

RITA MEDICAL SYSTEMS INC  
Form 10-Q  
May 07, 2004  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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 March 31, 2004**

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**

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**RITA MEDICAL SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

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**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)

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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 March 31, 2004, there were 18,015,427 shares of the registrant's Common Stock outstanding.

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

(In thousands, unaudited)

|  | <u>March 31,</u><br><u>2004</u> | <u>December 31,</u><br><u>2003</u> |
|--|---------------------------------|------------------------------------|
| <b>Assets</b>                                      |                                 |                                    |
| Current assets:                                    |                                 |                                    |
| Cash and cash equivalents                          | \$ 6,122                        | \$ 4,580                           |
| Marketable securities                              | 1,726                           | 4,022                              |
| Accounts and note receivable, net                  | 3,006                           | 2,990                              |
| Inventories  | 1,777                           | 2,192                              |
| Prepaid and other current assets                   | 796                             | 1,028                              |
|  | <u>13,427</u>                   | <u>14,812</u>                      |
| Total current assets                               | 13,427                          | 14,812                             |
| Long term marketable securities                    | 264                             | 933                                |
| Long term note receivable, net                     | 315                             | 338                                |
| Property and equipment, net                        | 905                             | 1,089                              |
| Intangible assets                                  | 4,673                           | 4,814                              |
| Other assets                                       | 47                              | 47                                 |
|  | <u>19,631</u>                   | <u>22,033</u>                      |
| Total assets                                       | \$ 19,631                       | \$ 22,033                          |
| <b>Liabilities and Stockholders' Equity</b>        |                                 |                                    |
| Current liabilities:                               |                                 |                                    |
| Accounts payable                                   | \$ 736                          | \$ 757                             |
| Accrued liabilities                                | 1,751                           | 2,169                              |
|  | <u>2,487</u>                    | <u>2,926</u>                       |
| Total current liabilities                          | 2,487                           | 2,926                              |
| Deferred maintenance revenue, less current portion | 25                              | 23                                 |
|  | <u>2,512</u>                    | <u>2,949</u>                       |
| Total liabilities                                  | 2,512                           | 2,949                              |
| <b>Stockholders' equity</b>                        |                                 |                                    |
| Common stock                                       | 18                              | 18                                 |
| Additional paid-in capital                         | 98,241                          | 98,037                             |
| Accumulated other comprehensive income             | 3                               | 2                                  |
| Accumulated deficit                                | (81,143)                        | (78,973)                           |

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|  |           |           |
|--|-----------|-----------|
| Total stockholders' equity                 | 17,119    | 19,084    |
| Total liabilities and stockholders' equity | \$ 19,631 | \$ 22,033 |

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<br>March 31, |            |
|---|---------------------------------|------------|
|   | 2004                            | 2003       |
| Sales   | \$ 4,644                        | \$ 4,497   |
| Cost of goods sold  | 1,615                           | 1,574      |
| Gross profit  | 3,029                           | 2,923      |
| Operating expenses:   |                                 |            |
| Research and development  | 843                             | 1,358      |
| Selling, general and administrative                                   | 4,366                           | 4,564      |
| Total operating expenses  | 5,209                           | 5,922      |
| Loss from operations  | (2,180)                         | (2,999)    |
| Interest income and other expense, net                                | 10                              | 75         |
| Net loss  | \$ (2,170)                      | \$ (2,924) |
| Net loss per common share, basic and diluted                          | \$ (0.12)                       | \$ (0.17)  |
| Shares used in computing net loss per common share, basic and diluted | 17,998                          | 17,223     |

