RITA MEDICAL SYSTEMS INC
Form 10-K
March 28, 2002

==========

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, 2001

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. [_]

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $53,027,474 as of February 28, 2002, based upon the closing sale price on the Nasdaq National Market reported for such date. Shares of Common Stock held by each officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

There were 14,630,671 shares of the registrant's Common Stock issued and outstanding as of February 28, 2002.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference from the definitive proxy statement for the 2002 annual meeting of shareholders to be filed in April 2002.

==========

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 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. In addition to liver 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 bone, lung, breast, uterus, prostate and kidney. We believe the market opportunity for these additional applications exceeds $1 billion annually.

We have received regulatory clearance for sale in major markets worldwide, including the United States. In March 2000, RITA became the first radiofrequency ablation company to receive specific FDA clearance for unresectable liver lesions in addition to its previous general FDA clearance for the ablation of soft tissue. Our system is distributed in the United States through our direct sales force and internationally through distribution partners. Since our product launch, we have sold over 35,000 disposable devices.

RITA has a broad patent portfolio. As of February 28, 2002, we had 46 issued patents worldwide and more than 50 United States and foreign patent applications pending. The issued patents cover, among other things, deployable

multi-array electrode technology and temperature feedback technology.

Market Opportunity

Cancer Market

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

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

Liver Cancer Market

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

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

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

Treatment Options for Liver Cancer

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

Surgery

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

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

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

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

Chemotherapy

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

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

Cryosurgery

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

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

- it is not an option for patients who cannot tolerate an open surgical procedure;

- it involves significant complications which are similar to other open surgical procedures, as well as liver fracture and hemorrhaging caused by the cycle of freezing and thawing;

- it is associated with mortality rates estimated to be between one and five percent; and

- it is expensive compared to other alternatives.

Percutaneous Ethanol Injection

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

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

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.

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(degrees)C, causing cellular death.

The physician inserts the RITA disposable needle electrode device into the target body tissue, typically under ultrasound guidance. Once the device is inserted, pushing on the handle of the device causes a group of curved wires to be deployed from the tip of the electrode. When the power is turned on, these wires deliver radiofrequency energy throughout the tumor. In addition, temperature sensors on the tips of the wires measure tissue temperature throughout the procedure. During the procedure, our system automatically adjusts the amount of energy delivered in order to maintain the temperature necessary to ablate the targeted tissue. For a typical five centimeter ablation using our latest product, the ablation process takes approximately ten minutes. When the ablation is complete, pulling back on the handle of the device causes the curved wire array to be retracted into the device so it can be removed from the body. Our disposable device 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. 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 laparoscopically and are generally sent home the next day. 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. Liver cancer is a recurrent disease. However, due to the invasive nature of other treatment options, the majority of patients who undergo traditional therapies cannot be retreated in the event that new tumors appear on their livers. Because of the minimally invasive nature of our procedure, patients treated with our system can often be retreated.

- Broadly Applicable Technology. Our extensive clinical experience with liver tumors and 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, bone, breast, prostate and kidney.

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 and abscesses. 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; in 2001 we trained over 400 physicians worldwide.

  - publish additional clinical research to provide data supporting the expanded use of our products;

  - drive patient awareness with marketing efforts and an expanded Internet site focused on educating patients on the benefits of the RITA system; in 2001 we launched livertumor.org, a patient education and referral website, and

  - broaden our market coverage by expanding our domestic direct sales force and international distribution channels; in 2001, we more than doubled the number of sales personnel in the United States.

- Expand the Application of Our Proprietary Technology to Markets Beyond Liver Cancer. We believe our minimally invasive proprietary technology can be broadly applied to the treatment of other types of cancerous and benign tumors, including tumors in the bone, lung, breast, prostate, uterus and kidney. We plan to build on our extensive clinical experience in liver tumors as well as feasibility 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. For example, in 2001, we launched the Starburst XLi disposable needle which is capable of a 7 centimeter ablation, about 4 times the volume of our previous generation.

