

RITA MEDICAL SYSTEMS INC
Form S-3/A
February 05, 2003
Table of Contents

As filed with the Securities and Exchange Commission on February 5, 2003

Registration No. 333-102896

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

AMENDMENT NO. 1
TO THE
FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

RITA MEDICAL SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of

94-3199149
(I.R.S. Employer

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form S-3/A

incorporation or organization)

Identification No.)

967 N. Shoreline Blvd.

Mountain View, CA 94043

(650) 390-8500

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Barry N. Cheskin

Chief Executive Officer

RITA Medical Systems, Inc.

967 N. Shoreline Blvd.

Mountain View, CA 94043

(650) 390-8500

(Name, address, including zip code, and telephone number, including area code, of agent for service)

COPIES TO:

Mark B. Weeks

Brooke Campbell

Ughetta T. Manzone

VENTURE LAW GROUP

A Professional Corporation

2775 Sand Hill Road

Menlo Park, CA 94025

Approximate date of commencement of proposed sale to the public:

As soon as practicable after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. _____

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registrations statement number of the earlier effective registration statement for the same offering. _____

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

Calculation of Registration Fee

Title of each class of securities to be registered	Amount to be registered	Proposed maximum offering price per share (1)	Proposed maximum aggregate offering price	Amount of registration fee (2)
Common Stock, par value \$0.001	2,045,453	\$5.13	\$10,493,173.89	\$965.37

- (1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933 based upon the average of the high and low prices of the Common Stock as reported on the Nasdaq National Market on January 27, 2003.
- (2) Previously paid.

The Company hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Company shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The Information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission becomes effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated February 5, 2003

PROSPECTUS

RITA MEDICAL SYSTEMS, INC.

2,045,453 shares of Common Stock

The shares of common stock of RITA Medical Systems, Inc. offered by this prospectus involve a high degree of risk. You should carefully consider the Risk Factors on page 1 in determining whether to purchase the common stock.

The selling stockholders identified on page 12 of this prospective are offering these shares of common stock. We issued these shares of common stock to the selling stockholders in connection with a private placement of our common stock on January 24, 2003. For additional information concerning this private placement, you should refer to the section entitled "Issuance of Common Stock to Selling Stockholders" on page 10. The selling stockholders may sell the shares of common stock from time to time on the Nasdaq National Market, or otherwise, at prices and at terms then prevailing or at prices related to the then current market price or in private sales at negotiated prices directly or through a broker or brokers, who may act as agent or principal or by a combination of such methods of sale. For additional information on the method of sale, you should refer to the section entitled "Plan of Distribution" on page 10. We will not receive any proceeds from the sale of these shares.

The selling stockholders may be deemed to be a underwriters, as such term is defined in the Securities Act of 1933, as amended.

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form S-3/A

Our common stock is quoted on the Nasdaq National Market under the symbol RITA .

On February 4, 2003, the last sale price of our common stock on the Nasdaq National Market was \$4.73 per share.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2003.

Table of Contents

TABLE OF CONTENTS

	<u>Page</u>
<u>RISK FACTORS</u>	1
<u>THE COMPANY</u>	9
<u>USE OF PROCEEDS</u>	10
<u>ISSUANCE OF COMMON STOCK TO SELLING STOCKHOLDERS</u>	10
<u>PLAN OF DISTRIBUTION</u>	10
<u>SELLING STOCKHOLDERS</u>	12
<u>LEGAL MATTERS</u>	13
<u>EXPERTS</u>	13
<u>WHERE YOU CAN FIND ADDITIONAL INFORMATION</u>	13
<u>FORWARD-LOOKING STATEMENTS</u>	14

Table of Contents

RISK FACTORS

An investment in our common stock involves significant risks. You should carefully consider the risks and uncertainties described below and the other information in or incorporated by reference into this prospectus including our financial statements before deciding whether to buy shares of our common stock. The trading price of our common stock could decline due to any of these risks, and you could lose part or all of your investment.

