RITA MEDICAL SYSTEMS INC
Form 10-K
March 28, 2003
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2002

OR

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

For the transition period from to

Commission file number: 000-30959

RITA MEDICAL SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3199149**

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

967 N. Shoreline Blvd.

Mountain View, CA 94043

(Address of principal executive offices, including zip code)

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

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $0.001 par value

(Title of Class)

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 than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $94,504,062 as of June 28, 2002, based upon the closing sale price on the Nasdaq National Market reported for such date. Shares of Common Stock held by each officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

There were 17,253,361 shares of the registrant s Common Stock issued and outstanding as of February 28, 2003.

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RITA Medical Systems, Inc.

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2002

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PART I

Item 1. Business.

Overview

We are 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.

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 minimal ly 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 sale 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 lesions involving bone. 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 63 United States and foreign patent applications pending. The issued patents cover, among other things, deployable multi-array electrode technology and temperature feedback technology.

Market Opportunity

Cancer Market

Millions of people throughout the world are afflicted with cancer. Only heart disease kills more people in the United States every year.

Cancer can be categorized into two broad groups: solid tumor cancers, such as liver, lung, bone, breast, prostate and kidney cancers as well as hematologic or blood-borne cancers, such as lymphomas and leukemias. Approximately 90 percent of all cancers are solid tumor cancers.

Liver Cancer Market

There are two forms of liver cancer: primary and metastatic. Primary liver cancer originates in the liver. Secondary, or metastatic, liver cancer originates elsewhere in the body and spreads to the liver. A significant number of patients treated for primary and metastatic liver cancer experience a recurrence of their disease.

The worldwide incidence of primary liver cancer is estimated to be one million new patients each year. The vast majority of primary liver cancer patients are located outside the United States, particularly in Asia and Southern Europe. Approximately 90 percent of patients diagnosed with primary liver cancer will die within five years. Due to a rise in the number of worldwide cases of Hepatitis B and C, both of which are correlated to the development of primary liver cancer, we believe that the incidence of primary liver cancer may increase in the future.

It is estimated that there are almost as many cases of metastatic liver cancer worldwide as there are cases of primary liver cancer and approximately 300,000 annual cases in the United States alone. The liver is one of the most common sites for the spread of cancer. For example, one of the most common forms of primary cancer is colorectal cancer, and approximately 60 percent of these patients will develop metastatic liver tumors. Due to numerous factors, including the absence of viable treatment options, metastatic liver cancer often causes death.

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Treatment Options for Liver Cancer

The prognosis for primary and secondary liver cancer is poor. Although limited treatment options are currently available for liver cancer, they are typically ineffective, are generally associated with significant side effects and can even cause death. Traditional treatment options include surgery, chemotherapy, cryosurgery, percutaneous ethanol injection and radiation therapy.

Surgery

While surgery is considered the gold standard treatment option to address liver tumors, approximately 70 to 90 percent of liver cancer patients are unresectable, which means they do not qualify for surgery. This is most often due to the following:

Operative risk: limited liver function or poor patient health threatens survival as a result of the surgery; or

Technical feasibility: the proximity of a cancerous tumor to a critical organ or artery, or the size, location on the liver or number of tumors makes surgery infeasible.

For the few patients who qualify for surgery, there are significant complications related to the procedure and the operative mortality rate is two percent. One-year recurrence rates following surgery have been reported to be as low as 12 percent; however, when tumors recur, surgery typically cannot be repeated.

Chemotherapy

Chemotherapy uses drugs to kill cancer cells. Chemotherapy can be used systemically or locally. In systemic chemotherapy, drugs are delivered throughout the body. In local chemotherapy, drugs are delivered directly to the liver tumor. Systemic chemotherapy is not considered an effective means of treating liver cancer. In some cases, treatment regimens using localized chemotherapy in addition to systemic treatment have been reported to increase the efficacy of these alternatives to a limited extent.

Chemotherapy causes significant side effects in the majority of patients, including loss of appetite, nausea and vomiting, hair loss and ulcerations of the mouth. In addition, chemotherapy can damage the blood-producing cells of the bone marrow, leading to a low blood cell count. As a result, chemotherapy patients have an increased chance of infection, bleeding or bruising after minor cuts or injuries, and fatigue or shortness of breath.

Cryosurgery

Cryosurgery is the destruction of cancer cells using sub-zero temperatures in an open surgical procedure. During cryosurgery, multiple stainless steel probes are placed into the center of the tumor and liquid nitrogen is circulated through the end of the device, creating an ice ball. Cryosurgery involves a cycle of treatments in which the tumor is frozen, allowed to thaw and then refrozen.

While cryosurgery is considered to be relatively effective with one-year local recurrence rates of approximately 10 percent, we believe adoption of this procedure has been limited by the following factors:

- it is not an option for patients who cannot tolerate an open surgical procedure;
- it involves significant complications which are similar to other open surgical procedures, as well as liver fracture and hemorrhaging caused by the cycle of freezing and thawing;
- it is associated with mortality rates estimated to be between one and five percent; and
- it is expensive compared to other alternatives.

Percutaneous Ethanol Injection

Percutaneous ethanol injection, or PEI, involves the injection of alcohol into the center of the tumor. The alcohol causes cells to dry out and cellular proteins to disintegrate, ultimately leading to tumor cell death.

While PEI can be successful in treating some patients with primary liver cancer and has a reported one-year local recurrence rate of approximately 13 percent, it is generally considered ineffective on large tumors as well as metastatic tumors. Patients are required to receive multiple treatments, making this option unattractive for many patients. Complications include pain and alcohol introduction to bile ducts and major blood vessels. In addition, this procedure can cause cancer cells to be deposited along the needle tract when the needle is withdrawn.

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Radiation Therapy

Radiation therapy uses high dose x-rays to kill cancer cells. Radiation therapy is not considered an effective means of treating liver cancer and is rarely used for this purpose.

Bone Metastases Market and Treatment Options

One of the most common sites of the spread of cancer or metastases is the bone. The worldwide incidence of bone metastases is estimated to be over 1 million cases each year with over 400,000 new cases in the U.S. alone. Most of these patients have breast and prostate cancer that eventually spreads to the bone, though some also have other types of cancer, such as kidney and lung cancer. More than 75% of patients with bone metastases report pain associated with this condition. The primary treatment options for painful bone metastases are analgesics and radiation therapy. Slightly over half of patients respond to conventional treatments such as these, but the remainder get inadequate relief or no relief at all.

The RITA Solution

Our Procedure

Our proprietary system is designed to use radiofrequency energy to provide a minimally invasive approach to ablating solid cancerous or benign tumors. Our system delivers radiofrequency energy to raise the temperature of cells above 45 to 50°C, causing cellular death.

The physician inserts the RITA disposable needle electrode device into the target body tissue, typically under ultrasound guidance. Once the device is inserted, pushing on the handle of the device causes a group of curved wires to be deployed from the tip of the electrode. When the power is turned on, these wires deliver radiofrequency energy throughout the tumor. In addition, temperature sensors on the tips of the wires measure tissue temperature throughout the procedure. During the procedure, our system automatically adjusts the amount of energy delivered in order to maintain the temperature necessary to ablate the targeted tissue. For a typical five centimeter ablation using our latest product, the ablation process takes approximately ten minutes. When the ablation is complete, pulling back on the handle of the device causes the curved wire array to be retracted into the device so it can be removed from the body. Our disposable device can cauterize the tissue along the needle tract, which we believe kills any residual cancer cells that might be removed from the tumor.