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)

|   | Three months ended<br>March 31, |                  |
|---|---------------------------------|------------------|
|   | 2004                            | 2003             |
| Cash flows from operating activities:                                       |                                 |                  |
| Net loss  | \$ (2,170)                      | \$ (2,924)       |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                 |                  |
| Depreciation and amortization   | 410                             | 331              |
| Loss on disposal of property and equipment                                  | 13                              |                  |
| Revaluation of common stock warrants for services received                  |                                 | (26)             |
| Amortization of stock-based compensation                                    | 107                             |                  |
| Allowance for doubtful accounts   | 27                              | 66               |
| Provision for obsolete inventories  | 86                              | 38               |
| Changes in operating assets and liabilities:                                |                                 |                  |
| Accounts and note receivable  | (43)                            | (165)            |
| Inventories   | 329                             | 340              |
| Prepaid and other current assets  | 232                             | 165              |
| Accounts payable and accrued liabilities                                    | (439)                           | (674)            |
| Deferred maintenance revenue  | 2                               |                  |
| <b>Net cash used in operating activities</b>                                | <b>(1,446)</b>                  | <b>(2,849)</b>   |
| Cash flows from investing activities:                                       |                                 |                  |
| Purchase of property and equipment  | (98)                            | (233)            |
| Purchase of marketable securities   | (4)                             | (143)            |
| Sales and maturities of marketable securities                               | 2,970                           | 4,367            |
| Capitalization of patent litigation costs                                   |                                 | (602)            |
| Note receivable and other assets  | 23                              | 35               |
| <b>Net cash provided by investing activities</b>                            | <b>2,891</b>                    | <b>3,424</b>     |
| Cash flows from financing activities:                                       |                                 |                  |
| Proceeds from issuance of common stock                                      | 97                              | 8,556            |
| <b>Net cash provided by financing activities</b>                            | <b>97</b>                       | <b>8,556</b>     |
| Net increase in cash and cash equivalents                                   | 1,542                           | 9,131            |
| Cash and cash equivalents at beginning of period                            | 4,580                           | 6,888            |
| <b>Cash and cash equivalents at end of period</b>                           | <b>\$ 6,122</b>                 | <b>\$ 16,019</b> |

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

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**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, 2003 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 of a normal recurring 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, 2003 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):

|   | <b>Three months ended</b> |               |
|---|---------------------------|---------------|
|   | <b>March 31,</b>          |               |
|   | <b>2004</b>               | <b>2003</b>   |
|   | <b>_____</b>              | <b>_____</b>  |
| Weighted average shares of common stock outstanding                         | 17,998                    | 17,235        |
| Less: weighted-average shares subject to repurchase                         |                           | (12)          |
|   | <b>_____</b>              | <b>_____</b>  |
| Weighted average shares used in basic and diluted net loss per common share | <b>17,998</b>             | <b>17,223</b> |
|   | <b>_____</b>              | <b>_____</b>  |

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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):

|   | <b>March 31,</b> |             |
|---|------------------|-------------|
|   | <b>2004</b>      | <b>2003</b> |
|   | <b>—</b>         | <b>—</b>    |
| Effect of potentially dilutive securities:  |                  |             |
| Unvested common stock subject to repurchase   |                  | 12          |
| Options   | 2,743            | 2,474       |
| Warrants  | 25               | 25          |
|   | <b>—</b>         | <b>—</b>    |
| Total potentially dilutive securities excluded from the computation of net loss per common share as their effect was antidilutive | 2,768            | 2,511       |
|   | <b>—</b>         | <b>—</b>    |

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## 3. Balance sheet components Inventories

The components of the Company's inventories at March 31, 2004 and December 31, 2003, respectively, were as follows (in thousands):

|                 | <b>March 31,<br/>2004</b> | <b>December 31,<br/>2003</b> |
|-----------------|---------------------------|------------------------------|
| Raw materials   | \$ 554                    | \$ 719                       |
| Work-in-process | 105                       | 214                          |
| Finished goods  | 1,118                     | 1,259                        |
|                 | <b>\$ 1,777</b>           | <b>\$ 2,192</b>              |

## 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 common share for the three month periods ended March 31, 2004 and 2003, 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):

|   | <b>Three months ended<br/>March 31,</b> |                   |
|---|---|-------------------|
|   | <b>2004</b>                             | <b>2003</b>       |
| Net loss, as reported   | \$ (2,170)                              | \$ (2,924)        |
| Deduct: Total stock-based employee compensation determined under the fair value based method for all awards | (809)                                   | (681)             |
| Net loss, pro-forma   | <b>\$ (2,979)</b>                       | <b>\$ (3,605)</b> |

