RITA MEDICAL SYSTEMS INC
Form 10-K
March 15, 2004
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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, 2003

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 $37,848,000 as of June 30, 2003, 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 17,974,728 shares of the registrant s Common Stock issued and outstanding as of January 30, 2004.

Documents Incorporated by Reference

Part III incorporates information by reference from the definitive proxy statement to be filed in connection with the registrant s 2004 annual meeting of stockholders.

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RITA Medical Systems, Inc.

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2003

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Filing Sections

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This Report on Form 10-K contains forward-looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks and other factors include, among other things, those listed under Risk factors and elsewhere in this prospectus. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expects, intends, plans, anticipates, believes, estimates, predicts, potential, continue, our future success depends, seek to continue or th terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially. In evaluating these statements, you should specifically consider various factors, including the risks outlined under Risk factors. These factors may cause our actual results to differ materially from any forward-looking statement.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We are under no duty to update any of the forward-looking statements after the date of this Report on Form 10-K to conform these statements to actual results.

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

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

We have received regulatory clearance for sale in major markets worldwide, including the United States. In March 2000, RITA became the first radiofrequency ablation company to receive specific Food and Drug Administration 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 nearly 60,000 disposable devices.

RITA has a broad patent portfolio. As of December 31, 2003, we had 56 issued patents worldwide and 59 United States and foreign patent applications pending. The issued patents cover, among other things, deployable multi-array electrode technology and temperature feedback technology.

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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.

Treatment Options for Liver Cancer

The prognosis for primary and metastatic 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 by the medical community to be the preferred 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.

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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.

Systemic 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 and, at times, excessive bleeding;
- 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.

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 or 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

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pain associated with this condition. The primary treatment options for painful bone metastases are analgesics and radiation therapy. More than half of patients experiencing pain respond to conventional treatments such as these, but the remainder receive 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, computed tomography or magnetic resonance imaging 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 Starburst Xli or Starburst XLie disposable device, 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 cauterizes 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 most often 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. In 2002 we 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

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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.

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:	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
	StarBurst Semi-Flex	Creates a scalable 3 to 5 centimeter ablation and has a partially flexible shaft. Compatible with the Model 1500 and 1500X generator.	2003	$ 2,195
	7 cm Starburst Xli and XLie	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.	Xli: 2001 Xlie: 2003	$ 2,495
Generators:	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.

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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 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 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.

In the United States, we market our products through a direct sales force consisting of 22 field representatives and 3 regional managers. Overseas, we market our products through distribution partners, supported by three full-time RITA field representatives. To date, we have entered into agreements with distributors in the major countries in Europe and Asia. One of our distributors has accounted for 10% or more of our sales in prior years. ITX Corporation distributes our products in Japan, Korea and Taiwan. It accounted for 4% of our sales in 2003, 14% of our sales in 2002 and 14% of our sales in 2001.

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. Most of our generators are sold to our customers at a discount from list price, and we have also established a variety of programs, including volume discount and preferred customer discount programs, to facilitate generator placement.

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, because 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 third-party payors, such as health insurance companies. 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, we believe that 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

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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;
- 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 and physicians in the United States are reimbursed for open, laproscopic and percutaneous liver procedures using procedural codes and CPT codes approved by the American Medical Association. Medicare has also established payment levels for the physician, inpatient hospital

and outpatient hospital settings associated with the codes. In most cases, reimbursement is highest for liver procedures when conducted on an inpatient basis. 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.

Effective January 1, 2004 a new CPT code established by the American Medical Association for percutaneous bone tumor ablation procedures became effective. Medicare has also set payment levels for the physician, inpatient hospital and outpatient hospital setting for this code. The AMA CPT code is applicable to government and private payor health insurance systems. Private payors commonly set reimbursement levels for medical treatments using the Medicare rates, although with any new code payor clinical review for coverage remains necessary. We believe initial clinical reviews will be favorable.

We have limited reimbursement experience for procedures using our system other than for liver and bone cancer. Reimbursement for such procedures in other organs may not be 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.

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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, kidney and lung, and initial results of our lung, kidney 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 and computer controlled radiofrequency ablation systems. We are working on a number of enhancements to our existing ablation products that we believe will further improve their ease of use and performance across a broad array of applications.

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, 2003, we had 56 issued patents worldwide and 59 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.

In April 2003 we entered an agreement with Boston Scientific Corporation and certain of its affiliates and licensors in settlement of various patent litigation disputes. This agreement includes cross licensing of several patents between Boston Scientific, the related affiliates and licensors and ourselves, providing us with access to a number of additional patents in the Boston Scientific portfolio in exchange for one-time payments totaling $2,650,000.

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 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)

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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 and infusion pumps 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 30, 2004 we had 77 full-time employees, including 37 in sales and marketing, 21 in manufacturing, 9 in research and development and 10 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 2004, should we choose to extend our lease, and that additional or alternative 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.

From 1999 through March 2003, the Company was involved in patent-related disputes that were settled in April 2003, and are more fully described in our annual report on Form 10-K filed on March 28, 2003, our report on Form 10-Q filed on May 15, 2003, and our report on Form 10-Q filed on August 13, 2003.

The Company may, from time to time, become a party to legal proceedings arising in the ordinary course of business. Such matters generally 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 are unable to estimate the range of possible loss from such future litigation or other legal proceedings and no amounts have been provided for such matters in the accompanying consolidated financial statements.

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 2002 and 2003, and through January 30, 2004, as reported by the Nasdaq National Market:

	HIGH	LOW
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	$ 5.71	$ 4.03
Second quarter	$ 4.40	$ 2.70
Third quarter	$ 3.59	$ 2.48
Fourth quarter	$ 4.94	$ 3.02
Year ended December 31, 2004		
First quarter (through January 30, 2004)	$ 4.70	$ 4.15

On January 30, 2004, the last reported sales price of our common stock on the Nasdaq National Market was $4.21. 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. As of January 30, 2004, there were 85 holders of our common stock, excluding persons whose stock is in nominee or street name accounts through brokers.