Benefits of the RITA System

The benefits of our system include:

Effective Treatment Option. We believe that our system provides an effective treatment option to liver cancer patients who previously had few options available to effectively address their unresectable liver tumors. Further, our system provides an effective treatment option for patients whose tumors have metastasized to the bone and cause pain that cannot be adequately relieved by other means. In the future, our system may offer patients with other types of tumors a better treatment option.

Minimally Invasive Procedure. The RITA system offers physicians an effective minimally invasive treatment option with few side effects or complications. Our products can be used in an outpatient procedure that requires only local anesthesia, and patients are typically sent home the same day with a small bandage over the entry site. Alternatively, patients can be treated with just an overnight hospital stay either through a small puncture in the skin or laparoscopically through several small incisions. Compared to existing alternatives, we believe our minimally invasive procedure is cost effective and can result in reduced hospital stays.

Proprietary Array Design and Temperature Feedback Provide Procedural Control. Our array design enables the physician to predictably ablate large volumes of targeted tissue. In addition, our temperature feedback feature allows physicians to ensure that the temperature is high enough throughout the tissue to achieve cell death.

Repeat Treatments Possible. Cancer is a recurrent disease. However, due to the invasive nature of other treatment options, such as surgery, the majority of patients who undergo traditional therapies cannot be retreated in the event that new tumors appear or previously treated tumors reappear. Because of the minimally invasive nature of our procedure, patients treated with our system can often be retreated.

Broadly Applicable Technology. Our significant clinical experience with liver tumors and bone tumors as well as feasibility studies in other organs indicates that our technology may in the future be broadly applied to the ablative treatment of solid tumors in the lung, uterus, breast, prostate and kidney.

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While there are numerous benefits of our system, there are some side effects of treatment as well. Published reports on the use of the RITA system indicate low overall complication rates. These include ground-pad burns, which are burns that can occur when there is a concentration of heat at the ground-pad site, bleeding, abscesses and, in cases involving the treatment of bone tumors, fractures and nerve damage. Studies have also shown some recurrence of tumors following treatment with our system. However, in many cases where tumors recur, our procedure can be repeated. In rare cases, physician misuse of our system has resulted in patient deaths.

Our Business Strategy

Our goal is to be the leading provider of minimally invasive devices for the treatment of solid cancerous or benign tumors. To achieve this goal, we plan to do the following:

Increase Our Penetration of the Liver Cancer Market. We believe we can capitalize on the opportunity to increase our penetration of the market for the radiofrequency ablation of unresectable liver tumors, which is currently estimated to be $500 million annually. We intend to execute this strategy by doing the following:

Increase awareness among key physicians through sales, marketing and training programs including programs directed specifically at medical oncologists, who are a key referral source for this procedure;

Conduct additional clinical research to provide data supporting the expanded use of our products; and

Drive patient awareness with marketing efforts and an Internet site focused on educating patients on the benefits of the RITA system for liver cancer.

Expand the Application of Our Proprietary Technology to Markets Beyond Liver Cancer. We believe our minimally invasive proprietary technology can be broadly applied to the treatment of other types of cancerous and benign tumors, including tumors in the bone, lung, breast, prostate, uterus and kidney. We recently received FDA clearance for treating painful bone metastases and plan to expand our marketing efforts to capitalize on this opportunity. We plan to build on our extensive clinical experience in liver tumors as well as studies in additional organs to support the extension of our technology to additional applications in the future. We estimate that the market for these additional applications exceeds $1 billion annually.

Continue to Advance Technology. We intend to aggressively pursue ongoing research and development of additional products and technologies. We plan to continue to expand and improve our product offerings to better serve patients with solid cancerous or benign tumors whose needs are not met by existing treatments.

Our Technology and Products

Technology

All of our products are based on our proprietary radiofrequency technology that is used to ablate tissue in a controlled manner. A radiofrequency generator supplies energy through our disposable device placed within the targeted tissue. Our devices contain curved, space-filling arrays of wires which are deployed from the tip to allow the radiofrequency energy to be dispersed throughout the tumor.

Radiofrequency energy supplied by the generator produces ionic agitation, or cellular friction, in the tissue closely surrounding the electrode. This friction produces heat that can be used to predictably ablate volumes of tissue. To effectively ablate tissue, it must be heated to an approximate temperature of 45 to 50°C, or 113 to 122°F.

Our system is designed to permit the physician to set the desired treatment time and temperature at the beginning of the procedure. Once that temperature is reached, our proprietary temperature control technology automatically adjusts the energy supplied from the generator to maintain the optimal temperature within the tissue during the course of the procedure. We believe our system has the potential to provide a more effective ablation than competing technologies by providing critical tissue temperature feedback during the procedure.

Some of our products make use of saline to enhance the ablation process. This saline is used to irrigate the ablation site and is delivered through the curved array of wires in our devices. The use of saline can significantly increase the speed of the ablation treatment.

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Products

The RITA system consists of a radiofrequency generator and a family of disposable devices. The following chart summarizes our current product offerings.

	Product Name	Description	Year of Introduction	U.S. List Price
Disposable Devices:	Model 70	Creates a scalable 2 to 3 centimeter ablation. Compatible with the Model 500 generator.	1999	$ 1,100
	StarBurst	Creates a scalable 2 to 3 centimeter ablation. Compatible with the Model 1500 and 1500X generator.	2000	$ 1,100
	StarBurst XL	Creates a scalable 3 to 5 centimeter ablation. Compatible with the Model 1500 and 1500x generator.	2000	$ 1,440
	StarBurst Flex	Creates a scalable 3 to 5 centimeter ablation and has a flexible shaft. Compatible with the Model 1500 and 1500X generator.	2002	$ 2,195
	5 cm Starburst XLi	Creates a scalable 4 to 5 centimeter ablation. Compatible with the Model 1500 and 1500X generator; requires an accessory infusion pump for irrigation of saline.	2001	$ 2,195
	7 cm Starburst XLi	Creates a scalable 4 to 7 centimeter ablation. Compatible with the Model 1500 and 1500X generator; requires an accessory infusion pump for irrigation of saline.	2001	$ 2,495
Generators:	Model 500	50 Watt Generator	1997	$ 30,000
	Model 1500	150 Watt Generator	2000	$ 37,500
	Model 1500X	250 Watt Capable Generator with Field-Software Upgradeability	2002	$ 37,500

Disposable Devices

Our disposable devices all consist of needle shaped electrodes containing curved wire arrays that are deployed into the targeted body tissue. Each device contains several thermocouples, or temperature sensors, which provide feedback to the physician of the tissue temperature during the ablation and which allow the generator to automatically adjust the amount of radiofrequency energy so that the desired tissue temperature can be achieved.