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

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

We are currently involved in a patent interference action and a patent opposition action involving RadioTherapeutics Corporation, a division of Boston Scientific 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 a division of Boston Scientific Corporation, in which the validity of a patent claim previously issued to us was called into question. The claims at issue in the interference cover a radiofrequency ablation device having an array of deployable electrodes effective, in a deployed state, to define a tissue ablation volume. In February 2001, the Patent and Trademark Office 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. On September 27, 2002, the Patent and Trademark Office Board of Patent Appeals and Interferences issued a final decision finding that RadioTherapeutics had failed to establish priority of invention over RITA's established invention date and, therefore, were not themselves entitled to any patent claims in the interference. It also affirmed the earlier preliminary decision, described above, regarding claim 32. On October 16, 2002, RadioTherapeutics filed an action in the United States District Court for the Northern District of California seeking to reverse the Patent and Trademark Office Board of Patent Appeals' priority decision, to affirm its decision regarding claim 32, and to initiate a new interference between certain issued patent claims licensed to RadioTherapeutics and certain of RITA's patent claims. Final determination of these patent interference proceedings may take several years. If the United States District Court reverses the decision of the Patent and Trademark Office Board of Patent Appeals as to RadioTherapeutics' entitlement to priority, and we were found to infringe RadioTherapeutics' patent claims and 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. If the District Court affirms the Patent and Trademark Board's decision regarding claim 32 or if RadioTherapeutics prevails on its new interference, we could lose one or more of our issued patent claims.

In March 2000, RadioTherapeutics filed an opposition to our European Patent No. 0777445 before the European Patent Office. This patent 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 European Patent No. 0777445. Both parties have appealed this ruling and 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.

Table of Contents

We have been sued for patent infringement by Boston Scientific Corporation and two of its divisions, UneMed Corporation and their respective licensors. If we do not prevail in these lawsuits or any that may be brought in the future, 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 divisions 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. RadioTherapeutics filed a first amended complaint on October 30, 2002 adding to the litigation a second patent assigned to the University of Nebraska and licensed to RadioTherapeutics. Also, in a separate action initiated on July 9, 2002, Boston Scientific Corporation and the University of Kansas filed a complaint against us alleging that certain of our products infringe a patent assigned to the University of Kansas and licensed by Boston Scientific. 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 lawsuits 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.

Although we anticipate that our operating expenses will begin to stabilize in absolute dollars over the next several quarters, to become profitable we must continue to increase our sales and manage our operating expenses. 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 \$13.5 million in 2002, \$13.0 million in 2001, \$12.8 million in 2000 and \$7.5 million in 1999. At December 31, 2002, we had an accumulated deficit of approximately \$67.9 million.

In addition, we have incurred significant expenses related to disputes concerning our intellectual property position, including a lawsuit filed by us against RadioTherapeutics Corporation and anticipate that these expenses will continue to be significant while these actions are ongoing. If our current patent actions are not settled in the near term, the timeframe to achieve profitability may be delayed.

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.

Table of Contents

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

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

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

We currently lack long-term data regarding the safety and efficacy of our products and may find that long-term data does not support our short-term clinical results or that further short or long-term studies do not support the safety and efficacy of our products in various applications.

Our products are supported by clinical follow-up data in published clinical reports or scientific presentations covering periods from five months to three 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. That could result in additional 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

Table of Contents

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 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 (for example, our distributor in Japan has built up a significant inventory of product in anticipation of the receipt of product and reimbursement approvals);

obtaining reimbursement for procedures using our devices in some foreign markets;

the burden of complying with complex and changing foreign regulatory requirements;

longer accounts receivable collection time;

significant currency fluctuations, which could cause our distributors to reduce the number of products they purchase from us because the cost of our products to them could increase relative to the price they could charge their customers;

reduced protection of intellectual property rights in some foreign countries; and

contractual provisions governed by foreign laws.

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

We are substantially dependent on a limited number of significant distributors in our international markets, and if we lose these distributors and fail to attract additional distributors, our international revenues could decline. ITX Corporation, formerly known as Nissho Iwai Corporation, is our primary distributor in Asia. It accounted for 55 percent of our international revenues in 2002 and 31 percent of our international revenues in 2001. M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, accounted for 17 percent of our international revenues for 2002 and 17 percent of our international revenues for 2001. Because international revenues accounted for 26 percent of our total revenues for 2002 and these two distributors represented 72 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

Table of Contents

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.

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. 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 recent quarters we have significantly increased our reserve for uncollectible accounts to address the risk associated with longer collection periods that have arisen principally with our European distributors. If difficult economic conditions persist, and our collection experience worsens as a result, we may need to further adjust our reserve for uncollectible accounts in future periods, thereby reducing 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. For example, 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.

