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 relatively low margin generators in connection with our generator placement program and because we recognized charges for obsolete inventory. We expect gross margins to improve later this year primarily as a result of continued improvements in sales mix and cost factors and also due to the growing acceptance of our premium-priced StarBurst XLi line of disposable devices.

For the three months ended March 31, 2002, 20% of our operating expenses were related to research and development activities, continuing a trend towards relatively less spending in this area as compared to

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sales and marketing activities. We expect our research and development activities to continue to grow more slowly than sales and marketing activities, at least through 2002, as we commit significantly more resources to market development and business expansion efforts. Selling, general and administrative activities represented 80% of our operating expenses for the quarter, higher than in recent preceding periods and reflecting our continuing investments in our domestic sales force, international distribution activities, physician training and patient awareness programs. We also made additional provisions to our allowance for uncollectible accounts, further affecting administrative expense, as difficult economic conditions have resulted in longer collection periods with many of our European distributors. While our investments in market growth and business development will continue to grow, we believe sales and operating exercises will stabilize in 2002.

In connection with grants of stock options to employees and non-employees, we record deferred stock-based compensation as a component of stockholders equity. This stock-based compensation is amortized as charges to operations over the vesting periods of the options. We recorded amortization of deferred compensation of $0.2 million for the three months ended March 31, 2002. We expect to record additional amortization expense for deferred compensation in diminishing amounts through 2004, at which point our existing deferred stock-based compensation will be fully amortized.

We incurred net losses of $4.0 million for the three months ended March 31, 2002. As of March 31, 2002, we had an accumulated deficit of $58.4 million. Due to the high costs associated with continued research and development programs, expanded clinical research programs and increased sales and marketing efforts, we expect to continue to incur net losses for the full year 2002, but losses should diminish through the first three quarters of the year, and we expect to be modestly profitable in the fourth quarter of 2002. Profitability beyond 2002 will depend on our success in expanding product usage in our current market and in developing new markets. To the extent current or new markets do not materialize in accordance with our expectations, our sales and profitability could be lower than expected and we may be unable to achieve or sustain profitability.

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

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Results of Operations

The following table sets forth the percentage of net revenue represented by certain items in our Statements of Operations for the current quarter ended March 31, 2002 and the four preceding fiscal quarters:

	Q1 2002	Q4 2001	Q3 2001	Q2 2001	Q1 2001
Domestic Sales	72%	65%	56%	46%	48%
International Sales	28%	35%	44%	54%	52%
Total Sales	100%	100%	100%	100%	100%
Cost of goods sold	(45%)	(30%)	(40%)	(44%)	(54%)
Gross Profit	(55%)	(70%)	(60%)	(56%)	(46%)
Operating Expenses:					
Research and Development	(30%)	(41%)	(44%)	(46%)	(44%)
Selling, general and administrative	(118%)	(127%)	(108%)	(100%)	(113%)
Total operating expenses	(148%)	(169%)	(152%)	(146%)	(158%)
Loss from operations	(94%)	(99%)	(92%)	(91%)	(111%)
Other income (expense), net	(3%)	(5%)	(9%)	(11%)	(17%)
Net loss	(90%)	(94%)	(83%)	(79%)	(94%)

Three months ended March 31, 2002 and 2001

Sales increased 34% to $4.4 million for the quarter ended March 31, 2002 from $3.3 million for the quarter ended March 31, 2001. Domestic sales increased by 101% over the comparable prior year period, although international sales decreased by 27%. Sales of our disposable products totaled $3.2 million for the quarter, an increase of 35% over the comparable prior year period. Higher unit shipments of disposable products resulted from increased physician awareness of our technology and the efforts of our expanded domestic sales force. Also, average selling prices of disposable products benefited from the increasing proportion of domestic business in our sales mix as well as the growing acceptance of our premium-priced StarBurst XLi line of disposable devices. Generator sales for the quarter were 31% higher than sales in the first quarter of 2001.