Our disposable devices are available in different array sizes to allow the physician to create a spherical ablation volume of anywhere from two to seven centimeters. Three centimeters is slightly smaller than a ping-pong ball. Seven centimeters is approximately the size of a tennis ball. In addition, depending on product line, the devices are available in 10,12,15 or 25 centimeter lengths to allow physicians to access tumors that are

located more or less deeply within the body. Each disposable device is supplied with one or more ground pads to allow a return path for the flow of radiofrequency energy from the patient back to the generator. Sales of disposable devices accounted for 75% of sales for the year ended December 31, 2002, 78% of sales for the year ended December 31, 2001 and 67% of sales for the year ended December 31, 2000.

Generators

All of our generators employ an internal computer to assist the physician in safely and effectively controlling the delivery of radiofrequency during the ablation. In addition, each generator has a display to convey information to the physician while using the system. Our Model 1500 generators have the ability, using optional software running on a laptop computer, to display real-time, color-coded graphs of items such as power, and temperature and impedance to aid the user in controlling the system and to collect procedural information for the patient s record. Our Model 1500X generators also have the ability to have their software changed in the field through the insertion of a small card containing electronic memory circuits. Sales of generators accounted for 25% of sales for the year ended December 31, 2002, 22% of sales for the year ended December 31, 2001 and 33% of sales for the year ended December 31, 2000.

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Sales and Marketing

We have a geographically diverse customer base which includes the United States, Europe and Asia. Our customers include surgical oncologists, hepatobiliary surgeons, liver transplant surgeons, laparoscopists and interventional radiologists. We also target patient referral sources, including colorectal surgeons, radiation oncologists and medical oncologists. Revenue from customers in the United States totaled $12.9 million for the year ended December 31, 2002, $8.0 million for the year ended December 31, 2001 and $3.9 million for the year ended December 31, 2000. Revenue from customers outside of the United States totaled $4.5 million for the year ended December 31, 2002, $6.8 million for the year ended December 31, 2001 and $6.1 million for the year ended December 31, 2000.

In the United States, we market our products through a direct sales force consisting of approximately 25 field representatives with 4 regional managers. Overseas, we market our products through distribution partners. To date, we have entered into agreements with distributors in the major countries in Europe and Asia. RITA also has several full-time field representatives or managers who are responsible for directing, supporting and monitoring our international distributors activities.

Our marketing and sales efforts are directed at placing generators at key cancer centers and other leading medical centers worldwide and then working with those centers physicians to increase their usage of our disposable devices. We recognize that our predominant source of recurring revenue will be from our disposable devices, which can only be used once a generator is placed. To facilitate generator placement at medical centers, we have established a variety of programs, including volume discount and preferred customer discount programs. However, the majority of our systems are sold to our customers.

We plan to continue to drive physician adoption by increasing awareness of the RITA system among potential users. We have established relationships with leading physicians at prominent cancer and other leading medical institutions, many of whom we believe are now strong advocates of our products. To increase adoption of our system, we are involving these physicians in formal courses, doctor-to-doctor preceptorship programs and hands-on training programs. We also offer programs to assist our customers in marketing the benefits of the RITA system to referring clinical oncologists and colorectal surgeons. In addition, since cancer treatment options are often affected by patient choice, we are expanding public awareness in this area through a patient education Internet site that focuses on liver cancer.

Competition

The medical device industry is subject to intense competition. Accordingly, our future success will depend on our ability to meet the clinical needs of physicians, improve patient outcomes and remain cost-effective for payors. There are a limited number of treatment alternatives available to patients with liver cancer. The traditional treatment options include surgery, chemotherapy, cryosurgery, percutaneous ethanol injections and radiation therapy. There are a limited number of treatment options available to patients with painful bone metastases. These options include radiation therapy and analgesics. We do not believe any of these treatments are directly competitive with our products, as none are intended to use heat to ablate liver lesions or painful bone metastases. Further, these treatments generally have limited efficacy and/or applicability.

RadioTherapeutics Corporation, a division of Boston Scientific Corporation, and Radionics, a division of Tyco Healthcare, which is a division of Tyco International, are the two companies whose products compete directly with ours in the United States and overseas. Both companies offer systems that include a generator and disposable electrodes and use radiofrequency energy to ablate soft tissue. However, neither system is

designed to provide physicians with the temperature feedback throughout the tissue that we believe is important to help ensure successful tissue ablation.

We believe the principal competitive factors in our markets are:

- improved patient outcomes;
- the publication of favorable peer-reviewed clinical studies;
- acceptance by leading physicians;
- ease of use of our generators and electrode devices;
- sales and marketing capability;
- reimbursement levels to customers;
- regulatory approvals;
- timing and acceptance of product innovation;
- patent protection;

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product quality and reliability; and

cost effectiveness.

While there are several international companies using radiofrequency technology to treat cancer, we do not expect these companies to establish a meaningful presence in our core domestic market in the near future. If companies that currently sell products that utilize radiofrequency energy enter our market or products using microwave or laser or other thermal energy prove to be useful, competition could increase.

Third-Party Reimbursement

Establishing reimbursement for any new technology is a challenge in the current environment of cost containment and managed care. Currently hospitals are reimbursed for procedures using our products based on established general reimbursement codes. Physicians submit a patient case history and data supporting the applicability of our system to the patient s condition in order to obtain reimbursement. To date, we believe most of our physician and hospital customers in the United States have been successful in obtaining reimbursement from third-party payors of the costs related to our liver procedure. We are also aware that reimbursement levels are highest when our liver procedure is conducted by physicians on an inpatient basis. The American Medical Association has recently approved specific physician reimbursement codes for open, laparoscopic and percutaneous liver tumor ablation procedures that became effective in 2002. While the approval of specific physician reimbursement codes will not require insurance providers to reimburse physicians for procedures using our products, it will eliminate the need for extra supporting documentation and simplify the process for hospitals and physicians to obtain reimbursement. There is limited reimbursement experience with applications outside liver cancer and the reimbursement for those applications may not be as favorable.

Outside the United States, reimbursement procedures and policies are country-specific. We believe physicians in our international markets can be successful in obtaining reimbursement for procedures using our products, though significant effort on the part of the physicians is required. However, in countries where specific reimbursement codes are strictly required and have not yet been issued, reimbursement has been denied on that basis. In conjunction with our distributors, we are pursuing strategies to address reimbursement issues in international markets.

Clinical Research and Product Development

Our clinical research staff regularly works with clinicians and medical and academic institutions in the development of new technologies and the evaluation and testing of our products. These relationships are valuable in generating data necessary for regulatory compliance. Our research and development efforts are currently focused on the extension of our technology to address tumors of the breast, bone and uterus, and initial results of our bone, lung, uterine fibroid and breast clinical investigations have been published or presented.

We believe that we have a strong base of proprietary design, development and manufacturing capabilities. We have particular expertise in the core research and development areas relevant to the production of new disposable electrode devices for use in conjunction with our radiofrequency generators. We are working on a number of enhancements to our existing ablation products that we believe will further improve their usefulness and performance. During the past three fiscal years, we have spent the following amounts on company-sponsored research and development efforts: $5.1 million in 2002, $6.5 million in 2001 and $5.6 million in 2000.

Patents and Proprietary Technology

We believe that a key element of our competitive advantage depends on our ability to develop and maintain the proprietary aspects of our technology. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws to protect our intellectual property. As of, December 31, 2002, we had 48 issued patents worldwide and 63 United States and foreign patent applications pending. The issued patents cover, among other things, deployable multi-array electrode technology and temperature feedback technology. Our United States patents expire between 2012 and 2018. Our European-wide patent expires in 2015 and our Japanese patent expires in 2015.