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. Even though in February of 2002 we were successful in establishing a new CPT code related to liver procedures with the American Medical Association, a payor still may not reimburse adequately for the procedure or product. We are aware of cases in which reimbursement for liver procedures using our system has been denied. 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. In addition, reimbursement levels are highest when our products are used in an inpatient setting. If there is a trend toward the use of our products on an outpatient basis, reimbursement levels could be lower and physician use could decline.

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

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form S-3/A

We are highly dependent on the principal members of our management, operations and research and development staff, including our Chief Executive Officer and Chief Financial Officer. Our future

Table of Contents

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 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;

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;

Table of Contents

changes in estimates of our financial performance or changes in recommendations by securities analysts; and

general market conditions, particularly for companies with small market capitalizations.

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

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

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

We are dependent on 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 business.

To date, there has been only one supplier available to provide us with a component that we include in our disposable devices. Recently, we have identified a second supplier, but we have not yet fully qualified them. However, a disruption in the supply of this component is still possible and could negatively affect revenues. If we were unable to remedy a disruption in supply of this component within twelve months, we could be required to redesign the handle of our disposable devices, which could divert engineering resources from other projects or add to product costs. In addition, a new or supplemental filing with applicable regulatory authorities may require clearance prior to our marketing a product containing new materials. This clearance process may take a substantial period of time, and we may be unable to obtain necessary regulatory approvals for any new material to be used in our products on a timely basis, if at all. This could also create supply disruptions that could negatively affect our business.

We are dependent on two suppliers as our only sources of an accessory device used in conjunction with our Starburst XLi line of disposable devices, and any disruption in the supply of these devices could negatively affect our revenues.

Until December of 2002, we had only one supplier available to provide us with accessory infusion pumps used in conjunction with our Starburst XLi line of disposable devices. During the quarters ended September 30, 2002 and December 31, 2002, we experienced shortages in the supply of

Table of Contents

accessory infusion pumps. In December of 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 of 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.

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

We are dependent on two third-party suppliers to produce our generators. While we have agreements with both of these suppliers, any delay in shipments of generators to us could result in our failure to ship generators to customers and could negatively affect revenues.

Complying with the FDA and other domestic and international regulatory authorities is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We are subject to a host of federal, state, local and international regulations regarding the manufacture and marketing of our products. In particular, our failure to comply with FDA regulations could result in, among other things, seizures or recalls of our products, an injunction, substantial fines and/or criminal charges against our employees and us. The FDA's medical device reporting regulations require us to report any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned in a way that would be likely to cause or contribute to a death or serious injury if the malfunction recurred.

Sales of our products outside the United States are subject to foreign regulatory requirements that vary from country to country. The time required to obtain approvals from foreign countries may be longer than that required for FDA approval or clearance, and requirements for foreign licensing may differ from FDA requirements. For example, some of our newer products have not received approval in Japan. Any failure to obtain necessary regulatory approvals for our new products in foreign countries could negatively affect revenues.

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

Unless we are exempt, we must obtain the appropriate FDA approval or clearance before we can sell a new medical device in the United States. Obtaining this approval or clearance can be a lengthy and time-consuming process. To date, all of our products have received clearances from the FDA through premarket notification under Section 510(k) of the Federal Food, Drug and Cosmetic Act. However, if the FDA requires us to submit a new premarket notification under Section 510(k) for modifications to our existing products, or if the FDA requires us to go through a lengthier, more rigorous examination than we now expect, our product introductions or modifications could be delayed or canceled which could cause our revenues to be below expectations. The FDA may determine that future products will require the more costly, lengthy and uncertain premarket approval process. In addition, modifications to medical device products cleared via the 510(k) process may require a new 510(k) submission. We have made minor modifications to our system. Using the guidelines established by the FDA, we have determined that some of these modifications do not require us to file new 510(k) submissions. If the FDA

Table of Contents

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, uterus and breast, for our current products. The FDA may either deny these requests outright, require additional extensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of approval or clearance. Therefore, obtaining necessary approvals or clearances for these additional applications could be an expensive and lengthy process. In addition, in the course of the FDA process leading to clearance or approval for a new indication, FDA may request an advisory panel meeting or meetings to discuss the clinical data, the appropriate study design or other criteria for clearance or approval. In the event that the advisory panel advises FDA that the clinical data are inadequate or the study design or other criteria are inappropriate, and FDA concurs, the FDA clearance or approval process could be lengthened and anticipated revenues from that new indication would be delayed.