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|  |           |           |
|--|-----------|-----------|
| Basic and diluted net loss per common share: |           |           |
| As reported                                  | \$ (0.12) | \$ (0.17) |
| Pro-forma                                    | \$ (0.17) | \$ (0.21) |

The determination of stock-based employee compensation, as relating to stock option plans, under the fair value based method used the following weighted average assumptions:

|                         | Three months ended<br>March 31, |         |
|-------------------------|---------------------------------|---------|
|                         | 2004                            | 2003    |
| Volatility              | 75%                             | 79%     |
| Risk-free interest rate | 3.13%                           | 2.81%   |
| Expected life           | 5 years                         | 5 years |
| Expected dividends      | 0%                              | 0%      |

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

|                         | Three months ended<br>March 31, |           |
|-------------------------|---------------------------------|-----------|
|                         | 2004                            | 2003      |
| Volatility              | 60%                             | 70%       |
| Risk-free interest rate | 1.01%                           | 3.15%     |
| Expected life           | 0.5 years                       | 1.3 years |
| Expected dividends      | 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. Intangible assets and related amortization

The Company's intangible assets and related accumulated amortization at March 31, 2004 and December 31, 2003, respectively, were as follows (in thousands):

|   | March 31, 2004           |                             | December 31, 2003        |                             |
|---|--------------------------|-----------------------------|--------------------------|-----------------------------|
|   | Gross Carrying<br>Amount | Accumulated<br>Amortization | Gross Carrying<br>Amount | Accumulated<br>Amortization |
| Capitalized patent defense litigation costs | \$ 2,755                 | \$ (412)                    | \$ 2,755                 | \$ (351)                    |
| Capitalized patent license agreements       | 2,650                    | (320)                       | 2,650                    | (240)                       |
|   | <u>\$ 5,405</u>          | <u>\$ (732)</u>             | <u>\$ 5,405</u>          | <u>\$ (591)</u>             |

Aggregate amortization expense for the three months ended March 31, 2004, and estimated amortization expense for the nine months ended December 31, 2004 and each of the five years ended December 31, 2005 through 2009 is as follows (in thousands):

**Aggregate amortization expense:**

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|   |        |
|---|--------|
| For the three months ended March 31, 2004 | \$ 141 |
|---|--------|

**Estimated amortization expense:**

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|   |        |
|---|--------|
| For the nine months ended December 31, 2004   | \$ 422 |
| 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 |
| For the twelve months ended December 31, 2009 | \$ 563 |

**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, 2003. 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 significantly expanded our direct domestic sales organization and our international distribution network. In 2002, the XLi family of disposable devices gained wide acceptance with our customers in the United States. In 2003, we introduced our next generation in infusion technology, the Xli-Enhanced (Xlie) disposable device. The Xlie device builds upon our established infusion expertise, making the ablation process easier and more efficient.

Management relies on certain statistical measurements to assess trends in sales growth and the effectiveness of our selling strategies. The following table, derived from our Consolidated Statements of Operations and other unaudited data for the three months ended March 31, 2004 and 2003, and for the years ended December 31, 2003, 2002 and 2001, sets forth some of these measurements:

|  | Three months<br>ended March 31, |          | Years ended December 31, |           |           |
|--|---------------------------------|----------|--------------------------|-----------|-----------|
|  | 2004                            | 2003     | 2003                     | 2002      | 2001      |
| Total sales (in thousands)               | \$ 4,644                        | \$ 4,497 | \$ 16,607                | \$ 17,393 | \$ 14,791 |
| Percentage of sales: United States       | 79%                             | 71%      | 80%                      | 74%       | 54%       |
| Percentage of sales: International       | 21%                             | 29%      | 20%                      | 26%       | 46%       |
| Percentage of sales: Disposable products | 94%                             | 88%      | 88%                      | 75%       | 78%       |
| Percentage of sales: Hardware products   | 6%                              | 12%      | 12%                      | 25%       | 22%       |
| Gross margin                             | 65%                             | 65%      | 63%                      | 60%       | 59%       |

