholders equity	28,777	32,145
Total liabilities and stockholders equity	$ 31,823	$ 35,834

See accompanying notes

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RITA MEDICAL SYSTEMS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data, unaudited)

	Three Months Ended March 31,	
	2002	**2001**
Sales	$ 4,418	$ 3,304
Cost of goods sold	2,003	1,769
Gross profit	2,415	1,535
Operating expenses		
Research and development	1,335	1,466
Selling, general and administrative	5,222	3,747
Total operating expenses	6,557	5,213
Loss from operations	(4,142)	(3,678)
Interest income and other expense, net	149	556
Net loss	$ (3,993)	$ (3,122)
Net loss per share, basic and diluted	$ (0.27)	$ (0.22)
Shares used in computing basic and diluted net loss per share	14,614	14,167

See accompanying notes

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RITA MEDICAL SYSTEMS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands, unaudited)

	Three Months Ended March 31,	
	2002	**2001**
Operating activities:		
Net loss	$ (3,993)	$ (3,122)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	375	244
Stock-based compensation	221	496
Allowance for doubtful accounts	100	9
Allowance for inventory reserve	87	242
Changes in operating assets and liabilities		
Accounts receivable	(406)	(804)
Inventory	(64)	(283)
Prepaid and other current assets	554	80
Accounts payable and accrued liabilities	(571)	105
Net cash used in operating activities	(3,697)	(3,033)
Cash flows from investing activities:		
Purchase of property and equipment	(405)	(207)
Purchases of short term investments		(5,243)
Maturities of investments	2,222	15,901
Capitalization of patent litigation costs	(297)	
Other assets	1	1
Net cash provided by investing activities	1,521	10,452
Cash flows from financing activities:		
Proceeds from issuance of common stock	446	396
Proceeds from revolving term loan		22
Payments on revolving term loan		(500)
Payments on capital lease obligations	(73)	(67)
Net cash provided by (used in) financing activities	373	(149)
Net increase (decrease) in cash and cash equivalents	(1,803)	7,270
Cash and cash equivalents at beginning of period	7,297	12,676
Cash and cash equivalents at end of period	$ 5,494	$ 19,946

See accompanying notes

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RITA MEDICAL SYSTEMS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared by RITA Medical Systems, Inc. (the Company) in accordance with accounting principles generally accepted in the United States of America for interim financial information. These principles are consistent in all material respects with those applied in the Company s financial statements contained in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2001 and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X promulgated by the Securities and Exchange Commission. However, interim financial statements do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all adjustments (all of which are normal and recurring in nature, including the elimination of intercompany accounts) necessary to present fairly the financial position, results of operations and cash flows of the Company for the periods indicated. Interim results of operations are not necessarily indicative of the results to be expected for the full year or any other interim periods. These unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and footnotes thereto for the year ended December 31, 2001 contained in the Company s annual report on Form 10-K.

2. Net loss per share

Basic earnings (loss) per share figures are calculated based on the weighted-average number of common shares outstanding during the period. Diluted earnings (loss) per share figures include the dilutive effect of common stock equivalents consisting of stock options, warrants and shares subject to repurchase, provided that the inclusion of such common stock equivalents is not antidilutive. For the three-month periods ended March 31, 2002 and March 31, 2001, the Company has excluded the following period end potentially dilutive securities (in thousands) from earnings per share computations because their inclusion would have the effect of reducing our loss per share:

	Three months ended March 31,	
	2002	**2001**
Options and warrants	2,821	2,313
Common shares subject to repurchase	37	74
	2,858	2,387

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

	Three months ended March 31,	
	2002	**2001**
Weighted average shares of common stock outstanding	14,651	14,241
Less: weighted-average shares subject to repurchase	37	74
Weighted average shares used in basic and diluted net loss per share	14,614	14,167

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3. Balance sheet components Inventories (in thousands)

	March 31, 2002	December 31, 2001
Raw materials	$ 1,168	$ 1,017
Work-in-process	362	377
Finished goods	2,092	2,251
	$ 3,622	$ 3,645

4. Recent Accounting Pronouncements

In July 2001, the Financial Accounting and Standards Board (FASB) issued Statements of Financial Accounting Standards No. 141 (SFAS 141), Business Combinations, and No. 142 (SFAS 142), Goodwill and Other Intangible Assets. SFAS 141 requires that all business combinations initiated after June 20, 2001 be accounted for under the purchase method. Use of the pooling-of-interests method is no longer permitted. The adoption of this standard has had no impact on the Company s financial statements. SFAS 142 requires that goodwill no longer be amortized to earnings, but instead be reviewed for impairment upon initial adoption of the Statement and on an annual basis going forward. The amortization of goodwill will cease upon adoption of SFAS 142. The provisions of SFAS 142 are effective for fiscal years beginning after December 15, 2001. The Company was required to adopt SFAS 142 in the first quarter of 2002. The adoption of this standard has had no impact on the Company s financial statements.