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

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

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

Because our executive officers and directors, and their respective affiliates, own approximately 26 percent of our outstanding common stock as of December 31, 2002, 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.

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

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

THE COMPANY

RITA is a medical device company that develops, manufactures and markets minimally invasive products to treat patients with solid cancerous or benign tumors. Our proprietary system uses radiofrequency energy to heat tissue to a high enough temperature to ablate it, or cause cell death. The RITA system includes radiofrequency generators and a family of disposable needle electrode devices that deliver controlled thermal energy to the targeted tissue.

Table of Contents

We are currently focused on addressing the liver cancer market and are increasing our focus on the bone cancer market. We believe our system offers a viable option to patients who previously had few or no effective alternatives. We estimate that the worldwide market opportunity for the radiofrequency ablation of unresectable liver cancer is approximately \$500 million annually and \$600 million annually for the radiofrequency ablation of painful tumors that have metastasized or spread to the bone.

In addition to liver and bone cancer, we believe that our minimally invasive technology may in the future be applied to the treatment of other types of cancerous or benign tumors, including tumors of the lung, breast, uterus, prostate and kidney. We believe the market opportunity for these additional applications exceeds \$1 billion annually.

We have received regulatory clearance for the sale of our products in major markets worldwide, including the United States. In March 2000, RITA became the first radiofrequency ablation company to receive specific FDA clearance for unresectable liver lesions in addition to its previous general FDA clearance for the ablation of soft tissue. In October 2002, RITA again became the first company to receive specific FDA clearance, this time, for the palliation of pain associated with metastatic bone lesions. Our system is distributed in the United States through our direct sales force and internationally through distribution partners. Since our product launch, we have sold over 45,000 disposable devices.

RITA has a broad patent portfolio. As of December 31, 2002, we had 48 issued patents worldwide and more than 60 United States and foreign patent applications pending. The issued patents cover, among other things, deployable multi-array electrode technology and temperature feedback technology.

RITA was incorporated in California on January 6, 1994 and reincorporated in Delaware on May 9, 2000. Our principal executive offices are located at 967 N. Shoreline Blvd. Mountain View, California 94043 and our telephone number at that location is (650) 314-3400. References in the prospectus to we, our, us, the Company and RITA refer to RITA Medical Systems, Inc., a Delaware corporation. Information contained in our Web site does not constitute part of this prospectus.

USE OF PROCEEDS

The proceeds from the sale of the shares of common stock offered pursuant to this prospectus are solely for the account of the selling stockholders. We will not receive any of the proceeds from the sale of these shares.

ISSUANCE OF COMMON STOCK TO SELLING STOCKHOLDERS

On January 24, 2003, we issued 2,045,453 shares of our common stock to the selling stockholders in a private placement transaction. This prospectus covers the resale of these shares of common stock.

PLAN OF DISTRIBUTION

We are registering shares on behalf of the selling stockholders. We are required to keep the Registration Statement on Form S-3 of which this prospectus is a part effective until the earlier of (i) the date when the selling stockholders have sold all the shares pursuant to the Registration Statement on Form S-3, (ii) the date on which all of the shares may be sold pursuant to Rule 144 under the Securities Act of 1933, as amended or (iii) January 24, 2005. As used in this prospectus, selling stockholders includes donees and pledgees selling shares received from a named selling stockholder after the date of

Table of Contents

this prospectus. All costs, expenses and fees in connection with the registration of the shares offered by this prospectus will be borne by us. Brokerage commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by the selling stockholders. Sales of shares may be effected by selling stockholders from time to time in one or more types of transactions (which may include block transactions) on the Nasdaq National Market, or otherwise, in negotiated transactions, through put or call options transactions relating to the shares, through short sales of shares, or a combination of such methods of sale, at market prices prevailing at the time of sale, or at negotiated prices. Such transactions may or may not involve brokers or dealers.

The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. The selling stockholders may effect such transactions by selling shares directly to purchasers or to or through broker-dealers, which may act as agents or principals. Such broker-dealers may receive compensation in the form of discounts, concessions, or commissions from the selling stockholders and/or the purchasers of shares for whom such broker-dealers may act as agents or to whom they sell as principal, or both (which compensation as to a particular broker-dealer might be in excess of customary commissions).