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, we issued 2,045,453 shares of our 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. We 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, our 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. We are required to keep this registration statement effective until the earlier of (i) the date when the selling stockholders have sold all the shares pursuant to the registration statement, (ii) the date on which all of the shares may be sold pursuant to Rule 144 under the Securities Act of 1933, as amended or (iii) January 24, 2005.

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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, 2003, 2002 and 2001 and our audited consolidated balance sheet at December 31, 2003 and 2002 are presented elsewhere in this Form 10-K. The information provided below is in thousands, except for per share data.

	Years ended December 31,				
	2003	2002	2001	2000	1999
Statement of Operations Data:					
Sales	$ 16,607	$ 17,393	$ 14,791	$ 10,010	$ 4,629
Cost of goods sold	6,166	6,908	6,132	6,048	2,994
Gross profit	10,441	10,485	8,659	3,962	1,635
Operating expenses:					
Research and development	4,294	5,052	6,489	5,615	3,931
Selling, general and administrative	17,418	19,366	16,646	12,052	5,452
Total operating expenses	21,712	24,418	23,135	17,667	9,383
Loss from operations	(11,271)	(13,933)	(14,476)	(13,705)	(7,748)
Interest and other income / expense, net	192	434	1,516	898	238
Net loss	$ (11,079)	$ (13,499)	$ (12,960)	$ (12,807)	$ (7,510)
Net loss per common share, basic and diluted	$ (0.63)	$ (0.91)	$ (0.90)	$ (1.99)	$ (9.33)
Shares used in computing net loss per common share, basic and diluted	17,647	14,890	14,353	6,440	805

	December 31,				
	2003	2002	2001	2000	1999
Balance Sheet Data:					
Cash, cash equivalents and marketable securities, current and long term	$ 9,535	$ 12,835	$ 23,537	$ 40,057	$ 12,153
Working capital	11,886	16,066	25,478	41,512	12,437
Total assets	22,033	24,166	35,834	46,270	15,705
Long-term obligations, net of current portion	23			180	1,854
Convertible preferred stock and preferred stock warrants					38,516
	98,055	88,540	88,474	88,435	3,652

Common stock and additional paid-in capital					
Total stockholders equity (deficit)	19,084	20,603	32,145	42,647	(26,991)

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

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 with our customers in the United States. In 2003, we introduced our next generation in infusion technology, the Xli-Enhanced (Xlie) disposable device. The Xlie device builds upon our established infusion expertise, making the ablation process easier and more efficient.

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

	Years ended December 31,		
	2003	2002	2001
Total sales (in thousands)	$ 16,607	$ 17,393	$ 14,791
Percentage of sales: United States	80%	74%	54%
Percentage of sales: International	20%	26%	46%
Percentage of sales: Disposable products	88%	75%	78%
Percentage of sales: Hardware products	12%	25%	22%
Gross margin	63%	60%	59%

Our products are sold in the United States through our direct sales force and internationally through distribution partners. Our sales in the United States are more profitable than our sales in international markets because direct selling, which avoids distributor discounts, permits higher average selling prices for our products. Accordingly, we have made significant investments in our domestic sales force in an effort to increase sales growth in the United States, and have, to date, introduced our premium-priced Starburst Xli and Xlie families of disposable needles only in this region. These actions have resulted in a growing percentage of sales derived from the domestic market. In contrast, our international markets in Europe and Japan have relatively more restrictive reimbursement conditions than those in the United States, which combined with our distributor discounts, limit our average selling prices in these markets. Further, some of our distributors in Europe and Japan have been reducing their inventory levels. These factors have resulted in slow growth or even declining volume in some of our international markets. Going forward, we expect 2004 sales growth in the United States to continue to outpace international growth, because we believe our international markets, particularly Japan, will continue to reduce inventory levels, and because we believe the introduction of premium products to our international distributors will have a relatively small impact on growth due to pricing limitations. However, we also note reimbursement approval for our procedure in Japan, effective April 1, 2004, and we believe that Japan will once again be an important source of international revenue beginning in 2005.

All of our revenue is derived from the sale of our disposable devices and radiofrequency generators. As the number of customers using our products grows, we expect that the percentage of sales related to disposable products will grow relative to that of hardware products, although we have, in the past, seen temporary deviations from this trend as a result of large hardware shipments to international distributors. Since our disposable products are self-manufactured and more profitable than our vendor-sourced hardware products, a growing percentage of disposable product sales is favorable to the Company. In 2004, we will continue to focus on expanding our base of customers and on increasing usage of

our disposable products in our established accounts. As a result, we expect revenue from the sale of our higher-margin disposable devices to grow faster than revenue from the sale of our generators. We have, in the past, experienced supply shortages that limited our sales. We are not currently experiencing such shortages and do not expect shortages in the future, although there cannot be complete assurance to this effect.

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To date, essentially all of our revenue has come from products sold in the treatment of cancerous liver tumors. In 2002, however, we began to see some additional nominal revenue from the use of the RITA system sold for the treatment of patients with metastatic bone tumors. Our sales from devices used in bone tumor procedures remained small in 2003, but we expect the January 2004 approval of a reimbursement code for bone procedures to have a favorable impact going forward. We are conducting research and clinical trials in other organs that may lead to additional sources of revenue in future years, although there can be no assurances that such additional revenue will materialize.