Our products are sold in the United States through our direct sales force and internationally through distribution partners. Our sales in the United States are more profitable than our sales in international markets because direct selling, which avoids distributor discounts, permits higher average selling prices for our products. Accordingly, we have made significant investments in our domestic sales force in an effort to increase sales growth in the United States, and have, to date, introduced our premium-priced Starburst Xli and Xlie families of disposable needles only in this region. These actions have resulted in a growing percentage of sales derived from the domestic market. In contrast, our international markets in Europe and Japan have relatively more restrictive reimbursement conditions than those in the United States, which combined with our distributor discounts, limit our average selling prices in these markets. Further, some of our distributors in Europe and Japan have been reducing

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their inventory levels. These factors have resulted in slow growth or even declining volume in some of our international markets. Going forward, we expect 2004 sales growth in the United States to continue to outpace international growth, because we believe our international markets, particularly Japan, will continue to reduce inventory levels, and because we believe the introduction of premium products to our international distributors will have a relatively small impact on growth due to pricing limitations. However, we also note reimbursement approval for our procedure in Japan, effective April 1, 2004, and we believe that Japan will once again be an important source of international revenue beginning in 2005.



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All of our revenue is derived from the sale of our disposable devices and radiofrequency generators. As the number of customers using our products grows, we expect that the percentage of sales related to disposable products will grow relative to that of hardware products, although we have, in the past, seen temporary deviations from this trend as a result of large hardware shipments to international distributors. Since our disposable products are self-manufactured and more profitable than our vendor-sourced hardware products, a growing percentage of disposable product sales is favorable to the Company. In 2004, we will continue to focus on expanding our base of customers 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. We have, in the past, experienced supply shortages that limited our sales. We are not currently experiencing such shortages and do not expect shortages in the future, although there cannot be complete assurance to this effect.

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 some additional nominal revenue from the use of the RITA system sold for the treatment of patients with metastatic bone tumors. Our sales from devices used in bone tumor procedures remained small in 2003 and the first quarter of 2004, but we expect that the January 2004 approval of a reimbursement code for bone procedures will have a favorable impact going forward. 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.

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. Our manufacturing costs are volume-dependent, and our unit costs should decrease as our production volumes increase. We also have the opportunity to reduce the cost of our vendor-supplied hardware products through higher order volumes or product redesign. Besides manufacturing costs, our cost of goods sold for 2003 and the three months ended March 31, 2004 reflects amortization of capitalized license fees associated with the April 2003 settlement of our patent litigation dispute with Boston Scientific Corporation. We expect these amortization charges to continue through 2015. Further, our cost of goods sold also includes provisions to our reserve for obsolete inventory. Technology in our marketplace has evolved rapidly and we have, from time to time, recognized relatively high expenses related to obsolete inventory as our product line has changed. We may experience similar product changes and related obsolete inventory provisions in the future, although we generally expect only modest impacts from such provisions.

Our gross margins reflect our selling prices, our domestic / international mix percentages, our product mix percentages, our production volumes, the costs we pay for vendor manufactured product and our provisions for obsolete inventory. Our gross margin for the three months ended March 31, 2004 was 65%, as was our gross margin for the three months ended March 31, 2003. In 2004, we expect modest improvement in our gross margin rate, based on projected improvements in domestic / international and product sales mix, lower manufacturing costs and relatively modest provisions for obsolete inventory.