Cost of goods sold for the quarter ended March 31, 2002 was $2.0 million compared to $1.8 million for the quarter ended March 31, 2001, a 13% increase. This increase primarily reflects higher unit volumes of our disposable devices. Growth in cost of goods sold would have been higher if not for reduced charges for amortization of deferred stock-based compensation, which totaled $35,000 for the first quarter of 2002, down from $0.2 million in the corresponding period of 2001. Charges for obsolete inventory decreased to $0.1 million for the quarter, compared to $0.2 million in the prior year period. Also, we continue to benefit from manufacturing efficiencies attained through higher volume production of our disposable devices. With sales up 34% and cost of goods sold increasing 13%, the company s gross margin rate improved to 55% for the quarter ended March 31, 2002, compared to 46% for the quarter ended March 31, 2001.

Research and development expenses for the quarter ended March 31, 2002 were $1.3 million compared to $1.5 million for the corresponding period in 2001. This decrease was primarily attributable to reduced new product development charges. Our investment in clinical programs investigating new applications for our technology has remained constant. Charges to research and development expense for amortization of deferred stock-based compensation were $0.1 million for the quarter, unchanged from charges in the corresponding period in 2001.

Selling, general and administrative expenses for the quarter ended March 31, 2002 were $5.2 million as compared to $3.7 million in the corresponding period in 2001. The increase was primarily due to the major expansion of our domestic sales organization, resulting in expenses of $3.1 million for the quarter compared to expenses of $1.8 million in the prior year period. Also, administrative expenses associated with business development efforts increased by $0.2 million and additional provisions to our reserve for uncollectible accounts resulted in $0.1 million in increased expenses. Charges to selling, general and administrative expense for amortization of deferred stock-based compensation were approximately $37,000 for the quarter compared to $0.2 million for the corresponding period in 2001.

Interest income, net of interest expense, was $0.1 million for the quarter ended March 31, 2002 compared to $0.6 million in the corresponding period of 2001. The change was primarily attributable to a

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

Liquidity and Capital Resources

Prior to August 2000, we financed our operations principally through private placements of convertible preferred stock, raising approximately $37.9 million net of expenses. On August 1, 2000, we completed our initial public offering of 3.6 million common shares at a price of $12 per share, raising approximately $39.0 million net of expenses. All outstanding convertible preferred shares were converted to common shares at that time. To a lesser extent, we also financed our operations through equipment financing and other loans, of which there was $0.1 million in principal outstanding at March 31, 2002. Also as of March 31, 2002, we had $5.5 million of cash and cash equivalents, $13.9 million of short-term marketable securities and $26.1 million of working capital.

For the three months ended March 31, 2002, net cash used in operating activities was $3.7 million, principally due to our net loss, increases in accounts receivable and the payment of liabilities accrued as of December 31, 2001, offset by reductions in our prepaid asset accounts. Our investing activities for this period were limited to the purchase of property and equipment in the amount of $0.4 million and net purchases or sales of both short-term and long-term investment instruments. Also, we capitalized $0.3 million in costs associated with legal action we initiated in 2001 in defense of our patent rights (see Part II, Legal Proceedings for discussion of this and other legal proceedings). Net cash provided by financing activities was $0.4 million, principally from the issuance of common shares.

We have, from time to time, financed equipment through capital and operating leases. As of March 31, 2002, our future minimum payments due under capital and operating leases are as follows (in thousands):

Future minimum capital lease payments	
Payments due in the remainder of 2002	$ 127
Less imputed interest (including warrants)	(7)
Present value of future minimum capital lease payments	$ 120

Future minimum operating lease payments	
Remainder of 2002	$ 408
2003	533
2004	356
Total of future minimum operating lease payments	$ 1,297

Our capital requirements depend on numerous factors including our research and development expenditures, expenses related to selling, marketing and administration as well as working capital to support business growth. Although it is difficult for us to predict future liquidity requirements with certainty, we believe that our current cash and cash equivalents will satisfy our cash requirements for at least the next 18 months. During or after this period, if cash generated by operations is insufficient to satisfy our liquidity requirements, we may need to sell additional equity or debt securities or obtain an additional credit facility. There can be no assurance that additional financing will be available to us or, if available, that such financing will be available on terms favorable to the Company and our stockholders.