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. The adoption of SFAS No. 144 has had no impact on the Company s financial position and results of operations.

In May 2000, the Emerging Issues Task Force (EITF) issued EITF Issue No. 00-14, Accounting for Certain Sales Incentives, addressing the recognition, measurement and income statement classification of sales incentives that a vendor voluntarily offers to its customers, without charge, and which customers may then use in, or exercise as a result of, a single exchange transaction. Sales incentives falling within the scope of EITF Issue No. 00-14 include offers that customers may use to receive a reduction in the price of products or services at the point of sale. In June 2001, the EITF issued EITF Issue No. 00-25, Vendor Income Statement Characterization of Consideration Paid to a Reseller of the Vendor s Products, addressing whether consideration from a vendor to a reseller is (a) an adjustment to the selling prices of the vendor s products and therefore a deduction from revenue when recognized in the vendor s statement of operations or (b) a cost incurred by the vendor for assets or services received from the reseller and therefore a cost or expense when recognized in the vendor s statement of operations. In September 2001, the EITF issued Issue No. 01-09, Accounting for Consideration Given by a Vendor to a Customer or a Reseller of the Vendor s Products, which is a codification of EITF Issues No. 00-14, No. 00-25 and also No. 00-22, Accounting for Points and Certain Other Time or Volume-Based Sales Incentive Offers and Offers for Free Products or Services to be Delivered in the Future. The requirements of EITF Issue No. 01-09, as with the preceding Issues No. 00-14, No. 00-22 and No. 00-25, became effective for annual or interim financial statements dated after December 15, 2001, and include a requirement to reclassify the financial statements of prior periods as necessary to conform with current income statement display standards. No impact on our financial statements has resulted from the adoption of the EITF Issues above.

5. Contingencies

In July 1999, the United States Patent and Trademark Office declared an interference involving us, which was provoked by RadioTherapeutics Corporation, a competitor of ours, 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

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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 final confirmation of that decision later this year. In the event that the decision is confirmed, we plan to file a motion in a United States District Court requesting review of the decision. Final determination of the patent interference proceeding may take several years. If the final determination of the United States District Court results in the issuance of patent rights related to the claim to RadioTherapeutics and we were unable to obtain a license to use the relevant patent or successfully modify our disposable device, we could be unable to sell our system and our business could suffer.

The Company is also involved in a patent opposition action pending before the European Patent Office. This opposition 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. On February 7, 2002, the European Patent Office determined that we are entitled to European Patent No. 0777445 that covers radiofrequency ablation technology. The European Patent Office approved 27 claims. A final decision is not expected in this proceeding for several years. If we do not prevail in the opposition proceeding, we could lose our only currently issued patent in Europe.

In August 2001 the Company filed a complaint in the United States District Court for the Northern District of California against RadioTherapeutics 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. As of March 31, 2002, the Company has capitalized approximately $629,000 in litigation costs incurred in defense of its patent positions.

In April 2002, a patent infringement suit against the Company was filed in the United States District Court for the Northern District of California by RadioTherapeutics Corporation and SciMed Life Systems, Inc., (two wholly-owned subsidiaries of Boston Scientific Corporation), the Board of Regents of the University of Nebraska and UneMed Corporation. The suit alleges that certain of the Company s products infringe a patent assigned to the University of Nebraska and licensed by UneMed and RadioTherapeutics and a patent owned by SciMed. The Company is assessing the potential impact of this suit on its financial position and results of operations.

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

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

Overview

We develop, manufacture and market minimally invasive products that use radiofrequency energy to treat patients with solid cancerous or benign tumors. From inception in 1994 through 1996, our operations consisted primarily of various start-up activities, including development of technologies central to our business, recruiting personnel and raising capital. In 1997, we began commercial product shipments. In 2001, we commercially launched our StarBurst XLi family of disposable devices and significantly expanded our direct domestic sales organization and our international distribution network.

Our products are sold in the United States through our direct sales force and internationally through distribution partners. For the three months ended March 31, 2002, sales in the United States accounted for 72% of our total sales while sales in our international markets accounted for 28% of our total sales. We expect domestic sales to account for a majority of our sales in future periods due to our significant investment in and the efforts of our domestic sales force. Conversely, we expect reimbursement issues in Europe and Japan to limit sales growth in these regions for the next several years. However, our international operations will continue to represent a significant, if decreasing, portion of our revenue 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 March 31, 2002, 73% of our sales were derived from our disposable devices and 27% were derived from the sale of our generators. We will continue to focus on expanding our base of customer accounts and on increasing usage of our disposable products in our established accounts. As a result, revenue from our higher-margin disposable devices should continue to predominate our sales.

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

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, average selling prices, the sales mix of higher-margin disposable devices versus generators and the mix of domestic direct sales versus international sales, which provide for standard distributor discounts. Our gross margin for the three months ended March 31, 2002 was 55%, lower than that in recent preceding quarters because we shipped more