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(degrees)C, or 113 to 122(degrees)F.

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

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. L Pric
Disposable Devices:	Model 70	Creates a scalable 2 to 3 centimeter ablation. Compatible with the Model 500 generator.	1999	$ 1,1
	StarBurst	Creates a scalable 2 to 3 centimeter ablation. Compatible with the Model 1500 generator.	2000	$ 1,1
	StarBurst XL	Creates a scalable 3 to 5 centimeter ablation. Compatible with the Model 1500 generator.	2000	$ 1,4

	5 cm Starburst XLi	Creates a scalable 4 to 5 centimeter ablation. Compatible with the Model 1500 generator	2001	$ 2,1
	7 cm Starburst XLi	Creates a scalable 4 to 7 centimeter ablation. Compatible with the Model 1500 generator	2001	$ 2,4
Generators:	Model 500	50 Watt Generator	1997	$30,0
	Model 1500	150 Watt Generator	2000	$37,5

Disposable Devices

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

Our disposable devices are available in different array sizes to allow the physician to create a spherical ablation volume of anywhere from two to seven centimeters. Three centimeters is slightly smaller than a ping-

pong ball. Seven centimeters is approximately the size of a tennis ball. In addition, depending on product line, the devices are available in 10,12,15 or 25 centimeter lengths to allow physicians to access tumors that are located more or less deeply within the body. Each disposable device is supplied with one or more ground pads to allow a return path for the flow of radiofrequency energy from the patient back to the generator. Sales of disposable devices accounted for 78% of sales for the year ended December 31, 2001, 67% of sales for the year ended December 31, 2000 and 64% of sales for the year ended December 31, 1999.

Generators

All of our generators employ an internal computer to assist the physician in safely and effectively controlling the delivery of radiofrequency during the ablation. In addition, each generator has a display to convey information to the physician while using the system. Our Model 1500 generators have the ability, using optional software running on a laptop computer, to display real-time, color-coded graphs of power, temperature and impedance to aid the user in controlling the system and to collect procedural information for the patient's record. Sales of generators accounted for 22% of sales for the year ended December 31, 2001, 33% of sales for the year ended December 31, 2000 and 36% of sales for the year ended December 31, 1999.

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 and medical oncologists. Revenue from customers in the United States totaled $8.0 million for the year ended December 31, 2001, $3.9 million for the year ended December 31, 2000 and $1.7 million for the year ended December 31, 1999. Revenue from customers outside of the United States totaled $6.8 million for the year ended December 31, 2001, $6.1 million for the

year ended December 31, 2000 and $2.9 million for the year ended December 31, 1999.

In the United States, we market our products through a direct sales force of 26 sales representatives and six regional managers. Overseas, we market our products through distribution partners. To date, we have entered into agreements with distributors in 40 countries including the major countries in Europe and Asia. RITA has four full-time sales managers who are responsible for directing, supporting and monitoring our international distributors' activities.

Our marketing and sales efforts are directed at placing generators at key cancer centers and other leading medical centers worldwide and then working with those centers' physicians to increase their usage of our disposable devices. We recognize that our predominant source of recurring revenue will be from our disposable devices, which can only be used once a generator is placed. To facilitate generator placement at medical centers, we have established a variety of programs, including long- or short-term loan, preferred customer discount, and leasing referral programs.

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

Clinical Research

To date, there have been over 55 publications in peer-reviewed journals on clinical studies using our products. An additional eight articles appeared in the November/December 2000 Special Supplement of The Cancer Journal. Over 50 abstracts on our products have been presented at medical conferences. These published and presented reports include over 500 patients. The majority of these clinical studies have been conducted on patients with unresectable liver cancer. These studies have demonstrated that liver tumors can be ablated safely and effectively using the RITA system.

In addition, clinicians have investigated or are currently investigating the feasibility of using our system to address other types of cancer, including tumors of the breast, lung, bone, prostate and kidney, and initial results in bone, lung and breast clinical investigations have been published or presented.