Factors That May Affect Future Results

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

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

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Because all of our revenue comes from the sale of the RITA system, our financial performance will depend upon physician adoption and patient awareness of this system. If we are unable to convince physicians to use the RITA system, we may not be able to generate revenues because we do not have alternative products.

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

In July 1999, the United States Patent and Trademark Office declared an interference involving us, which was provoked by RadioTherapeutics Corporation, a competitor of ours and now a wholly-owned subsidiary of Boston Scientific Corporation in which the validity of a patent claim previously issued to us is being called into question. The claim being questioned is one of a number of issued patent claims that cover the curvature of the array at the tip of our disposable devices. In February 2001, the USPTO issued a decision on preliminary motions filed in the patent interference proceeding. The decision found that one of the claims in our United States Patent No. 5,536,267 (claim no. 32) is invalid. We expect to receive 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.

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

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

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

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

We anticipate that our operating expenses will increase substantially in absolute dollars for the foreseeable future as we expand our sales and marketing, manufacturing, clinical research and product development efforts. To become profitable, we must continue to increase our sales. If sales do not continue to grow, we may not be able to achieve or maintain profitability in the future. In particular, we incurred net losses of $4.0 million in the first three months of 2002, $13.0 million in 2001, $12.8 million in 2000 and $7.5 million in 1999. At March 31, 2002, we had an accumulated deficit of approximately $58.4 million.

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

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

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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.

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

In addition to competing against other companies offering products that use radiofrequency energy to ablate soft tissue, we also compete against companies developing, manufacturing and marketing alternative therapies that address both cancerous and benign tumors. If these alternative therapies prove to offer treatment options that are superior to our system, physician adoption of our products could be negatively affected and our revenues could decline.

We currently lack long-term data regarding the safety and efficacy of our products and may find that long-term data does not support our short-term clinical results.

Our products are supported by an average clinical follow-up of between five and 14 months in published clinical reports. If longer-term studies fail to confirm the effectiveness of our products, our sales could decline. If longer-term patient follow-up or clinical studies indicate that our procedures cause unexpected, serious complications or other unforeseen negative effects, we could be subject to significant liability. Further, because some of our data has been produced in studies that were not randomized and/or included small patient populations 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, we may lose market share to a competitor and our business could suffer.

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products, and yet we may be unable to do so. A number of companies in our market, as well as universities and research institutions, have issued patents and have filed patent applications that relate to the use of radiofrequency energy to ablate soft tissue. Our pending United States and foreign patent applications may not issue or may issue and be subsequently successfully challenged by others and invalidated. In addition, our pending patent applications include claims to material aspects of our products that are not currently protected by issued patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

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

Our dependence on international revenues, which account for a significant portion of our revenues, could harm our business.

Because our future profitability will depend in part on our ability to grow product sales in international markets, we are exposed to risks specific to business operations outside the United States. These risks include:

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

- the risk of inventory build-up by our distributors which could negatively impact sales in future periods;

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- obtaining reimbursement for procedures using our devices in some foreign markets;
- the burden of complying with complex and changing foreign regulatory requirements;
- longer accounts receivable collection time;
- significant currency fluctuations, which could cause our distributors to reduce the number of products they purchase from us because the cost of our products to them could increase relative to the price they could charge their customers;
- reduced protection of intellectual property rights in some foreign countries; and
- contractual provisions governed by foreign laws.

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

We are substantially dependent on a limited number of significant distributors in our international markets, and if we lose these distributors and fail to attract additional distributors, our international revenues could decline. ITX Corporation, formerly known as Nissho Iwai Corporation, is our primary distributor in Asia. It accounted for 51 percent of our international revenues for the three months ended March 31, 2002 and 31 percent of our international revenues in 2001. M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, accounted for 27 percent of our international revenues for the three months ended March 31, 2002 and 17 percent of our international revenues for 2001. Because international revenues accounted for 28 percent of our total revenues for the three months ended March 31, 2002 and these two distributors represented 78 percent of that total, the loss of either distributor or a significant decrease in unit purchases by either distributor could cause revenues to decline substantially. If we are unable to attract additional international distributors, our international revenues may not grow.