Government Regulation

Our products are regulated in the United States by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDC Act, and require clearance of a premarket notification under Section 510(k) of the FDC Act or approval of a premarket approval application under Section 515 of the FDC Act by the FDA prior to commercialization. Material changes or modifications to medical devices, including changes to product labeling, are also subject to FDA review and clearance or approval. Under the FDC Act, the FDA regulates, among other things, the research, clinical testing, manufacturing, safety, effectiveness, labeling, storage, record keeping, advertising, distribution, sale and promotion of medical devices in the United States. Non-compliance with applicable requirements can result in, among other actions, warning letters, fines, injunctions, civil and criminal penalties against

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us, our officers, and our employees, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket approval or clearance for devices, withdrawal of marketing approvals and recommendation that we not be permitted to enter into government contracts.

Before a new device can be marketed in the United States, the manufacturer or distributor must obtain FDA clearance of a 510(k) premarket notification submission or FDA approval of a premarket approval application. It generally takes three to twelve months from the date of the submission to obtain clearance of a 510(k) submission, but it may take longer. The FDA is increasingly requiring a more rigorous demonstration of substantial equivalence, including clinical trials for some devices.

To date, all of our products have received 510(k) clearances or are exempt from the 510(k) clearance process. Our initial clearances in the United States were general in nature and allow our products to be marketed for the ablation of soft tissue. In March 2000, we received a specific 510(k) clearance from the FDA for the partial or complete ablation of nonresectable liver lesions. In October 2002, we received another specific 510(k) clearance, this time for the palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard pain therapy. While we have been successful to date in obtaining regulatory clearance of our products through the 510(k) notification process, if the FDA concludes that any product does not meet the requirements for 510(k) clearance, then a premarket approval would be required and the time required for obtaining regulatory approval would be significantly lengthened.

Once 510(k) clearance has been received, any products that we manufacture or distribute are subject to extensive and continuing regulation by the FDA. Modifications to devices, including changes to product labeling, cleared via the 510(k) process may require a new 510(k) submission. We have made some modifications to some of our devices and we believe that such modifications do not require the filing of new 510(k) submissions. If the FDA requires us to file a new 510(k) submission for any device modification, we may be prohibited from marketing the modified device until the 510(k) is cleared by the FDA.

We are required to register as a medical device manufacturer with the FDA and with the California Department of Health Services and to list our products with the FDA. As such, we are subject to inspection by both the FDA and the California Department of Heath and Safety for compliance with good manufacturing practices, quality systems regulations, and other applicable regulations, including labeling and the adulteration and misbranding provisions of the FDC Act. In addition, our manufacturing processes are required to comply with good manufacturing practices and quality system regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products.

We are also required to comply with medical device reporting regulations that require us to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury, or in which our product malfunctioned and, if the malfunction were to recur, it would be likely to cause or contribute to a death or serious injury. If the FDA believes that a company is not in compliance with the law or regulations, it can institute proceedings to, among other things, detain or seize products, order a recall, enjoin future violations or distributions and assess civil and criminal penalties against a company, its officers, and employees. We have filed medical device reports with the FDA related to skin burns primarily caused by a ground pad, arterial bleeding caused by improper needle placement and abscesses which resulted from the large volume of ablated tissue. We believe that none of these incidents were attributed to a device malfunction.

We are also subject to regulations and product registration requirements in many of the foreign countries in which we sell our products in the areas of product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. The time required to obtain marketing approval or clearance required by foreign countries may be longer or shorter than that required for FDA approval or clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements. Either our distributors or we have received registrations and approvals to market certain of our products in international markets that include the European Economic Area, Japan, Korea, Canada, Australia, New Zealand, and other countries.

The European Union has promulgated rules, under the Medical Devices Directive, or MDD, which require medical devices to bear the CE mark . The CE mark is an international symbol of adherence to quality assurance standards. We obtained MDD certification in December 1996. We received our ISO9001/EN46001 recertification in January 2000 and have instituted all the systems necessary to meet the Medical Device Directive, thus acquiring the ability to affix the CE mark to our devices and export our devices to any EC-member country. New devices may be required to meet additional requirements before we affix the CE mark.

Manufacturing

Our manufacturing process for electrodes includes the inspection, assembly, testing, packaging and external sterilization of finished products. Our generators are currently manufactured to our specifications by outside contractors.

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We devote significant attention to quality control of our products. We have established quality systems in conformance with the Quality System Regulation as mandated by the FDA. Our Mountain View, California facility received ISO 9001/EN46001 recertification in January 2000 and is in conformance with the European Medical Device Directive for sale of products in Europe.

Corporate History, Headquarters and Website Information

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. Our telephone number at that location is (650) 314-3400 and our website is www.ritamedical.com. We make our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports available free of charge on our website as soon as reasonably practicable after we file these reports with the Securities and Exchange Commission.

Employees

As of January 31 February 28, 2003, we had 856 full-time employees, including 44 in sales and marketing, 20 in manufacturing, 10 in research and development and 112 in general and administrative functions. From time to time, we also employ independent contractors to support our organization.

Item 2. Properties.

We are headquartered in Mountain View, California, where we lease one building with approximately 18,000 square feet of office, research and development and manufacturing space. The lease is noncancellable and expires in August 2004. We believe the facility is suitable and adequate to meet our current or foreseeable requirements through 2003 and that additional space will be available at commercially reasonable terms to meet future growth requirements. See also Note 4 in the Notes to Consolidated Financial Statements contained elsewhere in this Form 10-K.

Item 3. Legal Proceedings.

On July 16, 1999, the United States Patent and Trademark Office declared an interference involving us, which was instituted by RadioTherapeutics Corporation, a competitor of ours and now a division of Boston Scientific Corporation, in which the validity of a patent claim previously issued to us was called into question. The principal parties in the proceeding are RadioTherapeutics and RITA. 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 no. 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, affirm its decision regarding claim no. 32, and to initiate a new interference

between certain issued patent claims licensed to RadioTherapeutics and certain of the RITA s patent claims. The factual basis alleged to underlie the new interference proceeding is the claim that our patent and the patent licensed to RadioTherapeutics interfere. RadioTherapeutics seeks to invalidate our 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 Office Board of Patent Appeals decision regarding claim no. 32 or if RadioTherapeutics prevails on its new interference, we could lose one or more of our issued patent claims.

On July 9, 2002, Boston Scientific Corporation, the University of Kansas and the University of Kansas Medical Center Research Institute filed a complaint against us in United States District Court for the Northern District of California. The principal parties in the dispute are Boston Scientific Corporation, the University of Kansas, the University of Kansas Medical Center Research Institute and RITA. The factual basis alleged to underlie the claim is that certain of our products infringe a patent licensed by Boston Scientific from the University of Kansas. The complaint seeks unspecified monetary damages and injunctive relief.

On April 11, 2002, RadioTherapeutics 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 in United States District Court for the Northern District of California. The principal parties in the dispute are RadioTherapeutics, SciMed, the Board of

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Regents of the University of Nebraska, UneMed Corporation and RITA. The factual basis alleged to underlie the claim is that certain of our products infringe a patent licensed by UneMed and RadioTherapeutics and a patent owned by SciMed. The complaint seeks unspecified monetary damages and injunctive relief. 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.