In addition to the selling statistics discussed above, management relies on certain measurements to assess the effectiveness of our operations. The following tables sets forth some of these measurements, derived from our Condensed Consolidated Statements of Operations for the three months ended March 31, 2004 and 2003 (unaudited), our Consolidated Statements of Operations for the years ended December 31, 2003, 2002 and 2001, our Condensed Consolidated Balance Sheets as of March 31, 2004 and December 31, 2003 (unaudited), and our Consolidated Balance Sheets as of December 31, 2003, 2002 and 2001:

|                                  | <b>Three months</b>    |             |                                 |             |             |
|----------------------------------|------------------------|-------------|---------------------------------|-------------|-------------|
|                                  | <b>ended March 31,</b> |             | <b>Years ended December 31,</b> |             |             |
|                                  | <b>2004</b>            | <b>2003</b> | <b>2003</b>                     | <b>2002</b> | <b>2001</b> |
| Research and development expense | \$ 843                 | \$ 1,358    | \$ 4,294                        | \$ 5,052    | \$ 6,489    |

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|   |          |          |           |           |           |
|---|----------|----------|-----------|-----------|-----------|
| Selling, general and administrative expense | 4,366    | 4,564    | 17,418    | 19,366    | 16,646    |
| Total operating expenses                    | \$ 5,209 | \$ 5,922 | \$ 21,712 | \$ 24,418 | \$ 23,135 |

|  | March 31, | December 31, |           |           |
|--|-----------|--------------|-----------|-----------|
|  | 2004      | 2003         | 2002      | 2001      |
| Cash and cash equivalents                    | \$ 6,122  | \$ 4,580     | \$ 6,888  | \$ 7,297  |
| Marketable securities, current and long term | 1,990     | 4,955        | 5,947     | 16,240    |
| Total cash and marketable securities         | \$ 8,112  | \$ 9,535     | \$ 12,835 | \$ 23,537 |

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If we are to become profitable, we must continue to manage our operating expenses. Our operating expenses consist of product development costs, clinical trial expenses, patent litigation expenses, sales and marketing expenses 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. Changes in these expenses are 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 rights and the extent to which credit issues and economic conditions constrain our ability to collect our receivables. For the three months ended March 31, 2004, research and development expense was 38% lower than in the three months ended March 31, 2003 as a result of a \$0.3 million reduction in patent litigation expense and a \$0.2 million reduction in clinical trial activity. Selling, general and administrative expense for the three months ended March 31, 2004 was 4%, or \$0.2 million, lower than in the three months ended March 31, 2003. This decrease reflected \$0.7 million in lower expenses, due to lower headcount, in our domestic sales group, offset by a \$0.5 million increase in marketing and administrative expenses. In 2004, we expect a modest increase in research expenditures, reflecting the ongoing need to develop innovative technology, but little or no growth in selling, general and administrative expense.

In addition to management of our operating expenses, we must continue to conserve our cash and / or raise additional cash. Our combined total of cash, cash equivalents and marketable securities was \$8.1 million as of March 31, 2004, down from \$9.5 million as of December 31, 2003. Our net cash used in operating activities for the three months ended March 31, 2004 was \$1.4 million. We believe we have sufficient cash on hand for at least 12 months of operations.

We incurred a net loss of \$2.2 million for the three months ended March 31, 2004 compared to \$2.9 million for the three months ended March 31, 2003. Due to the costs associated with research and development programs and our sales and marketing efforts, we expect to incur net losses throughout 2004. Profitability depends on our success in expanding product usage in our current markets 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.

**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, 2003. No changes in these policies and estimates have occurred during the three months ended March 31, 2004.

**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 March 31, 2004 and the four preceding fiscal quarters:

|                     | <u>Q1 2004</u> | <u>Q4 2003</u> | <u>Q3 2003</u> | <u>Q2 2003</u> | <u>Q1 2003</u> |
|---------------------|----------------|----------------|----------------|----------------|----------------|
| Domestic sales      | 79%            | 83%            | 86%            | 81%            | 71%            |
| International sales | 21%            | 17%            | 14%            | 19%            | 29%            |
| Total sales         | 100%           | 100%           | 100%           | 100%           | 100%           |
| Cost of goods sold  | 35%            | 39%            | 32%            | 42%            | 35%            |