Our manufacturing costs consist of raw materials, including generators and ancillary hardware components produced for us by third-party suppliers, labor to produce our disposable devices and to inspect incoming, in-process and finished goods, sterilization performed by an outside service provider and general overhead expenses. Our manufacturing costs are volume-dependent, and our unit costs should decrease as our production volumes increase. We also have the opportunity to reduce the cost of our vendor-supplied hardware products through higher order volumes or product redesign. Besides manufacturing costs, our cost of goods sold for 2003 reflects amortization of capitalized license fees associated with the April 2003 settlement of our patent litigation dispute with Boston Scientific Corporation. We expect these amortization charges to continue through 2015. Further, our cost of goods sold also includes provisions to our reserve for obsolete inventory. Technology in our marketplace has evolved rapidly and we have, from time to time, recognized relatively high expenses related to obsolete inventory as our product line has changed. We may experience similar product changes and related obsolete inventory provisions in the future, although we generally expect only modest impacts from such provisions.

Our gross margins reflect our selling prices, our domestic / international mix percentages, our product mix percentages, our production volumes, the costs we pay for vendor manufactured product and our provisions for obsolete product. The net effect of these factors has been improvement in our gross margin rate from 59% in 2001, to 60% in 2002 and to 63% in 2003. In 2004, we expect continued modest improvement in our gross margin rate, based on projected improvements in domestic / international and product sales mix, lower manufacturing costs and relatively modest provisions for obsolete product.

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

	Years ended December 31,		
	2003	**2002**	**2001**
Research and development expense	$ 4,294	$ 5,052	$ 6,489
Selling, general and administrative expense	17,418	19,366	16,646
Total operating expenses	$ 21,712	$ 24,418	$ 23,135

	December 31,		
	2003	**2002**	**2001**
Cash and cash equivalents	$ 4,580	$ 6,888	$ 7,297
Marketable securities, current and long term	4,955	5,947	16,240
Total cash and marketable securities	$ 9,535	$ 12,835	$ 23,537

If we are to become profitable, we must continue to manage our operating expenses. Our operating expenses consist of product development costs, clinical trial expenses, patent litigation expenses, sales and marketing expenses related to our selling efforts in the United States and Europe, and administrative expenses, including the costs associated with our status as a public company, professional service expenses and our provisions for uncollectible accounts. Changes in these areas are determined by the breadth of our new product development

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portfolio, the number of headcount we maintain in our selling and administrative functions, the scope of our marketing efforts, the costs we incur in defense of our patents and intellectual property rights and the extent to which credit issues and economic conditions constrain our ability to collect our receivables. For the year ended December 31, 2003, research and development expense was 15% lower than in 2002, while selling, general and administrative expense was down by 10% from 2002, reflecting lower headcount and reduced activity in research projects and clinical trials. In 2004, we expect a modest increase in research expenditures, reflecting the ongoing need to develop innovative technology, but little or no growth in selling, general and administrative expense.

In addition to management of our operating expenses, we must continue to conserve our cash and / or raise additional cash. Our combined total of cash, cash equivalents and marketable securities was $9.5 million as of December 31, 2003, down from $12.8 million as of December 31, 2002. Our net cash used in operating activities for the year ended December 31, 2003 was $8.8 million. However, our rate of net cash used in operating activities fell to $2.6 million in the second half of 2003, as compared to $6.2 million in the first half of 2003, and with this lower rate of cash use we believe we have sufficient cash on hand for at least 12 months of operations.

We incurred net losses of $11.1 million for the year ended December 31, 2003. Due to the costs associated with research and development programs and our sales and marketing efforts, we expect to incur net losses throughout 2004. Profitability depends on our success in expanding product usage in our current markets and in developing new markets. To the extent current or new markets do not materialize in accordance with our expectations, our sales and profitability could be lower than expected and we may be unable to achieve or sustain profitability.

Critical Accounting Policies and Estimates

Management s Discussion and Analysis of Financial Condition and Results of Operations discusses our 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.

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

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deemed reasonably assured. Our customers, including our distributors, 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 future transactions, revenue recognized for any reporting period could be adversely affected. Payments for maintenance services are usually prepaid and the related maintenance revenue is deferred and recognized ratably over the service contract term. Service contract terms range from 12 to 36 months. We do not generally engage in bundling transactions that would call for the deferral of revenue. Through December 31, 2003, all of our billings have been denominated in U.S. dollars, although we expect relatively minor billings in foreign currencies in future periods.

Deferred Tax Valuation Allowance: Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. We have established a full valuation allowance to reduce our deferred tax assets to zero. While we have considered potential future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the full valuation allowance, in the event that we were to determine that we would be able to realize our deferred tax assets in the future, an adjustment to the deferred tax asset would increase net income in the period such determination was made.

Results of Operations

The following table sets forth the percentage of sales represented by certain items in our Consolidated Statements of Operations for the years ended December 31, 2003, 2002 and 2001:

	Years ended December 31,		
	2003	**2002**	**2001**
Sales	100%	100%	100%
Cost of goods sold	37%	40%	41%
Gross profit	63%	60%	59%
Operating expenses:			
Research and development	26%	29%	44%
Selling, general and administrative	105%	111%	113%
Total operating expenses	131%	140%	156%
Loss from operations	(68)%	(80)%	(98)%
Interest and other income / expense, net	1%	2%	10%
Net loss	(67)%	(78)%	(88)%

Years Ended December 31, 2003 and 2002

For the year ended December 31, 2003, sales totaled $16.6 million, a decrease of 5% from $17.4 million in 2002. This result was due to a reduction of $1.8 million, or 77%, in year-to-year sales to our distributor in Japan, where the reduction of in-country inventory levels severely limited demand in 2003. Elsewhere, our business grew. Domestic sales were 3% higher in 2003 than in 2002, as we increased our installed customer base. International sales, excluding Japan, grew by 29% in 2003, compared with 2002, reflecting higher sales in the rest of Asia and some European markets. For the year ended December 31, 2003, domestic sales represented 80% of total sales, compared to 74% in 2002. Sales of our disposable products grew by 11% compared with 2002 results, although hardware sales, influenced by the decrease in shipments to Japan, decreased 53%. For the year ended December 31, 2003, disposable sales accounted for 88% of total revenue, compared to 75% in 2002.