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

We are also involved in a patent opposition pending before the European Patent Office. This opposition was instituted on March 2, 2000. The principal parties are RadioTherapeutics and RITA. This patent also covers the curvature of the array at the tip of our disposable devices. The factual basis alleged to underlie the claim is the allegation by RadioTherapeutics that our European patent is not valid. RadioTherapeutics seeks to invalidate our patent claim and to establish the patentability of the claims in their patent application. We seek to maintain the priority of our patent claim. On February 7, 2002, the European Patent Office determined that we are entitled to Patent No. 0777445 covering radiofrequency ablation technology, approving 27 claims. Both parties have appealed this ruling.

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

Item 4. Submission of Matters to a Vote of Security Holders.

Not applicable.

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PART II

Item 5. Market for Registrant s Common Equity and Related Stockholder Matters.

Our common stock is traded on the Nasdaq National Market under the symbol RITA . We commenced trading on July 27, 2000. The following table shows the high and low closing sales prices of our common stock by quarter for 2001 and 2002, and for January 1, 2003 through February 28, 2003, as reported by the Nasdaq National Market:

	HIGH	LOW
Year ended December 31, 2001		
First quarter	$ 9.50	$ 2.81
Second quarter	$ 5.44	$ 3.38
Third quarter	$ 5.41	$ 2.66
Fourth quarter	$ 6.67	$ 2.81
Year ended December 31, 2002		
First quarter	$ 10.05	$ 5.41
Second quarter	$ 10.25	$ 7.90
Third quarter	$ 9.77	$ 3.84
Fourth quarter	$ 7.04	$ 4.95
Year ended December 31, 2003		
First quarter (through February 28, 2003)	$ 5.71	$ 4.10

On February 28, 2003, the last reported sales price of our common stock on the Nasdaq National Market was $4.5813. As of February 28, 2003, there were 94 holders of our common stock. This does not include the number of persons whose stock is in the nominee or street name accounts through brokers. The market price of our common stock has been and may continue to be subject to wide fluctuations in response to a number of events and factors, such as quarterly variations in our operating results, announcements of technological innovations or new products by us or our competitors, changes in financial estimates and recommendations by securities analysts, the operating and stock performance of other companies that investors may deem comparable to us, and news reports relating to trends in our markets. These fluctuations, as well as general economic and market conditions, may adversely affect the market price for our common stock.

No dividends have been declared on our common stock. We currently intend to retain any future earnings to fund the development and growth of our business. It is not expected that any dividends will be declared on our capital stock in the foreseeable future.

On January 24, 2003, the Company issued 2,045,453 shares of its unregistered common stock at a price of $4.40 per share to SF Capital Partners Ltd., Riverview Group, LLC, Baystar Capital II, L.P., and Baystar International II, L.P. The Company netted approximately $8.3 million after issuance fees and expenses. The issuance was deemed to be exempt from registration under the Securities Act in reliance upon Section 4(2) thereof as transactions by an issuer not involving any public offering. On February 14, 2003, the Company s Registration Statement on Form S-3, which registered the shares of common stock sold to SF Capital Partners Ltd., Riverview Group, LLC, Baystar Capital II, L.P., and Baystar International II, L.P., was declared effective by the SEC.

Item 6. Selected Financial Data.

You should read the following selected financial data in conjunction with our financial statements and related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this Form 10-K. The annual data presented below is derived from our audited consolidated financial statements. Our audited consolidated statement of operations for the years ended December 31, 2002, 2001 and 2000 and our audited consolidated balance sheet at December 31, 2002 and 2001 are presented elsewhere in this Form 10-K. The information provided below is in thousands, except for per share data.

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	Years ended December 31,				
	2002	2001	2000	1999	1998
Statement of Operations Data:					
Sales	$ 17,393	$ 14,791	$ 10,010	$ 4,629	$ 1,137
Cost of goods sold	6,908	6,132	6,048	2,994	1,523
Gross profit (loss)	10,485	8,659	3,962	1,635	(386)
Operating expenses:					
Research and development	5,052	6,489	5,615	3,931	2,729
Selling, general and administrative	19,366	16,646	12,052	5,452	3,606
Total operating expenses	24,418	23,135	17,667	9,383	6,335
Loss from operations	(13,933)	(14,476)	(13,705)	(7,748)	(6,721)
Interest and other income (expense), net	434	1,516	898	238	(28)
Net loss	$ (13,499)	$ (12,960)	$ (12,807)	$ (7,510)	$ (6,749)
Net loss per share, basic and diluted	$ (0.91)	$ (0.90)	$ (1.99)	$ (9.33)	$ (10.10)
Shares used in computing net loss per share, basic and diluted	14,890	14,353	6,440	805	668

	December 31,				
	2002	2001	2000	1999	1998
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 12,835	$ 19,184	$ 40,057	$ 12,153	$ 7,644
Working capital	16,066	25,478	41,512	12,437	7,560
Total assets	24,166	35,834	46,270	15,705	9,009
Long-term obligations, net of current portion			180	1,854	
Convertible preferred stock and preferred stock warrants				38,516	28,337
Common stock and additional paid-in capital	88,540	88,474	88,435	3,652	165
Total stockholders equity (deficit)	20,603	32,145	42,647	(26,991)	(20,510)

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

This Management s Discussion and Analysis of Financial Condition and Results of Operations and other parts of this Form 10-K contain forward-looking statements that involve risks and uncertainties. Words such as anticipates , expects , intends , plans , believes , seeks , estim and similar expressions identify such forward-looking statements. These statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or forecasted. Factors that might cause such a difference include, but are not limited to, those discussed in the section entitled Factors That May Affect Future Results and those appearing elsewhere in this Form 10-K. 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.

Business Overview and Discussion of Known Trends

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 in the United States. Also in 2002, we received regulatory approval from the FDA to use our products to treat pain associated with bone tumors, greatly increasing the potential market for our products.

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Our products are sold in the United States through our direct sales force and internationally through distribution partners. For the year ended December 31, 2002, sales in the United States accounted for 74% of our total sales while sales in our international markets accounted for 26% of our total sales. We expect domestic sales to account for an increasing percentage the majority of total sales in future years due to our significant investment in our domestic sales force and because we expect only limited distribution of our premium-priced Starburst XLi family of disposable needles in international markets for the next several years of the favorable market environment. Also, we expect that inventory reductions by our distributors in Europe and Japan, coupled with ongoing reimbursement issues, to limit sales growth in these regions, at least for 2003. However, our international operations will continue to represent a significant, if decreasing, portion of our revenue because of the high incidence of primary liver cancer in Asian and European markets.

All of our revenue is derived from the sale of our disposable devices and radiofrequency generators. For the year ended December 31, 2002, 75% of our sales were derived from our disposable devices and 25% were derived from the sale of our generators. Generator revenue grew 34% in 2002 compared with 2001, while disposable product revenue grew by only 13% over the prior year period, primarily as a result of reduced disposable sales to our international distributors. Going forward, we will continue to focus on expanding our base of customer accounts and on increasing usage of our disposable products in our established accounts. As a result, we expect revenue from the sale of our higher-margin disposable devices to grow faster than revenue from the sale of our generators.