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|  |       |       |       |       |       |
|--|-------|-------|-------|-------|-------|
| Gross profit                           | 65%   | 61%   | 68%   | 58%   | 65%   |
| Operating expenses:                    |       |       |       |       |       |
| Research and development               | 18%   | 21%   | 25%   | 26%   | 30%   |
| Selling, general and administrative    | 94%   | 94%   | 109%  | 117%  | 102%  |
| Total operating expenses               | 112%  | 115%  | 134%  | 143%  | 132%  |
| Loss from operations                   | (47%) | (54%) | (66%) | (85%) | (67%) |
| Interest income and other expense, net | 0%    | 0%    | 1%    | 1%    | 2%    |
| Net loss                               | (47%) | (54%) | (65%) | (84%) | (65%) |

Three months ended March 31, 2004 and 2003

For the three months ended March 31, 2004, sales totaled \$4.6 million, an increase of 3% over sales of \$4.5 million in the three months ended March 31, 2003. Our domestic sales for the first quarter of 2004 grew 15%, \$0.5 million, to \$3.7 million, compared to \$3.2 million in the prior period. The increase in domestic sales reflects increases in our installed customer base and in higher product utilization by our customers. Our international sales for the first quarter of 2004 decreased 25%, or \$0.3 million, to

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\$1.0 million, compared to \$1.3 million in the prior period. Our international sales results reflect negligible sales to our Japanese distributor in the first quarter of 2004, compared to \$0.5 million in the first quarter of 2003, which more than offset 24% higher sales to our remaining international distributors in Europe and Asia. For the quarter ended March 31, 2004, domestic sales represented 79% of total sales, compared to 71% in first quarter of 2003. Sales of our disposable products in the first quarter of 2004 grew by 10% compared with 2003 results, although hardware sales decreased 46%.

Cost of goods sold for the quarters ended March 31, 2004 and March 31, 2003 was \$1.6 million. Our gross margin rate was 65% in both periods. We generally expect higher percentages of domestic sales and disposable sales to improve our gross margin rate, but in the first quarter of 2004 the effect of these factors was offset by \$0.1 million amortization of capitalized license fees associated with the settlement of our patent litigation dispute with Boston Scientific Corporation. As this settlement was not effective until April 1, 2003, there were no similar amortization charges included in cost during the first quarter of 2003. We expect such amortization charges to continue through 2015.

Research and development expenses for the quarter ended March 31, 2004 were \$0.8 million, compared to \$1.4 million in the first quarter of 2003. This decrease was due to \$0.3 million in reduced expenses relating to patent litigation and lower expenses for clinical trial activity. We expect a modest increase in research program expenditures for 2004, driven by developmental charges associated with technical innovation of our products.

Selling, general and administrative expenses for the quarter ended March 31, 2004 were \$4.4 million, compared to \$4.6 million in the first quarter of 2003. Our domestic selling expenses decreased by \$0.7 million, reflecting lower headcount in our U.S. based sales force. However, marketing expenses increased \$0.2 million, reflecting higher headcount and program activity, and reimbursement and administrative expenses increased by \$0.3 million. We expect our selling, general and administrative expense to show little or no growth in 2004, compared to 2003, reflecting the full-year impact of our 2003 organizational changes.

Interest income was negligible for the first quarter of 2004, down from \$0.1 million in the first quarter of 2003, because average daily cash balances fell over the intervening twelve months as we utilized cash for operations. We had no interest expense in either period.

## **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 (see below), which were fully repaid as of December 31, 2002. In January of 2003, we raised an additional \$8.3 million, net of expenses, through a private placement of our common shares. As of March 31, 2004, we had \$6.1 million of cash and cash equivalents, \$2.0 million of marketable securities and \$10.9 million of working capital.

For the three months ended March 31, 2004, net cash used in operating activities was \$1.4 million principally due to our net loss of \$2.2 million, offset by non-cash charges of \$0.6 million, including depreciation and amortization, provisions to reserves for uncollectible accounts and inventory, and expenses associated with options granted to consultants. Approximately \$0.1 million in cash was provided in the first quarter ended March 31, 2004 by changes in working capital accounts, with \$0.3 million in reduced inventory and \$0.2 million in reduced prepaid expenses offset by a \$0.4 million reduction in accounts payable and accrued liabilities. Our investing activities for the year were limited to the purchase of property and equipment in the amount of \$0.1 million. Maturities and (net) sales of investment instruments provided \$3.0 million in cash in

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support of operations. Financing activities for the year provided \$0.1 million in cash, generally through the issuance of common stock in conjunction with the exercise of stock options.