To the extent required, we may amend or supplement this prospectus from time to time to describe a specific plan of distribution. In connection with distributions of the shares or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with those transactions, broker-dealers or other financial institutions may engage in short sales of the common stock in the course of hedging the positions they assume with the selling stockholders. The selling stockholders also may sell the common stock short and redeliver the shares to close out those short positions. The selling stockholders also may enter into option or other transactions or the creation of one or more derivative securities with broker-dealers or other financial institutions that require the delivery to the broker-dealer or other financial institution of shares offered by this prospectus, which shares the broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect those transactions). The selling stockholders also may pledge or hypothecate shares to a broker-dealer or other financial institution, and, upon a default, that broker-dealer or other financial institution may effect sales of the pledged shares pursuant to this prospectus (as supplemented or amended to reflect that transaction). In effecting sales, broker-dealers or agents engaged by the selling stockholders may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the selling stockholders in amounts to be negotiated immediately prior to the sale.

The selling stockholders and any broker-dealers that act in connection with the sale of the common stock may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act of 1933, and any commission received by them and any profit on the resale of the shares of common stock as principal might be deemed to be underwriting discounts and commissions under the Securities Act of 1933. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares against some liabilities, including liabilities arising under the Securities Act of 1933. Liabilities under the federal securities laws cannot be waived.

The selling stockholders will be subject to prospectus delivery requirements under the Securities Act of 1933. In the event of a distribution of shares by a selling stockholder, the selling stockholder, any selling broker or dealer and any affiliated purchasers may be subject to Regulation M under the Securities Exchange Act of 1934, which would generally prohibit these persons from bidding for or purchasing any security that is the subject of the distribution until his or her participation in that distribution is completed. In addition, Regulation M generally prohibits any stabilizing bid or stabilizing purchase for the purpose of pegging, fixing or stabilizing the price of common stock in connection with this offering.

Table of Contents

Selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided they meet the criteria and conform to the requirements of such Rule.

The shares of common stock offered pursuant to this prospectus were originally issued by us to the selling stockholders on January 24, 2003 in a private placement transaction. As part of that transaction, we agreed to indemnify each selling stockholder against certain liabilities, including liabilities arising under the Securities Act that could arise in connection with the sale of the shares by the selling stockholders. The selling stockholders have also agreed to indemnify us against certain liabilities arising under the Securities Act.

SELLING STOCKHOLDERS

The following table sets forth certain information as of January 31, 2003 with respect to the selling stockholders. We are unable to determine the exact number of shares that actually will be sold by the selling stockholders. We do not know how long the selling stockholders will hold the shares before selling them.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the tables below have sole voting and investment power with respects to all shares of common stock that they beneficially own, subject to applicable community property laws. We have based our calculation of the percentage of beneficial ownership on 17,199,959 shares of common stock outstanding upon completion of this offering.

Asterisks represent beneficial ownership of less than one percent. No selling stockholder has had any material relationship with us or any of our predecessors or affiliates within the last three years. None of the selling stockholders are broker/dealers or affiliates of broker/dealers.

Selling Stockholder	Shares Beneficially Owned Prior to the Offering		Shares Offered by this Prospectus	Shares Beneficially Owned After the Offering	
	Number	Percent		Number	Percent
	SF Capital Partners Ltd. 3600 South Lake Drive St. Francis, WI 53235	1,136,363	6.6%	1,136,363	1,136,363
RIVERVIEW GROUP, LLC c/o Millennium Partners, L.P.	455,245	2.6%	454,545	455,245	2.6%

666 5th Avenue, 8th Floor

New York, NY 10103

Table of Contents

<u>Selling Stockholder</u>	<u>Shares Beneficially</u>		<u>Shares Offered by</u>	<u>Shares Beneficially</u>	
	<u>Owned Prior</u>			<u>Owned After</u>	
	<u>to the Offering</u>			<u>the Offering</u>	
	<u>Number</u>	<u>Percent</u>	<u>this Prospectus</u>	<u>Number</u>	<u>Percent</u>
BAYSTAR CAPITAL II, L.P. c/o BayStar Capital 80 E. Sir Francis Drake, Suite 2B Larkspur, CA 94939	227,273	1.3%	227,273	227,273	1.3%
BAYSTAR INTERNATIONAL II, Ltd. c/o BayStar Capital 80 E. Sir Francis Drake, Suite 2B Larkspur, CA 94939	227,272	1.3%	227,272	227,272	1.3%

LEGAL MATTERS

The validity of the common stock offered hereby will be passed upon for RITA by Venture Law Group, A Professional Corporation, 2775 Sand Hill Road, Menlo Park, California 94025. Mark B. Weeks, a director of Venture Law Group, is our Secretary.