To date, essentially all of our revenue has come from products sold in the treatment of cancerous liver tumors. In 2002, however, we began to see some additional nominal revenue from the use of the RITA system sold for the treatment of patients with metastatic bone tumors, a market we expect to grow in 2003 and beyond. We are conducting research and clinical trials in other organs that may lead to additional sources of revenue in future years.

Our manufacturing costs consist of raw materials, including generators and ancillary hardware components produced for us by third-party suppliers, labor to produce our disposable devices and to inspect incoming, in-process and finished goods, sterilization performed by an outside service provider and general overhead expenses. Gross margins are affected by production volumes, average selling prices, the sales mix of higher-margin disposable devices versus generators and the mix of domestic direct sales versus international sales, which provide for standard distributor discounts. Our gross margin improved slightly in 2002, increasing to 60% from 59% in 2001, in response to the increasing percentages of domestic business in our sales mix and higher selling prices associated with our Starburst XLi family of disposable products, but was limited by charges associated with provisions for obsolete inventory. We believe our charges for obsolete product to be essentially complete. We expect gross margins to improve modestly in 2003 primarily as a result of improvements in our sales mix, the growing acceptance of our premium-priced Starburst XLi line of disposable devices, and reduced inventory reserve requirements.

For the year ended December 31, 2002, 21% of our operating expenses were related to research and development activities, down from 28% in 2001, with charges of $5.1 million compared with $6.5 million in the prior year period. We expect expenses for product development and clinical trials to remain stable in 2003, but legal expenses associated with our ongoing patent litigation are expected to significantly increase in 2003, resulting in higher reported research and development expense. Selling, general and administrative activities represented 79% of our operating expenses for the year, up from 72% in 2001, with charges of $19.4 million compared with $16.6 million in the prior year period. This increase resulted from investments in the expansion of our domestic sales force and international distribution support activities as well as physician training and patient awareness programs. Also, because we experienced collection difficulties with several of our international distributors in 2002, we increased our allowance for uncollectible accounts to 32% of gross trade receivables as of December 31, 2002, from 11% at December 31, 2001, further affecting growth in administrative expense. We plan to continue to invest in market growth and business development and as a result expect selling, general and administrative expenses to represent an increasing percentage of our operating expenses in 2003 and beyond. We also believe that the deterioration we experienced in international collections in 2002 will begin to stabilize in 2003. However, if we continue to experience difficulties with international collections we may need to further increase our allowance for uncollectible accounts in 2003, and may identify specific accounts that would be required to post a letter of credit or pay in advance to minimize credit risk to the Company.

Our working capital decreased to $16.1 million at December 31, 2002, from $25.5 million at December 31, 2001, primarily due to cash used to fund operations, although operating cash requirements were notably mitigated by a reduced investment in accounts and notes receivable. Our capital expenditures for 2002 totaled $0.9 million, down from $1.6 million in 2001, but we capitalized $1.8 million in legal costs incurred in defense of our patent rights during 2002, up from $0.3 million in 2001. We do not expect significantly increased capital expenditures in the near term, but capitalized legal costs are expected to grow significantly in 2003.

In connection with grants of stock options issued below fair market value to employees and options issued to non-employees, we have recorded deferred stock-based compensation as a component of stockholders equity. This stock-based compensation has been amortized as a charge to operations over the vesting periods of the options. We recorded amortization of deferred compensation of $0.5 million for the year ended December 31, 2002. As of December 31, 2002, all deferred stock-based compensation recorded by the Company has been fully amortized. We do not expect in the future to issue options below their fair market value, and therefore expect no further expenses associated with stock-based compensation.

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We incurred net losses of $13.5 million for the year ended December 31, 2002. As of December 31, 2002, we had an accumulated deficit of $67.9 million. Due to the high costs associated with continued research and development programs, expanded clinical research programs and increased sales and marketing efforts, we expect to incur net losses for the full year 2003, but losses should diminish through the first three quarters of the year, and we expect to be modestly profitable around the end of 2003 or the first part of 2004. Profitability beyond this time frame will depend on our success in expanding product usage in our current market and in developing new markets. To the extent current or new markets do not materialize in accordance with our expectations, our sales and profitability could be lower than expected and we may be unable to achieve or sustain profitability.

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

Critical Accounting Policies and Estimates

Management s Discussion and Analysis of Financial Condition and Results of Operations discusses the Company s consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We believe the following accounting policies have been critical in the preparation of our financial statements because they involve a high degree of judgment and complexity. We believe users of our financial statements, including potential and current investors, will find an explanation of these policies important to understanding our discussions of financial condition, results of operations and liquidity. A more extensive review of all accounting policies considered to be significant in the preparation of our financial statements appears in the Notes to the Consolidated Financial Statements included elsewhere in this Form 10-K.

Trade accounts receivable and allowance for doubtful accounts: We extend credit to our customers, who are primarily private companies in the United States, Europe and Asia. We perform ongoing credit evaluations of our customers financial condition and past transaction credit-worthiness and generally require no collateral. We maintain an allowance for doubtful accounts receivable based on our assessment of the likelihood of collection of individual accounts. This allowance may prove to be inadequate if collections fail to meet current estimates, which could occur as a result of general economic conditions or the insolvency of specific key customers.

Inventories and inventory reserves: Inventories are stated at the lower of cost (determined on a first-in, first-out basis) or market. We maintain a reserve for obsolete, unmarketable or excess product based on assumptions regarding future demand or market conditions. We may be required to make further provisions to our reserve if market conditions prove less favorable than our current expectations, or if the introduction of new products renders existing products obsolete.

Litigation costs: In August 2001, we filed a complaint in the United States District Court for the Northern District of California against RadioTherapeutics Corporation. As discussed in Note 4 of our consolidated financial statements appearing elsewhere in this Form 10-K, the complaint alleges that RadioTherapeutics radiofrequency ablation products infringe six of our patents. The litigation costs thereby incurred in defense of our patents, approximately $2.1 million as of December 31, 2002, have been capitalized. Amortization of this asset has been matched to the remaining life of the six patents, approximately 10 years as of December 31, 2002. Although we expect a favorable outcome in this matter, an unsuccessful outcome would require an immediate charge to earnings of any remaining unamortized costs. It is probable that additional

litigation costs will be capitalized in future periods.

Contingencies: In addition to routine legal matters arising in the ordinary course of our business, we are involved in several matters relating to the defense of our patent rights or alleged infringement of the patent rights of others. While we believe that the

outcome of our outstanding legal proceedings, claims and litigation will not have a material adverse effect on our business, results of operations, financial condition or cash flows, such matters involve complex questions of fact and law and could involve significant costs and the diversion of resources to defend. Additionally, the results of litigation are inherently uncertain, and an adverse outcome is at least reasonably possible. We record loss contingencies in the financial statements when it is determined that we have incurred a loss that is probable and the amount of the loss is reasonably estimable, in accordance with SFAS 5, Accounting for Contingencies. As of December 31, 2002, we have not recorded any liabilities for legal contingencies because we do not believe we have probable potential losses. This assessment could change in the future based on changes in the status of these matters and/or their ultimate outcomes.