We have, from time to time, financed equipment through capital and operating leases. As of March 31, 2004, we had no future minimum payments due under capital leases. In March 2004, we extended the lease on our primary facility through January 2005, affecting our future minimum payments due under operating lease, which are now as follows (in thousands):

|  |        |
|--|--------|
| Payments due in 2004                             | \$ 308 |
| Payments due in 2005                             | 24     |
|  | <hr/>  |
| Total of future minimum operating lease payments | \$ 332 |
|  | <hr/>  |

Our capital requirements depend on numerous factors including our 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 averaged \$0.5 million per month for the year three months ended March 31, 2004. Net cash used in operating

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activities averaged \$0.4 million per month for the last half of the 2003. Although it is difficult for us to predict future liquidity requirements with certainty, we believe that our current balances of cash and cash equivalents, and the sale of marketable securities as necessary, will satisfy our cash requirements for at least the next 12 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.

## **Recent Accounting Pronouncements**

Our annual report on Form 10-K for the fiscal year ended December 31, 2003 discussed recent accounting pronouncements that could potentially affect the Company's financial results. During the three months ended March 31, 2004, there have been no additional accounting pronouncements that, in the opinion of management, have the potential to materially affect the Company's financial results.

## **Factors That May Affect Future Results**

In addition to the other information in this report, 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.**

We incurred net losses of \$2.2 million in the first quarter of 2004, \$11.1 million in 2003, \$13.5 million in 2002, \$13.0 million in 2001, \$12.8 million in 2000 and \$7.5 million in 1999. At March 31, 2004, we had an accumulated deficit of \$81.1 million. To become profitable we must increase our sales and continue to limit the growth of our operating expenses. If our sales do not grow, or if expenses grow excessively, we may not be able to achieve or maintain profitability in the future.

**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 that 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 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 solid cancerous and benign tumors. If these alternative therapies prove to offer treatment options that are perceived to be superior to our system or to have less severe side effects than those resulting from our system, physician adoption of our products could be negatively affected and our revenues could decline.



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**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. If the safety or efficacy of our products is questioned, our sales could decline.**

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.**

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. Under certain circumstances these 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.

**Our dependence on international revenues, which account for a significant portion of our total 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 reimbursement approvals);

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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.

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**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. Although it accounted for essentially none of our revenue in the first quarter of 2004, it accounted for 21% of our international revenues in 2003. M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, accounted for 45% of our international revenue in the first quarter of 2004 and 22% of our international revenues in 2003. International revenues accounted for 21% of our total revenues for the three months ended March 31, 2004, and these two distributors represented 45% of that total. For the year ended December 31, 2003, international revenues accounted for 20% of our total revenues and these distributors represented 43% 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.**

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 contracted with replacement distributors, we expended significant time and resources in doing so, and our sales in the three affected markets suffered during the transition period that we estimate ended September 30, 2003. If our distributors or we terminate other distributor agreements, we could incur similar or more burdensome expenses, we could 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. Sales to our Japanese distributor in 2003 and the first quarter 2004 were 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 stabilized in 2003, and remained stable in the first quarter of 2004, 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.

**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. If our distributors or 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, negatively impacting 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 the American Medical Association has established CPT codes relating to liver procedures and bone tumor procedures, some third-party payors still may not cover or reimburse adequately for liver or bone tumor procedures 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 organs other than liver or bone. Further, we believe the advent of the Medicare fixed

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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.

### **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;

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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 by us or our competitors;

product liability claims;

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.