In a recent study published in The Cancer Journal, data showed that the RITA procedure appears to be safe and may significantly relieve intense pain and back pain-related disabilities associated with metastatic spinal tumors. Pain and back pain-related disability was reduced and neurological function was preserved or stabilized with average pain reduction exceeding 70% in the 9 of 10 patients that experienced pain relief. Results of a 12 patient feasibility study presented at the 2001 annual meeting of the Radiological Society of North America (RSNA) demonstrated that the RITA procedure may provide a potential alternative method to address painful metastatic bone lesions that is safe and offers dramatic pain relief.

Preliminary lung results were presented at the 2001 meetings of the American Society of Clinical Oncology and RSNA. These results demonstrated that the RITA system can be successfully used to address pulmonary metastases and may provide an option for local tumor control in patients for whom surgery is not an option. Data from a clinical study involving 34 patients with unresectable lung tumors who were treated with the RITA system was reported at the European Congress of Radiology in March 2002. For 26 patients who had been followed for at least three months (mean follow-up was 8.6 months), 95 percent of the treated tumors were fully ablated and demonstrated no recurrence. There were no major complications reported.

Breast feasibility data presented at RSNA 2000 reported successful complete ablation achieved in the first 10 patients studied. No major complications were reported.

We plan to complete the current clinical investigation of the safety and effectiveness of the RITA procedure for relief of pain associated with metastases involving bone in 2002. Clinical investigations for breast and lung applications will continue into 2003 or beyond.

Competition

The medical device industry is subject to intense competition. Accordingly, our future success will depend on our ability to meet the clinical needs of physicians, improve patient outcomes and remain cost-effective for payors. There are a limited number of treatment alternatives available to patients with liver cancer. The traditional treatment options include surgery, chemotherapy, cryosurgery, percutaneous ethanol injections and radiation therapy. 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. Further, these treatments generally have limited efficacy and/or applicability.

RadioTherapeutics Corporation, which was recently acquired by Boston Scientific Corporation, and Radionics, a division of Tyco Healthcare, which is a division of Tyco International, are the two companies whose products compete directly with ours in the United States and overseas. Both companies offer systems that include a generator and disposable electrodes and use radiofrequency energy to ablate soft tissue. However, neither system is designed to provide physicians with the temperature feedback throughout the tissue that we believe is important to help ensure successful tissue ablation.

We believe the principal competitive factors in our markets are:

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

- patent protection;
- product quality and reliability; and
- cost effectiveness.

While there are small international companies using radiofrequency technology to treat cancer, we do not expect these companies to establish a meaningful presence in our market in the near future. If companies that currently sell products that utilize radiofrequency energy enter our market, competition could increase.

Third-Party Reimbursement

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

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.

Product Development

We believe that we have a strong base of proprietary design, development and manufacturing capabilities. We have particular expertise in the core research and development areas relevant to the production of new disposable electrode devices for use in conjunction with our radiofrequency generators. In the fourth quarter of 2001, we introduced next-generation ablation products, including our line of Starburst XLi disposable electrodes. We are working on a number of enhancements to our existing products that we believe will further improve the ablation process. During the past three fiscal years, we have spent the following amounts on company-sponsored research and development efforts: $6.5 million in 2001, $5.6 million in 2000 and $3.9 million in 1999.

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 February 28, 2002, we had 46 issued patents worldwide and more than 50 United States and foreign patent applications pending. The issued patents cover, among other things, deployable multi-array electrode technology and temperature feedback technology. Our United States patents expire between 2012 and 2018. Our European-wide patent expires in 2015 and our Japanese patent expires in 2015.