EXPERTS

The consolidated financial statements incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2001 have been so incorporated on reliance on the report of PricewaterhouseCoopers LLP, independent accountants, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

This prospectus is part of a Registration Statement on Form S-3 that we filed with the Securities and Exchange Commission. Certain information in the registration statement has been omitted from this prospectus in accordance with the rules of the SEC. We file our annual, quarterly and special reports, proxy statements and other information with the SEC. You can inspect and copy the registration statement as well as reports, proxy statements and other information we have filed with the SEC at the public reference room maintained by the SEC at 450 Fifth Street, NW,

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form S-3/A

Washington, D.C. 20549, and at the following Regional Offices of the SEC: Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661-2511 and the Woolworth Building, 233 Broadway Street, New York, New York. You can obtain copies from the public reference room of the SEC at 450 Fifth Street, NW, Washington, D.C. 20549 upon payment of certain fees. You can call the SEC at 1-800-732-0330 for further information about the public reference room. We are also required to file electronic versions of these documents with the SEC, which may be accessed through the SEC's World Wide Web site at <http://www.sec.gov>. Our common stock is quoted on the Nasdaq National Market. Reports, proxy and information statements and other information concerning RITA may be inspected at the Nasdaq Stock Market at 1735 K Street, NW, Washington, D.C. 20006.

The SEC allows us to incorporate by reference certain of our publicly-filed documents into this prospectus, which means that information included in these documents is considered part of this prospectus. Information that we file with the SEC subsequent to the date of this prospectus will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, until the selling stockholders have sold all the shares.

Table of Contents

The following documents filed with the SEC are incorporated by reference in this prospectus:

1. Our Annual Report on Form 10-K for the year ended December 31, 2001 dated March 28, 2002 (File No. 000-30959).
2. Our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2002 dated May 15, 2002, for the quarter ended June 30, 2002 dated August 14, 2002 and for the quarter ended September 30, 2002 dated November 14, 2002.
3. Our Proxy Statement dated May 3, 2002, filed on April 26, 2002 in connection with our May 30, 2002 Annual Meeting of Stockholders (File No. 000-30959).
4. The description of our common stock set forth in our Registration Statement on Form 8-A, filed with the SEC on July 7, 2000 (File No. 000-30959).
5. The description of our Preferred Stock Purchase Rights set forth in our Registration Statement on Form 8-A filed with the SEC on August 7, 2001 (File No. 000-30959).

All documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended after the date of this registration statement and prior to the effectiveness of this registration statement, shall be deemed to be incorporated by reference.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, other than exhibits to such documents. You should direct any requests for documents to Donald Stewart, 967 N. Shoreline Blvd. Mountain View, CA 94043, (650) 314-3400.

FORWARD-LOOKING STATEMENTS

This prospectus contains or incorporates by reference certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including those identified by the words believes, expects, may, will, should, seeks, pro forma, anticipates and similar expressions. These forward-looking statements include, among others, statements regarding:

the trends we see in our business and the markets in which we operate;

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form S-3/A

the features, functionality and market acceptance of our products (including newly launched products and services); and

our expectations for our future operating results and cash flows.

These statements are subject to risks and uncertainties, including those set forth in the **Risk Factors** section beginning on page 1, and actual results could differ materially from those expressed or implied in these statements. All forward-looking statements included in this prospectus are made as of the date hereof. We assume no obligation to update any such forward-looking statement or reason why actual results might differ except as required by the Exchange Act. You should carefully review the section entitled **Risk Factors** and of our subsequently filings with the SEC.

Table of Contents**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution**

The following table sets forth the costs and expenses payable by the registrant in connection with the sale and distribution of the shares of common stock being registered. Selling commissions and brokerage fees and any applicable transfer taxes and fees and disbursements of counsel for the selling stockholders are payable individually by the selling stockholders. All amounts shown are estimates except the SEC registration fee.