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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 may be required to relocate, or choose to relocate, to a new facility in 2004. If so, we will incur moving expenses, and if we become unable to meet customer demand, our business could suffer.**

The operating lease on our current facility expires in August of 2004. We believe that during 2004 we will be able to either renew the lease on our existing facility, or lease alternative space, at commercially reasonable terms. If we choose to relocate to a new facility, we will incur normal and customary moving costs and may experience an interruption in our manufacturing operations. If we become 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 2003, there was 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 and Xlie lines of disposable devices, and any disruption in the supply of these devices could negatively affect our revenues.**

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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. Our Starburst Xlie product line, introduced in 2003, also requires an accessory infusion pump. 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.

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**We are dependent on two 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 foreign 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 foreign 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, the 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 the FDA concurs, the FDA clearance or approval process could be lengthened and anticipated revenues from that new indication would be delayed.

**We may acquire technologies or companies in the future, which could result in the dilution of our stockholders and disruption of our business, and reduce our revenues.**

We are continually evaluating business alliances and external investments in technologies related to our business. Acquisitions of companies, divisions of companies, businesses or products entail numerous risks, any of which could materially harm our business in several ways, including:

diversion of management's attention from our core business objectives and other business concerns;

failure to integrate efficiently businesses or technologies acquired in the future with our pre-existing business or technologies;

potential loss of key employees from either our pre-existing business or the acquired business;

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dilution of our existing stockholders as a result of issuing equity securities; and

assumption of liabilities of the acquired company.

Some or all of these problems may result from future acquisitions or investments. Furthermore, we may not realize any value from such acquisitions or investments.

### **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 March 31, 2004, 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.

### **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, 2003, filed on March 15, 2004.

### **Item 4. Controls and Procedures**

Based on our management's evaluation (with the participation of our principal executive officer and principal financial officer), as of the end of the period covered by this report, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

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There was no change in the Company's internal control over financial reporting during the first quarter of fiscal 2004 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

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**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings.** Not applicable.

**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:

- 31.1 Rule 13a-14(a) / 15d-14(a) Certification of Chief Executive Officer
- 31.2 Rule 13a-14(a) / 15d-14(a) Certification of Chief Financial Officer
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, of Chief Executive Officer
- 32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, of Chief Financial Officer

(b) Reports on Form 8-K:

On March 24, 2004, a Current Report on Form 8-K was filed with the Securities and Exchange Commission, or SEC, to report the issuance of a press release regarding a scheduled investor presentation.

On March 11, 2004, a Current Report on Form 8-K was filed with the SEC to report the issuance of a press release regarding approval of reimbursement for the treatment of liver cancer with radiofrequency ablation by Japan's Ministry of Health, Labor and Welfare.

On March 5, 2004, a Current Report on Form 8-K was filed with the SEC to report the issuance of a press release regarding the establishment of positive written reimbursement policies by several Blue Cross Blue Shield systems for the treatment of liver cancer with radiofrequency ablation.

On February 19, 2004, a Current Report on Form 8-K was filed with the SEC to report the issuance of a press release regarding multi-center study results for patients treated with radiofrequency ablation for osteolytic bone metastases (bone

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cancer) by lead clinical investigators at the Mayo Clinic in Rochester, Minnesota.

On February 13, 2004, a Current Report on Form 8-K was filed with the SEC to report the issuance of a press release regarding results of operations for the fourth quarter year ended December 31, 2003.

On February 11, 2004, a Current Report on Form 8-K was filed with the SEC to report the issuance of a press release regarding sales and earnings results for the fourth quarter and year ended December 31, 2003.

On January 21, 2004, a Current Report on Form 8-K was filed with the SEC to report the issuance of a press release regarding the assignment of a new Current Procedural Terminology code for radiofrequency ablation of bone tumors by the American Medical Association.

On January 13, 2004, a Current Report on Form 8-K was filed with the SEC to report the issuance of a press release regarding the appointment of Darrin R. Uecker as Chief Technology Officer of the Company.

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**SIGNATURES**

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

RITA MEDICAL SYSTEMS, INC

By: /s/ JOSEPH DeVIVO

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Joseph DeVivo

President and Chief Executive Officer

Date: May 7, 2004

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