Cost of goods sold for the year ended December 31, 2003 was $6.2 million as compared to $6.9 million in 2002, resulting in a 63% gross margin for 2003 compared to a 60% gross margin rate in 2002. Cost of goods sold

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was affected by charges for obsolete inventory that totaled approximately $0.5 million for 2003, down from $0.7 million in 2002. We may experience similar product changes and related obsolete inventory provisions in the future, although we generally expect only modest impacts from such provisions. Costs for the first two quarters of 2003 were further increased by temporary price increases of approximately $0.5 million on our vendor sourced ancillary infusion pumps. These temporary price increases ceased by June of 2003 and we do not expect increases of this sort in the future. Our cost of goods sold in 2003 also included $0.2 million amortization of capitalized license fees associated with the settlement of our patent litigation dispute with Boston Scientific Corporation. We expect such amortization charges to continue through 2015.

Research and development expenses for the year ended December 31, 2003 were $4.3 million as compared to $5.1 million in 2002. This decrease was due to reduced new product development and clinical trial costs. Also, there were no charges for amortization of deferred stock-based compensation in 2003, compared to $0.2 million of such charges for 2002. We expect a modest increase in research expenditures for 2004, driven by developmental charges associated with technical innovation of our products.

Selling, general and administrative expenses for the year ended December 31, 2003 were $17.4 million as compared to $19.4 million in 2002. About $1.2 million of this decrease is due to lower selling expenses, on lower headcount, reflecting organizational changes in our domestic sales group. Another $1.0 million in reduced expense resulted from lower provisions to our allowance for uncollectible accounts, as our collection experience with our international customers stabilized. Also, there were no charges for amortization of deferred stock-based compensation in 2003, compared to $0.2 million of such charges for 2002. Other marketing and general administrative expense areas increased by $0.4 million in 2003 over 2002. We expect our selling, general and administrative expense to show little or no growth in 2004, reflecting the full-year impact of our 2003 organizational changes.

Interest income was $0.2 million for the year ended December 31, 2003, down from $0.5 million in 2002, because average daily cash balances fell during 2003 as we utilized cash for operations. We had no interest expense for 2003, compared with $12,000 for 2002.

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% in 2002 compared to 2001, 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 sales, 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 sales, 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 have had no further significant impact on sales in 2003. 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 devices 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 $0.7 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. Our gross margin was 60% in 2002, compared to 59% in 2001.

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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 a $1.1 million reduction 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.

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.

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.

Liquidity and Capital Resources

Prior to August 2000, we financed our operations principally through private placements of convertible preferred stock, raising approximately $37.9 million net of expenses. On August 1, 2000, we completed our initial public offering of 3.6 million common shares at a price of $12 per share, raising approximately $39.0 million net of expenses. All outstanding convertible preferred shares were converted to common shares at that time. To a lesser extent, we also financed our operations through equipment financing and other loans (see below), which were fully repaid as of December 31, 2002. In January of 2003, we raised an additional $8.3 million, net of expenses, through a private placement of our common shares. As of December 31, 2003, we had $4.6 million of cash and cash equivalents, $4.0 million of marketable securities, $0.9 million in investments intended for resale and $11.9 million of working capital.

For the year ended December 31, 2003, net cash used in operating activities was $8.8 million principally due to our net loss of $11.1 million, offset by non-cash charges of $2.3 million, including depreciation and amortization and provisions to reserves for uncollectible accounts and inventory. Amortization of our deferred stock-based compensation was completed in the year ended December 31, 2002, so there were no further charges in 2003. Approximately $0.1 million in cash was used in 2003 by changes in working capital accounts, with $0.8 million in reduced inventory offset by reduced payables and liabilities, and a $0.2 million increase in accounts receivable. Our investing activities for the year were limited to the purchase of property and equipment in the amount of $1.0 million. Through April of 2003, when we settled our outstanding patent disputes with Boston Scientific Corporation, we capitalized certain patent defense litigation costs; such costs totaled $0.6 million for the year ended December 31, 2003. In April of 2003, we also capitalized $2.65 million in payments made in settlement of those disputes. Maturities and (net) sales of investment instruments provided $1.0 million in cash in support of operations. Financing activities for the year provided $9.6 million in cash, including the $8.3 million we raised in our January 2003 private placement of common stock and $1.3 million related to the issuance of common stock in conjunction with the exercise of stock options.

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 $3.4 million in non-cash charges and $1.3 million provided by reduced accounts receivable and other changes in working capital accounts. Our investing activities for the year were limited to the purchase of property and equipment in the amount of $0.9 million and $10.2 million of net sales of short-term investment instruments. Net cash provided by financing activities for the year was $1.4 million, primarily the proceeds received from issuance of common stock in conjunction with the exercise of stock options.

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We have, from time to time, financed equipment through capital and operating leases. As of December 31, 2003, we had no future minimum payments due under capital leases, and future minimum payments due under operating leases were as follows (in thousands):

Payments due in 2004	$ 356
Total of future minimum operating lease payments	$ 356

Our capital requirements depend on numerous factors including our research and development expenditures, expenses related to selling, general and administrative operations and working capital to support business growth. Our net cash used in operating activities averaged $0.7 million per month for the year ended December 31, 2003, but net cash used in operating activities averaged only $0.4 million per month for the last half of the year. Although it is difficult for us to predict future liquidity requirements with certainty, we believe that our current balances of cash and cash equivalents, and the sale of marketable securities as necessary, will satisfy our cash requirements for at least the next 12 months. During or after this period, if cash generated by operations is insufficient to satisfy our liquidity requirements, we may need to sell additional equity or debt securities or obtain an additional credit facility. There can be no assurance that additional financing will be available to us or, if available, that such financing will be available on terms favorable to the Company and our stockholders.