	Amount
	To be Paid
SEC registration fee	\$ 965.37
Legal fees and expenses	60,000.00
Accounting fees and expenses	30,000.00
Transfer agent fees	800.00
Miscellaneous expenses	540,000.00
Total	\$ 631,765.37

Item 15. Indemnification of Directors and Officers

Our Amended Bylaws provide generally for indemnification of our officers, directors, agents and employees to the extent authorized by the General Corporation Law of the State of Delaware ("DGCL"). Pursuant to Section 145 of the DGCL, a corporation generally has the power to indemnify its present and former directors, officers, employees and agents against expenses incurred by them in connection with any suit to which they are, or are threatened to be made, a party by reason of their serving in such positions so long as they acted in good faith and in a manner they reasonably believed to be in, or not opposed to, the best interests of a corporation, and with respect to any criminal action, they had no reasonable cause to believe their conduct was unlawful. With respect to suits by or in the right of a corporation, however, indemnification is not available if such person is adjudged to be liable for negligence or misconduct in the performance of his duty to the corporation unless the court determines that indemnification is appropriate. In addition, a corporation has the power to purchase and maintain insurance for such person. The statute also expressly provides that the power to indemnify that it authorizes is not exclusive of any rights granted under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise.

As permitted by Section 102 of the DGCL, our stockholders have approved and incorporated provisions into Article XIII of our Amended and Restated Certificate of Incorporation and Article VI of our Amended Bylaws eliminating a director's personal liability for monetary damages to us and our stockholders arising from a breach of a director's fiduciary duty, except for liability under Section 174 of the DGCL or liability for

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form S-3/A

any breach of the director's duty of loyalty to us or its stockholders, for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law or for any transaction in which the director derived an improper personal benefit. RITA has also entered into agreements with its directors and certain of its officers that will require RITA, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors to the fullest extent not prohibited by law.

II-1

Table of Contents

In connection with this offering, the selling stockholders have agreed to indemnify RITA, its directors and officers and each such person who controls RITA, against any and all liability arising from inaccurate information provided to RITA by the selling stockholders and contained herein up to a maximum of the net proceeds received by the selling stockholders from the sale of their shares hereunder.

Item 16. Exhibits

Exhibit

Number	Description of Exhibit
4.2*	Stock Purchase Agreement with SF Capital Partners Ltd., dated January 24, 2003
4.3*	Stock Purchase Agreement with RIVERVIEW GROUP, LLC, dated January 24, 2003
4.4*	Stock Purchase Agreement with BAYSTAR CAPITAL II, L.P. dated January 24, 2003
4.5*	Stock Purchase Agreement with BAYSTAR INTERNATIONAL II, Ltd., dated January 24, 2003
5.1*	Opinion of Venture Law Group, A Professional Corporation
23.1	Consent of PricewaterhouseCoopers, LLP, Independent Accountants
23.2*	Consent of Counsel (included in Exhibit 5.1)
24.1*	Power of Attorney (see page II-4)

* Previously filed.

Item 17. Undertakings

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement to include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form S-3/A

report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

II-2

Table of Contents

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions referred to in Item 15 above or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted against the registrant by such director, officer or controlling person in connection with the securities being registered hereunder, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Mountain View, State of California, on the 5th day of February, 2003.

**RITA MEDICAL SYSTEMS,
INC.**

By: /s/ DONALD
STEWART

Donald Stewart

Chief Financial
Officer and Vice
President, Finance
and Administration

Table of Contents

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
* <hr/> Barry Cheskin	President, Chief Executive Officer and Director (Principal Executive Officer)	February 5, 2003
/s/ DONALD STEWART <hr/> Donald Stewart	Chief Financial Officer and Vice President, Finance and Administration (Principal Accounting Officer)	February 5, 2003
* <hr/> Vincent Bucci	Director	February 5, 2003
* <hr/> Janet Effland	Director	February 5, 2003
* <hr/> John Gilbert	Director	February 5, 2003
* <hr/> Scott Halsted	Director	February 5, 2003
* <hr/> Gordon Russell	Director	February 5, 2003
* <hr/> F. Thomas (Jay) Watkins	Director	February 5, 2003

*By: /s/ DONALD
STEWART

Donald Stewart
Attorney-in-Fact