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

We sell our products in international markets through third-party distributors over whom we have limited control, and, if they fail to adequately support our products, our sales could decline. If our distributors or we terminate our existing agreements, finding companies to replace them could be an expensive and time-consuming process and sales could decrease during any transition period.

In addition, we are aware that some of our international distributors have built up inventory of our disposable devices. As a result, future sales of our newer generation disposable devices by these distributors could be negatively impacted. In addition, while these distributors have no price protection and no right of return relating to purchased products, if we permit the return of any of these products, we will have to adjust our revenues relating to these products.

If customers in markets outside the United States experience difficulty obtaining reimbursement for procedures using our products, international sales could decline.

Certain of the markets outside the United States in which we sell our products require that specific reimbursement codes be obtained before reimbursement for procedures using our products can be approved. As a result, in countries where specific reimbursement codes are strictly required and have not yet been issued, reimbursement has been denied on that basis. ITX, our distributor in Japan, is seeking to obtain reimbursement coverage in Japan, but to date has not yet received this approval. If we are unable to either obtain the required reimbursement codes or develop an effective strategy to resolve the reimbursement issue, physicians may be unwilling to purchase our products which could negatively impact our international revenues.

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

Physicians, hospitals and other health care providers may be reluctant to purchase our products if they do not receive substantial reimbursement for the cost of the procedures using our products from third-party payors, such as Medicare, Medicaid and private health insurance plans. Although we have been notified by the American Medical Association that specific reimbursement codes for radiofrequency ablation of liver tumors have been established, they reserve the right to reverse this decision. In this case, we would be required to reapply for a specific code. This process is time consuming and costly and may require us to provide extensive supporting scientific, clinical and cost-effectiveness data for our products to the American Medical Association. Even though we were successful in establishing a new CPT code via the A.M.A., a payor still may not reimburse adequately for the procedure or product. In addition, there is no specific reimbursement code for radiofrequency ablation of tumors in other organs. Further, we believe the advent of fixed payment schedules has made it difficult to receive reimbursement for disposable products, even if the use of these products improves clinical outcomes. Fixed payment schedules typically permit reimbursement for a procedure rather than a device. If physicians believe that our system will add cost to a procedure but will not add sufficient offsetting economic or clinical benefits, physician adoption could be slowed.

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

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

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

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

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

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

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

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

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

It is critical to our sales effort to train a sufficient number of physicians and to instruct them properly in the procedures that utilize our products. We have established formal physician training programs and rely on physicians to devote adequate time to understanding how and when our products should be used. If physicians are not properly trained, they may misuse or ineffectively use our products. This may result in

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

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

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

- failure of the public market to support the valuation established in our initial public offering;
- our ability to successfully commercialize our products;
- announcements regarding patent litigation or the issuance of patents to us or our competitors;
- quarterly fluctuations in our results of operations;
- announcements of technological or competitive developments;
- regulatory developments regarding us or our competitors;
- acquisitions or strategic alliances by us or our competitors;
- changes in estimates of our financial performance or changes in recommendations by securities analysts; and
- general market conditions, particularly for companies with small market capitalizations.

Securities class action litigation is often brought against a company after a period of volatility in the market price of its stock. If our future quarterly operating results are below the expectations of securities analysts or investors, the price of our common stock would likely decline. Stock price fluctuations may be exaggerated if the trading volume of our common stock is low. Any securities litigation claims brought against us could result in substantial expense and divert management s attention from our core business.

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

If we fail to execute our sales strategy and develop further our products, our business could suffer. To manage anticipated growth in operations, we must increase our quality assurance staff for both our generators and our disposable devices and expand our manufacturing staff and facility for our disposable devices. Our systems, procedures and controls may not be adequate to support our expected growth in operations.