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, our 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, 2003, we had federal net operating loss carryforwards of approximately $66.1 million and state net operating loss carryforwards of approximately $22.0 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 2008 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 November 2002, the Emerging Issues Task Force (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 apply to revenue arrangements entered into in fiscal

periods beginning after June 15, 2003. Adoption of this statement has had no material impact on the Company s financial position or results of operations.

In December 2003, the SEC issued Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition, which codifies, revises and rescinds certain sections of SAB No. 101, Revenue Recognition, in order to make this interpretive guidance consistent with current authoritative accounting and auditing guidance and SEC rules and regulations. The changes noted in SAB No. 104 did not have a material effect on the Company s financial position or results of operations.

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Factors That May Affect Future Results

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

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

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

We have a history of losses and may never achieve profitability.

Although operating expenses during the final two quarters of the year ended December 31, 2003 were lower than in preceding quarters, and although we believe that our quarterly operating expenses will stabilize at or below these levels throughout 2004, to become profitable we must increase our sales and continue to manage our operating expenses. If our sales do not grow, we may not be able to achieve or maintain profitability in the future. In particular, we incurred net losses of $11.1 million in 2003, $13.5 million in 2002, $13.0 million in 2001, $12.8 million in 2000 and $7.5 million in 1999. At December 31, 2003, we had an accumulated deficit of approximately $79.0 million.

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

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

We compete directly with two companies in the domestic and international markets: RadioTherapeutics Corporation, a division of Boston Scientific Corporation, and Radionics, Inc., a division of Tyco Healthcare, which is a division of Tyco International. Boston Scientific Corporation and Tyco International are publicly traded companies with substantially greater resources than we have. Both RadioTherapeutics and Radionics sell products that use radiofrequency energy to ablate soft tissue. Furthermore, in April 2003, we entered into a license agreement with Boston Scientific, its affiliates and licensors, pursuant to which we granted Boston Scientific rights to manufacture and sell products using our infusion technology after October 5, 2004. As a result, Boston Scientific may develop and sell some competing products that would, in the absence of this license agreement, infringe our patents.

We are also aware of several companies in international markets 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 received FDA clearance for using radiofrequency energy to ablate soft tissue.

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

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

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

Our products are supported by clinical follow-up data in published clinical reports or scientific presentations covering periods from five months to five years after radiofrequency ablation. If additional studies in liver cancer or in other applications fail to confirm or demonstrate the effectiveness of our products, our sales could decline. If longer-term patient follow-up or clinical studies indicate that our procedures cause unexpected, serious complications or other unforeseen negative effects, we could be subject to significant liability. Further, because some of our data has been produced in studies that were retrospective, not randomized, or included small patient populations and because, in certain circumstances, we rely on clinical data developed by independent third party physicians, our clinical data may not be reproduced in wider patient populations.

If we are unable to protect our intellectual property rights or if we are found to infringe the rights of others, we may lose market share to our competitors and our business could suffer.

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

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

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

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

- the challenge of managing international sales without direct access to the end customer;
- the risk of inventory build-up by our distributors which could negatively impact sales in future periods (for example, our distributor in Japan has built up a significant inventory of product in anticipation of the receipt of reimbursement approvals);

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;

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

contractual provisions governed by foreign laws.

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

We are substantially dependent on a limited number of significant distributors in our international markets, and if we lose these distributors and fail to attract additional distributors, our international revenues could decline. ITX Corporation, formerly known as Nissho Iwai Corporation, is our primary distributor in Asia. It accounted for 21% of our international revenues in 2003 and 55% of our international revenues in 2002. M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, accounted for 22% of our international revenues in 2003 and 17% of our international revenues for 2002. Because international revenues accounted for 20% of our total revenues for 2003 and these two distributors represented 43% of that total, the loss of either distributor or a significant decrease in unit purchases by either distributor could cause our revenues to decline substantially. If we are unable to attract additional international distributors, our international revenues may not grow.

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

We sell our products in international markets through third-party distributors over whom we have limited control, and, if they fail to adequately support our products, our sales could decline. During the first quarter of 2003, we terminated our agreements with three of our international distributors and although we contracted with replacement distributors we have expended significant time and resources in doing so, and our sales in the three affected markets have suffered during the transition period that we estimate ended September 30, 2003. However, if our distributors or we terminate other distributor agreements, we could incur similar or more burdensome expenses, have to expend significant time and resources in finding replacement distributors and our sales could decrease during any related transition period.

We are aware that some of our international distributors have built up inventory of our products. As a result, future sales to these distributors could be negatively impacted and 2003 sales to our Japanese distributor were so affected. In addition, while these distributors have no price protection and no right of return relating to purchased products, if we permit the return of any of these products, we will have to adjust our revenues relating to these products which may also impact our revenue recognition policy on future distributor sales.

In 2002, we significantly increased our allowance for uncollectible accounts to address the risk associated with longer collection periods that have arisen principally with our European distributors. Although the deterioration we experienced in international collections in 2002 stabilized in 2003, we may encounter new difficulties with collections that require further increases in our allowance for uncollectible accounts in the future, and we may require specific accounts to post letters of credit or pay in advance to minimize credit risk to the Company. Additional future increases in our allowance for uncollectible accounts would reduce our profits.

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

Certain of the markets outside the United States in which we sell our products require that specific reimbursement codes be obtained before reimbursement for procedures using our products can be approved. As a result, in countries where specific reimbursement codes are strictly

required and have not yet been issued, reimbursement has been denied on that basis. For example, ITX Corporation, our distributor in Japan, is seeking to obtain reimbursement coverage in Japan, but to date has not received this approval. If we or our distributors are unable to either obtain the required reimbursement codes or develop an effective strategy to resolve the reimbursement issue, physicians in foreign markets may be unwilling to purchase our products which could negatively impact our international revenues.