Revenue recognition: Revenue is recognized upon receipt of a customer purchase order and subsequent product shipment provided no significant obligations remain and collection of the associated receivable is deemed reasonably assured. This policy is applied to all of our customers, including our distributors, who have no price protection and no return rights on product purchased. Should changes in conditions or the status of obligations cause us to determine that our criteria are not met for certain

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future transactions, revenue recognized for any reporting period could be adversely affected. We do not generally engage in bundling transactions that would call for the deferral of revenue. Through December 31, 2002, all of our billings have been denominated in US dollars, although we expect relatively minor billings in foreign currencies in future periods.

Results of Operations

The following table sets forth the percentage of net revenue represented by certain items in our Consolidated Statements of Operations for the years ended December 31, 2002, 2001 and 2000 respectively:

	Years Ended December 31,		
	2002	2001	2000
Sales	100%	100%	100%
Cost of goods sold	40%	41%	60%
Gross profit	60%	59%	40%
Operating expenses:			
Research and development	29%	44%	56%
Selling, general and administrative	111%	113%	120%
Total operating expenses	140%	156%	176%
Loss from operations	(80%)	(98%)	(137%)
Interest and other income (expense), net	2%	10%	9%
Net loss	(78%)	(88%)	(128%)

Years Ended December 31, 2002 and 2001

For the year ended December 31, 2002, sales totaled $17.4 million, an increase of 18% from $14.8 million in 2001. We experienced growth in our domestic market, with domestic sales increasing by 61% over 2001, reflecting increased physician awareness of our technology and increased coverage from our domestic sales group, which was larger in 2002 than in 2001. Sales in our international markets decreased by 33%, as our global distributor network reduced inventories and coped with weak economic conditions. For the year ended December 31, 2002, domestic sales represented 74% of total revenue, compared to 54% in 2001. Sales of our disposable products grew by 13% and generator sales increased by 34% compared with 2001 results. Also, for the year ended December 31, 2002, disposable sales accounted for 75% of total revenue, compared to 78% in 2001. Results in 2002 in our domestic business were constrained by supply issues relating to accessory infusion pumps used with our Starburst XLi line of disposable products. We believe that these issues have been addressed and should have no further significant impact on revenues, but in the event that supply issues recur, our revenues and results could be negatively impacted. Our generator placements increased 51% compared with 2001, reflecting both the expansion of our customer base and the introduction of newer technology to our existing customers.

Cost of goods sold for the year ended December 31, 2002 was $6.9 million as compared to $6.1 million in 2001. Costs associated with increased unit shipments of generators and other hardware components of the RITA system increased by $1.0 million over 2001, but lower unit shipments of disposables resulted in a $0.7 million reduction in costs associated with these products. Also, cost of goods sold was affected by charges for obsolete inventory, which totaled $0.9 million for 2002, but were only nominal in 2001. Further, amortization of deferred stock-based compensation of $42,000 was included in 2002 cost of goods sold, down from $558,000 in 2001. Excluding the effect of the amortization of deferred stock-based compensation, our gross margin was 61% in 2002 compared with 62% in 2001, reflecting the higher percentage of sales accounted for by relatively low margin hardware sales and the increase in charges for obsolete inventory.

Research and development expenses for the year ended December 31, 2002 were $5.1 million as compared to $6.5 million in 2001. This decrease was primarily due to reductions in new product development costs and clinical trial costs, as the large development expenses associated with the introduction of our Starburst XLi product line in 2001 were not matched by similarly scaled programs in 2002. Also, amortization of deferred stock-based compensation was $216,000 for the year, down from $465,000 in 2001. We expect to continue to make substantial investments in research and development, and accelerating legal costs associated with defense of patent litigation matters may result in substantial increases in our research and development expenses in 2003 and beyond.

Selling, general and administrative expenses for the year ended December 31, 2002 were $19.4 million as compared to $16.6 million in 2001. The increase was primarily attributable to the 2001 expansion of our domestic sales organization, which resulted in higher compensation and travel expenses in 2002. Also, we made additional investments in market development and public relations, and recognized higher administrative expenses relating to provisions to our allowance for uncollectible accounts. Amortization of deferred stock-based compensation was $196,000 for the year, down from $349,000 in 2001. We anticipate that selling, general and administrative expenses will stabilize for 2003, as further significant growth in selling expenses is not expected for at

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least twelve months, and because we believe that future provisions to our allowance for uncollectible accounts will not be as large as those made in 2002.

Interest income was $0.5 million for the year ended December 31, 2002, down from $1.6 million in 2001, because average daily cash balances fell during 2002 as we utilized cash for operations. Interest expense for 2002 was $12,000, down from $86,000 in 2001, as we carried no bank debt in 2002 and recognized only nominal amounts of interest expense associated with capital lease payments.

Years Ended December 31, 2001 and 2000

For the year ended December 31, 2001, sales totaled $14.8 million, an increase of 48% from $10.0 million in 2000. We experienced growth in both domestic and international markets, with domestic sales increasing by 104% and international sales increasing by 11% over the previous year. For the year ended December 31, 2001, domestic sales represented 54% of total revenue, as compared to 39% in 2000. Sales of our disposable products grew by 73% and generator sales decreased by 4% compared with 2000 results. Also, for the year ended December 31, 2001, disposable sales accounted for 78% of total revenue, up from 67% in 2000. Higher unit shipments of generators and disposables resulted from increased physician awareness of our technology, a major expansion of our domestic sales force, increased geographical representation through the appointment of new international distributors and the launch of our StarBurst XLi family of disposable devices.

Cost of goods sold for the year ended December 31, 2001 was $6.1 million as compared to $6.0 million in 2000. The growth in cost of goods sold was attributable primarily to higher material, labor, and overhead costs associated with increased unit shipments. Included in cost of goods sold was amortization of deferred stock-based compensation of $558,000, down from $926,000 in 2000. Excluding the effect of the amortization of deferred stock-based compensation, gross margins improved to 62% in 2001 from 49% in 2000. The improvement was due to higher average selling prices of our disposable devices, related to the launch of our premium-priced five and seven centimeter StarBurst XLi electrodes, and to the increasing proportions of domestic business and disposable products in our sales mix. Gross margins also benefited from manufacturing efficiencies attained through higher volume production of our disposable devices.

Research and development expenses for the year ended December 31, 2001 were $6.5 million as compared to $5.6 million in 2000. This increase was due to expenses associated with the development of our next-generation technology, increased clinical program spending, and increased spending related to the growth and protection of our patent portfolio. Amortization of deferred stock-based compensation was $465,000 for the year, down from $998,000 in 2000.

Selling, general and administrative expenses for the year ended December 31, 2001 were $16.6 million as compared to $12.1 million in 2000. The increase was primarily attributable to the major expansion of our domestic sales organization, additional investments in market development and public relations, and administrative expenses relating to provisions to our allowance for uncollectible accounts. Amortization of deferred stock-based compensation was $349,000 for the year, down from $2.9 million in 2000.

Interest income was $1.6 million for the years ended December 31, 2001 and 2000. Although average daily cash balances were higher in 2001 than in 2000, lower market interest rates resulted in no growth in interest income. Interest expense for 2001 was $86,000, down from $683,000 in 2000, as a result of repayment during the year of bank debt, all of which had been eliminated by June 2001.