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

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

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

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

We are dependent on third-party contractors for the supply of our generators, and any failure to deliver generators to us could result in lower than expected revenues.

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. This can be a lengthy and time-consuming process. To date, all of our products have received clearances from the FDA through premarket notification under Section 510(k) of the Federal Food, Drug and Cosmetic Act. However, if the FDA requires us to submit a new premarket notification under Section 510(k) for modifications to our existing products, or if the FDA requires us to go through a lengthier, more rigorous examination than we now expect, our product introductions or modifications could be delayed or canceled which could cause our revenues to be below expectations. The FDA may determine that future products will require the more costly, lengthy and uncertain premarket approval process. In addition, modifications to medical device products cleared via the 510(k) process may require a new 510(k) submission. We have made minor modifications to our system. Using the guidelines established by the FDA, we have determined that some of these modifications do not require us to file new 510(k) submissions. If the FDA disagrees with our determinations, we may not be able to sell the RITA system until the FDA has cleared new 510(k) submissions for these modifications. In addition, we intend to request additional label indications, such as approvals or clearances for the ablation of tumors in additional organs, including lung, bone and breast, for our current products. The FDA may either deny these requests outright, require additional extensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of approval or clearance. Therefore, obtaining necessary approvals or clearances for these additional applications could be an expensive and lengthy process.

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We may need to raise additional capital in the future resulting in dilution to our stockholders.

We may need to raise additional funds for our business operations and to execute our business strategy. We may seek to sell additional equity or debt securities or to obtain an additional credit facility. The sale of additional equity or convertible debt securities could result in additional dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights that are senior to holders of common stock and could contain covenants that would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, if at all.

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

Because our executive officers and directors, and their respective affiliates, own approximately 28 percent of our outstanding common stock, these stockholders may, as a practical matter, be able to exert significant influence over matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. This concentration of voting stock could have the effect of delaying or preventing a change in control.

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risk disclosures have not changed significantly from those set forth in Management s Discussion and Analysis of Financial Condition and Results of Operations in our Form 10-K filing dated March 28, 2002.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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

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

We are also involved in a patent interference proceeding before the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office. On July 16, 1999 the United States Patent and Trademark Office declared an interference between a claim of one of our issued patents and claims of a patent application controlled by RadioTherapeutics. The principal parties in the proceeding are RadioTherapeutics and RITA. The factual basis underlying the claim is the determination by the

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commissioner of the United States Patent and Trademark Office that our patent and the RadioTherapeutics patent application interfere. In the interference proceeding, RadioTherapeutics seeks to invalidate our patent claim and to establish the patentability of the claims in their patent application. We seek to maintain the priority of our patent claim. The European opposition is pending before the European Patent Office and was instituted on March 2, 2000. The principal parties are RadioTherapeutics and RITA. The factual basis underlying the claim is the allegation by RadioTherapeutics that our European patent is not valid. In the opposition, RadioTherapeutics seeks to have our patent declared invalid and to have our patent cancelled. We are defending our patent and seek to defend it as issued.

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

Item 2. Changes in Securities and Use of Proceeds. 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:	10.23:	Form of Change of Control Agreement entered into between the Company, Trent Reutiman on November 16, 2001, between the Company and Donald Stewart on April 16, 2001 and between the Company and Kenneth Waters on November 5, 2001.
	10.24:	Change of Control Agreement entered into between the Company and David Horn on September 10, 2001.
	10.25:	Form of Indemnification Agreement between the Company and David Horn on September 10, 2001, between the Company and Trent Reutiman on November 16 , 2001, between the Company and Donald Stewart on April 16, 2001, between the Company and Kenneth Waters on November 5, 2001, and between the Company and F. Thomas (Jay) Watkins on April 15, 2002.

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

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

RITAMEDICAL SYSTEMS, INC.

By: /s/ Donald Stewart

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

Date: May 15, 2002

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