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

Physicians, hospitals and other health care providers may be reluctant to purchase our products if they do not receive coverage or adequate reimbursement for the cost of procedures using our products from third-party payors, such as Medicare, Medicaid and private health insurance plans. If physicians believe that using our system will add cost to a procedure but will not add sufficient offsetting economic or clinical benefits, physician adoption of our products could be delayed. Even though the American Medical Association has established CPT codes relating to liver procedures and bone tumor procedures, some third-party payors still may not cover or reimburse adequately for liver or bone tumor procedures using our products. We are aware of liver procedures using our system where the patient s insurance has denied coverage. In addition, there are no assigned CPT codes for radiofrequency ablation of tumors in organs other than liver or bone. Further, we believe the advent of the Medicare fixed payment schedules has made it difficult to receive adequate liver reimbursement for procedures using our products in the outpatient setting. Medicare reimbursement levels for procedures using our products are highest when our products are used in an in-patient setting. If there is a trend toward the use of our products on an outpatient basis or if coverage continues to be denied or reimbursement levels continue to be inadequate, physician use of our products could decline which would cause our revenues to decline.

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

We are highly dependent on the principal members of our management team, including our Chief Executive Officer and Chief Financial Officer, as well as key staff in the areas of finance, operations and research and development. Our future success will depend in part on the continued service of our staff and our ability to identify, hire and retain additional personnel. The market for qualified management personnel in Northern California, where our offices are located, is competitive and is expected to remain so. Because the environment for good personnel is so competitive, costs related to compensation may increase significantly. If we are unable to attract and retain both the management team and key personnel we need to support and grow our business, our business will suffer.

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

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

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

It is critical to our sales effort to train a sufficient number of physicians and to instruct them properly in the procedures that utilize our products. We have established formal physician training programs and rely on physicians to devote adequate time to understanding how and when our products should be used. If physicians are not properly trained, they may misuse or ineffectively use our products. Such use may result in unsatisfactory patient outcomes, patient injury and related liability or negative publicity that could have an adverse effect on our product sales.

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

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

failure of the public market to support the valuation established in our initial public offering or our 2003 private placement transaction;

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our ability to successfully commercialize our products;

announcements regarding patent litigation or the issuance of patents to us or our competitors;

quarterly fluctuations in our results of operations;

announcements of technological or competitive developments by us or our competitors;

product liability claims;

regulatory developments regarding us or our competitors;

acquisitions or strategic alliances by us or our competitors;

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

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

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

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

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

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

The operating lease on our current facility expires in August of 2004. We believe that during 2004 we will be able to either renew the lease on our existing facility, or lease alternative space, at commercially reasonable terms. If we choose to relocate to a new facility, we will incur normal and customary moving costs and may experience an interruption in our manufacturing operations. If we become unable to meet customer demand for our products, our business could suffer.

We are dependent on two suppliers as the only sources of a component that we use in our disposable devices, and any disruption in the supply of this component could negatively affect our business.

Until 2003, there was only one supplier available to provide us with a component that we include in our disposable devices. During the quarter ended June 30, 2003, we qualified a second supplier. However, a disruption in the supply of this component is still possible and could negatively affect revenues. If we were unable to remedy a disruption in supply of this component within twelve months, we could be required to

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redesign the handle of our disposable devices, which could divert engineering resources from other projects or add to product costs. In addition, a new or supplemental filing with applicable regulatory authorities may require clearance prior to our marketing a product containing new materials. This clearance process may take a substantial period of time, and we may be unable to obtain necessary regulatory approvals for any new material to be used in our products on a timely basis, if at all. This could also create supply disruptions that could negatively affect our business.

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

Until December 2002, we had only one supplier available to provide us with accessory infusion pumps used in conjunction with our Starburst XLi line of disposable devices. Our Starburst Xlie product line, introduced in 2003, also requires an accessory infusion pump. During the quarters ended September 30, 2002 and December 31, 2002, we experienced shortages in the supply of accessory infusion pumps. In December 2002, we qualified a new accessory infusion pump from our existing supplier for which we now have approval from UL and conditional approval from TUV for use in the United States and Europe. Also in December 2002, we qualified a second supplier of an accessory infusion pump, although we have not yet shipped this product to our customers commercially. Although we were able to remedy this supply disruption, future disruptions in the supply of this component are still possible and, in that event, our business could suffer through lower revenues or higher costs. Additionally, we have limited experience with both the primary and alternative pump and if either pump fails to perform as desired, revenues could be negatively affected.

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

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

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

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

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

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

Unless we are exempt, we must obtain the appropriate FDA approval or clearance before we can sell a new medical device in the United States. Obtaining this approval or clearance can be a lengthy and time-consuming process. To date, all of our products have received clearances from the FDA through premarket notification

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under Section 510(k) of the Federal Food, Drug and Cosmetic Act. However, if the FDA requires us to submit a new premarket notification under Section 510(k) for modifications to our existing products, or if the FDA requires us to go through a lengthier, more rigorous examination than we now expect, our product introductions or modifications could be delayed or canceled which could cause our revenues to be below expectations. The FDA may determine that future products will require the more costly, lengthy and uncertain premarket approval process. In addition, modifications to medical device products cleared via the 510(k) process may require a new 510(k) submission. We have made minor modifications to our system. Using the guidelines established by the FDA, we have determined that some of these modifications do not require us to file new 510(k) submissions. If the FDA disagrees with our determinations, we may not be able to sell the RITA system until the FDA has cleared new 510(k) submissions for these modifications, or it may require us to recall previously sold products. In addition, we intend to request additional label indications, such as approvals or clearances for the ablation of tumors in additional organs, including lung, uterus and breast, for our current products. The FDA may either deny these requests outright, require additional extensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of approval or clearance. Therefore, obtaining necessary approvals or clearances for these additional applications could be an expensive and lengthy process. In addition, in the course of the FDA process leading to clearance or approval for a new indication, the FDA may request an advisory panel meeting or meetings to discuss the clinical data, the appropriate study design or other criteria for clearance or approval. In the event that the advisory panel advises FDA that the clinical data are inadequate or the study design or other criteria are inappropriate, and the FDA concurs, the FDA clearance or approval process could be lengthened and anticipated revenues from that new indication would be delayed.