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. As of December 31, 2002, we had $7.0 million of cash and cash equivalents, $5.9 million of marketable securities, $0.5 million in investments intended for resale and $16.1 million of working capital.

For the year ended December 31, 2002, net cash used in operating activities was $8.8 million principally due to our net loss of $13.5 million, offset by non-cash charges of $3.4 million, including depreciation and amortization, provisions to reserves for uncollectible accounts and inventory, and amortization of deferred stock-based compensation. Approximately $1.3 million in cash was provided by changes in working capital accounts, particularly reduced accounts receivable balances that resulted from the shift to domestic accounts, which are generally collected much faster than international accounts. Our investing activities for the year were limited to the purchase of property and equipment in the amount of $0.9 million and capitalization of certain patent defense litigation costs in the amount of $1.8 million. Maturities and (net) sales of investment instruments provided $10.2 million in cash in support of operations. Financing activities for the year provided $1.4 million in cash, including $1.6 million from the issuance of common stock offset by $0.2 million in capital lease payments.

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For the year ended December 31, 2001, net cash used in operating activities was $14.2 million principally due to our net loss and increases in accounts receivable and inventory resulting from higher revenues, a lengthened collection cycle and the introduction of our Starburst XLi product line. Our investing activities for the year were limited to the purchase of property and equipment in the amount of $1.6 million and net purchases or sales of short-term investment instruments. Net cash used by financing activities for the year was $0.4 million, as payments on bank debt and lease obligations exceeded the proceeds received from issuance of common stock.

We have, from time to time, financed equipment through capital and operating leases. As of December 31, 2002, we had no future minimum payments due under capital leases; future minimum payments due under operating leases were as follows:

2003	$ 533
2004	356
Total of future minimum operating lease payments	$ 889

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. Although it is difficult for us to predict future liquidity requirements with certainty, based on our cash-burn rate of approximately $0.9 million per month in 2002, we believe that our current cash and cash equivalents, including cash raised in the securities offering described below, will satisfy our cash requirements for at least the next 18 months. During or after this period, if cash generated by operations is insufficient to satisfy our liquidity requirements, we may need to sell additional equity or debt securities or obtain an additional credit facility. There can be no assurance that additional financing will be available to us or, if available, that such financing will be available on terms favorable to the Company and our stockholders.

Recent Development: Private Placement of Securities

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

Income Taxes

As of December 31, 2002, we had federal net operating loss carryforwards of approximately $57.5 million and state net operating loss carryforwards of approximately $22.3 million, available to offset future regular taxable income. We have fully reserved our deferred tax assets, however, because realization of favorable tax assets in future returns is very uncertain. The federal net operating loss carryforwards will expire between 2011 and 2022, and the state net operating loss carryforwards will expire between 2004 and 2013, if not utilized. The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of the Company, and our utilization of our carryforwards could be restricted. See also Note 7 to Notes to Consolidated Financial Statements appearing elsewhere in this Form 10-K.

Recent Accounting Pronouncements

In July 2002, The Financial Accounting Standards Board (FASB) issued SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities, which is effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. The standard nullifies EITF Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity including Certain Costs Incurred in a Restructuring. SFAS No. 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. Examples of costs covered by the standard include lease termination costs and certain employee severance costs that are associated with a restructuring, discontinued operation, plant closing or other exit or disposal activity. The Company does not believe adoption of this statement will materially impact its financial position or results of operations.

In November 2002, the FASB issued FIN No.45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others. FIN No. 45 requires that a liability be recorded in the guarantor s balance sheet upon issuance of a guarantee. In addition, FIN No. 45 requires disclosures about the guarantees that an entity has issued, including a reconciliation of changes in the entity s product warranty liabilities. The initial recognition and initial measurement provisions of FIN No. 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor s fiscal year-end. The disclosure requirements of FIN No. 45 are effective for financial

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statements of interim or annual periods beginning after December 15, 2002. The Company does not believe adoption of this statement will materially impact its financial position or results of operations.

In November 2002, the EITF reached a consensus on Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company does not believe adoption of this statement will materially impact its financial position or results of operations.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for fiscal years ended after December 15, 2002. The interim disclosure requirements are effective for interim periods endingbeginning after December 15, 2002. Adoption of this statement did not materially impact the Company s financial position or results of operations.

In January 2003, the FASB issued FIN No. 46, Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN No. 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN No. 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN No. 46 must be applied for the first interim or annual period beginning after June 15, 2003. The Company does not believe adoption of this standard will materially impact its financial position or results of operations.

Factors That May Affect Future Results

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

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

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 no. 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 no. 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 no. 32 or if RadioTherapeutics prevails on its new interference, we could lose one or more of our issued patent claims.

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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.

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 resolved 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.

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.

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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.

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 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

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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 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 allowance 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 allowance 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.

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 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.

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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;

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.

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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 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 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 they 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

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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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Our exposure to interest rate risk at December 31, 2002 is related to our investment portfolio; we have no interest rate sensitive borrowings as of that date. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. Floating rate investments may produce less income than expected if interest rates fall, and floating rate borrowings, should we acquire any, will lead to additional interest expense if interest rates increase. Due in part to these factors, our future investment income may fall short of expectations, and our interest expense may be above our expectations. Further, we may suffer losses in investment principal if we are forced to sell securities that have declined in market value due to changes in interest rates.

We invest our excess cash in debt instruments of the United States government and its agencies and in high quality corporate issuers. The average contractual duration of our investments in 2002 was less than one year. Due to the short-term nature of these investments, we believe that there is no material exposure to interest rate risk arising from our investments.

All of our sales and purchases have historically been denominated in United States dollars. In the future, we may begin to make sales in other currencies such as the Euro. We believe we currently have no significant direct foreign currency exchange rate risk and that such risk in the future will be minimal.

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Item 8. Consolidated Financial Statements and Supplementary Data.

RITA Medical Systems, Inc.

Index to Consolidated Financial Statements

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Report of Independent Accountants

To the Stockholders and Board of Directors

of RITA Medical Systems, Inc.:

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of RITA Medical Systems, Inc. and its subsidiaries at December 31, 2002 and 2001, and the results of their operations and comprehensive loss and their cash flows for each of the three years in the period ended December 31, 2002 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California

January 24, 2003

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RITA MEDICAL SYSTEMS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2002	**2001**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,888	$ 7,297
Marketable securities	5,427	11,887
Accounts and note receivable, net of allowance for doubtful accounts of $1,353 at December 31, 2002 and $629 at December 31, 2001	2,798	5,056
Inventories, net	3,521	3,645
Prepaid assets and other current assets	995	1,282
Total current assets	19,629	29,167
Long term marketable securities	520	4,353
Long term note receivable, net of collection allowance of $141 at December 31, 2002	381	
Property and equipment, net	1,565	1,934
Intangibles and other assets	2,071	380
Total assets	$ 24,166	$ 35,834
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,053	$ 822
Accrued liabilities	2,510	2,675
Capital lease obligations		192
Total liabilities	3,563	3,689
Commitments and contingencies (Note 4)		
Stockholders equity :		
Preferred stock, $0.001 par value:		
Authorized: 2,100 shares at December 31, 2002 and 2001		
Issued and outstanding: No shares at December 31, 2002 and 2001		
Common stock, $0.001 par value:		
Authorized: 100,000 shares at December 31, 2002 and 2001		