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

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

- diversion of management s attention from our core business objectives and other business concerns;
- failure to integrate efficiently businesses or technologies acquired in the future with our pre-existing business or technologies;
- potential loss of key employees from either our pre-existing business or the acquired business;
- dilution of our existing stockholders as a result of issuing equity securities; and
- assumption of liabilities of the acquired company.

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

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

We may need to raise additional funds for our business operations and to execute our business strategy. We may seek to sell additional equity or debt securities or to obtain an additional credit facility. The sale of additional equity or convertible debt securities could result in additional

dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights that are senior to holders of common stock and could contain covenants that would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, if at all.

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

Because our executive officers and directors, and their respective affiliates, own approximately 10 percent of our outstanding common stock as of December 31, 2003, these stockholders may, as a practical matter, be able

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to exert significant influence over matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. This concentration of voting stock could have the effect of delaying or preventing a merger or acquisition or other change of control that a stockholder may consider favorable.

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

Our exposure to interest rate risk at December 31, 2003 and December 31, 2002 is related to our investment portfolio. We had no interest rate sensitive borrowings as of December 31, 2003 or December 31, 2002. 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 2003 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 Auditors

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, 2003 and 2002, 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, 2003 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

March 8, 2004

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RITA MEDICAL SYSTEMS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2003	**2002**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,580	$ 6,888
Marketable securities	4,022	5,427
Accounts and note receivable, net of allowance for doubtful accounts of $1,117 at December 31, 2003 and $1,353 at December 31, 2002	2,990	2,798
Inventories	2,192	3,521
Prepaid assets and other current assets	1,028	995
Total current assets	14,812	19,629
Long term marketable securities	933	520
Long term note receivable, net of collection allowance of $45 at December 31, 2003 and $141 at December 31, 2002	338	381
Property and equipment, net	1,089	1,565
Intangibles and other assets	4,861	2,071
Total assets	$ 22,033	$ 24,166
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 757	$ 1,053
Accrued liabilities	2,169	2,510
Total current liabilities	2,926	3,563
Deferred maintenance revenue, less current portion	23	
Total liabilities	$ 2,949	$ 3,563
Commitments (Note 4)		
Stockholders equity :		
Preferred stock, $0.001 par value:		
Authorized: 2,100 shares at December 31, 2003		
Issued and outstanding: No shares at December 31, 2003 and 2002		
Common stock, $0.001 par value:		
Authorized: 100,000 shares at December 31, 2003		
Issued and outstanding: 17,975 shares at December 31, 2003 and 15,155 shares at December 31, 2002	18	15
Additional paid-in capital	98,037	88,525
Stockholder notes receivable		(50)
Accumulated other comprehensive income	2	7

Accumulated deficit	(78,973)	(67,894)
Total stockholders equity	19,084	20,603
Total liabilities and stockholders equity	$ 22,033	$ 24,166

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

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RITA MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share data)

	Years Ended December 31,		
	2003	2002	2001
Sales	$ 16,607	$ 17,393	$ 14,791
Cost of goods sold (including stock-based compensation of $0, $42 and $558 in 2003, 2002 and 2001, respectively)	6,166	6,908	6,132
Gross profit	10,441	10,485	8,659
Operating expenses:			
Research and development (including stock-based compensation of $0, $216 and $465 in 2003, 2002 and 2001, respectively)	4,294	5,052	6,489
Selling, general and administrative (including stock-based compensation of $0, $196 and $349 in 2003, 2002 and 2001, respectively)	17,418	19,366	16,646
Total operating expenses	21,712	24,418	23,135
Loss from operations	(11,271)	(13,933)	(14,476)
Interest income	201	473	1,610
Interest expense		(12)	(86)
Other expense, net	(9)	(27)	(8)
Net loss	(11,079)	(13,499)	(12,960)
Other comprehensive income (expense):			
Change in unrealized gain (loss) on marketable securities	(5)	(63)	57
Comprehensive loss	$ (11,084)	$ (13,562)	$ (12,903)
Net loss per common share, basic and diluted	$ (0.63)	$ (0.91)	$ (0.90)
Shares used in computing net loss per common share, basic and diluted	17,647	14,890	14,353

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

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RITA MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands)

	Common Stock		Additional	Deferred	Stockholder	Accumulated Other Compre-hensive		Total Stockholders
	Shares Issued	Amount	Paid-in Capital	Stock-based Compensation	Notes Receivable	Income	Accumulated Deficit	Equity
Balances, December 31, 2000	13,970	$ 14	$ 88,421	$ (4,202)	$ (164)	$ 13	$ (41,435)	$ 42,647
Issuance of common stock	89		324					324
Stock options and warrants exercised	551	1	406					407
Cancellation of common stock	(19)		(31)		31			
Issuance of common stock warrants for services received			264					264
Deferred stock-based compensation			(925)	925				
Amortization of deferred stock-based compensation				1,372				1,372
Forgiveness of stockholder note receivable					34			34
Change in unrealized gain on marketable securities						57		57
Net loss							(12,960)	(12,960)
Balances, December 31, 2001	14,591	15	88,459	(1,905)	(99)	70	(54,395)	32,145
Issuance of common stock	125		421					421
Stock options and warrants exercised	466		1,130					1,130
Cancellation of common stock	(27)		(15)		15			
Revaluation of common stock warrant			(19)					(19)
Deferred stock-based compensation			(1,451)	1,451				
Amortization of deferred stock-based compensation				454				454
Forgiveness of stockholder note receivable					34			34
Change in unrealized gain on marketable securities						(63)		(63)
Net loss							(13,499)	(13,499)
Balances, December 31, 2002	15,155	15	88,525		(50)	7	(67,894)	20,603
Issuance of common stock.	2,126	2	8,605					8,607
Stock options exercised .	714	1	1,028					1,029
Cancellation of common stock	(20)		(20)		20			

Revaluation of common stock warrant			(101)					(101)
Forgiveness of stockholder note receivable					30			30
Change in unrealized gain on marketable securities						(5)		(5)
Net loss							(11,079)	(11,079)
Balances, December 31, 2003	17,975	$ 18	$ 98,037	$	$	$ 2	$ (78,973)	$ 19,084

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

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RITA MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,		
	2003	2002	2001
Cash flows from operating activities:			
Net loss	$ (11,079)	$ (13,499)	$ (12,960)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	1,713	1,401	1,018
Loss on disposal of property and equipment	275		
Issuance and revaluation of common stock warrants for services received	(101)	(19)	264
Allowance for doubtful accounts	(99)	865	526
Provision for obsolete inventories	551	670	137
Amortization of stock-based compensation		454	1,372
Changes in operating assets and liabilities:			
Accounts and note receivable	(190)	1,534	(3,145)
Inventories	778	(546)	(2,144)
Prepaid and other current assets	(33)	287	(459)
Accounts payable and accrued liabilities	(637)	66	1,177
Deferred warranty revenue	23		
Net cash used in operating activities	(8,799)	(8,787)	(14,214)
Cash flows from investing activities:			
Purchase of property and equipment	(1,003)	(893)	(1,648)
Purchase of investments	(9,387)	(404)	(19,451)
Sales and maturities of investments	10,374	10,634	30,650
Capitalization of patent litigation costs	(621)	(1,802)	(332)
Acquisition of intangibles	(2,650)		
Note receivable and other assets	142	(516)	6
Net cash provided by (used in) investing activities	(3,145)	7,019	9,225
Cash flows from financing activities:			
Proceeds from issuance of common stock	9,636	1,551	731
Proceeds from revolving term loan			25
Payments on revolving term loan			(858)
Payments on capital lease obligations		(192)	(288)
Net cash provided by (used in) financing activities	9,636	1,359	(390)
Net decrease in cash and cash equivalents	(2,308)	(409)	(5,379)
Cash and cash equivalents at beginning of year	6,888	7,297	12,676

Cash and cash equivalents at end of year	$ 4,580	$ 6,888	$ 7,297
Supplemental disclosures of cash flow information:			
Cash paid for taxes	$ 9	$ 27	$ 8
Cash paid for interest	$	$ 12	$ 75

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

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: FORMATION AND BUSINESS OF THE COMPANY

RITA Medical Systems, Inc. (the Company) was incorporated in January 1994. The Company is engaged in developing, manufacturing and marketing innovative products that use radiofrequency energy to treat patients with solid cancerous or benign tumors. Products include radiofrequency generators and disposable needle electrode devices that deliver controlled thermal energy to targeted tissue.

NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements include the accounts of RITA Medical Systems, Inc. and its wholly owned subsidiaries, RITA Medical Systems Netherlands, BV, and Rita Medical Systems France, S.A.R.L. Intercompany transactions and accounts have been eliminated.

Liquidity

As of December 31, 2003, the Company s total assets were $22.1 million, total liabilities were $2.9 million, working capital was $11.9 million and cash and cash equivalents totaled $4.6 million. Current and anticipated demand for the Company s products as well as procurement and production affect the need for capital. Changes in these or other factors could have a material impact on capital requirements and may require the Company to raise additional capital. While the Company believes that its existing cash resources, including short-term and long-term marketable securities, will be sufficient to fund its operating needs for the next twelve months, additional financing may be required for the Company s currently envisioned long term needs. There can be no assurance that any additional financing will be available on terms acceptable to the Company, or at all. In addition, future equity financings could result in dilution to shareholders, and future debt financings could result in certain financial and operational restrictions.

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that effect the reported amounts of assets and liabilities and 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. Significant estimates include those required in the assessment of allowances for doubtful accounts and for potentially excess and obsolete inventory. Actual

results could differ from those estimates.

Concentration of credit risk and other risks and uncertainties

The Company s products include components subject to rapid technological change. Certain components used in manufacturing the product have relatively few alternative sources of supply and establishing additional or replacement suppliers for such components cannot be accomplished quickly. The Company has been constrained by supply issues in the past, but was not affected by supply constraints as of December 31, 2003. While the Company has ongoing programs to minimize the adverse effect of such changes and considers technological change in estimating its allowances, such estimates could change in the future.

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, marketable securities, accounts receivable and notes receivable. Cash and cash equivalents are deposited in demand and money market accounts in three financial institutions in the United States, one

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

financial institution in the Netherlands and one financial institution in France. Deposits held with financial institutions may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses on its deposits of cash, cash equivalents or marketable securities.

The Company extends credit to its customers, which are primarily comprised of accounts of private companies in the United States, Europe and Asia. The Company performs ongoing credit evaluations of its customers financial conditions and generally requires no collateral. The Company maintains an allowance for doubtful accounts receivable and/or notes receivable based on the expected collectibility of individual accounts. For the year ended December 31, 2003, the Company reduced its allowance for doubtful accounts by approximately $99,000. For the years ended December 31, 2002 and 2001, provisions to the allowance for doubtful accounts were made in the approximate amounts of $902,000 and $535,000, respectively. Charges against the allowance were approximately $233,000, $37,000 and $9,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

Cash and cash equivalents

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