Government Regulation

Our products are regulated in the United States by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDC Act, and require clearance of a premarket notification under Section 510(k) of the FDC Act or approval of a premarket approval application under Section 515 of the FDC Act by the FDA prior to commercialization. Material changes or modifications to medical devices, including changes to product labeling, are also subject to FDA review and clearance or approval. Under the FDC Act, the FDA regulates, among other things, the research, clinical testing, manufacturing, safety, effectiveness, labeling, storage, record keeping, advertising, distribution, sale and promotion of medical devices in the United States. Non-compliance with applicable requirements can result in, among other actions, warning letters, fines, injunctions, civil and criminal penalties against 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. 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 which we believe 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 our products in international markets that include the European Economic Area, Japan, Korea, Canada, Australia, New Zealand, and other countries. We are seeking or intend to seek, regulatory registrations or approvals in other international markets.

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.

Manufacturing

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

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.

Employees

As of February 28, 2002, we had 113 full-time employees, including 47 in sales and marketing, 36 in manufacturing, 16 in research and development and 14 in general and administrative functions. From time to time, we also employ independent contractors to support our organization.

Executive Officers of the Registrant

The following table shows specific information about our executive officers as of February 28, 2002.

Name	Age	Position(s)
Barry Cheskin...	41	Chief Executive Officer, President and Director
Donald Stewart..	46	Chief Financial Officer and Vice President, Finance and Administration
Daniel Balbierz.	40	Vice President, Research and Development
Vicki Hacker....	45	Vice President, Clinical Affairs
David Horn.....	34	Vice President, Business Development
Eric Mueninghoff	44	Vice President, Marketing
Trent Reutiman..	37	Vice President, U.S. Sales
Ronald Steckel..	48	Senior Vice President, Operations
Kenneth Waters..	50	Senior Vice President, Global Sales

Barry Cheskin has served as our President and Chief Executive Officer since May 1997. Prior to joining us, he held various positions at Datascope Corp, a medical device company. He was President, Collagen Products Division and Corporate Vice President from May 1994 to April 1997, General Manager, Vasoseal/Bioplex Division from November 1992 to May 1994, and Director, Corporate Business Development from April 1992 to November 1992. Mr. Cheskin holds a B.S. in Mechanical Engineering from Massachusetts Institute of Technology, an M.S. in Mechanical Engineering from Stanford University, and an M.B.A. from Columbia University.

Donald Stewart has served as our Vice President, Finance and Administration and Chief Financial Officer since April 2001. Prior to joining us, Mr. Stewart served from May 1998 to April 2001 as the Vice President of Finance and Administration, CFO and Secretary at Abaxis Corporation in Union City, California. Previously, from March 1997 through February 1998, Mr. Stewart held the position of Vice President, Finance and Administration for Mimetix, Inc. Prior to his employment with Mimetix, Inc., he was employed for thirteen years at SEQUUS Pharmaceuticals, Inc. in a series of positions culminating with the role of Vice President, Finance and Treasurer. Mr. Stewart holds a B.S. in Accounting from San Francisco State University and an M.B.A. from Santa Clara University. He is a Certified Public Accountant.

Daniel Balbierz has served as our Vice President, Research and Development since April 1998. Prior to joining us, he held the position of Worldwide Director, Research and Development for the Vascular Access Division of Johnson & Johnson Medical, Inc., a medical device company, from March 1996 to March 1998. Previously, Mr. Balbierz held the position of Director, Research and Development at Menlo Care, a medical device company, from June 1987 to March 1996. Mr. Balbierz holds a B.S. in Mechanical Engineering from California

Polytechnic State University.

Vicki Hacker has served as our Vice President, Clinical Affairs since February 2000. Prior to joining us, she held various positions at Cardima Corporation, an electro-physiology company, including Director of Clinical Research from March 1999 to January 2000 and Manager of Clinical Programs from June 1997 to February 1999. Previously, Ms. Hacker held the position of Senior Clinical Education/Research Specialist at Heartport, a minimally invasive cardiac surgery company, from June 1996 to May 1997. From July 1993 to May 1996, she held the position of Associate Director of Clinical Research at Advanced Bioresearch Associates, a contract research association. Ms. Hacker holds a B.S. in Nursing from Rush University and an M.S. in Nursing and Administration from San Jose State University.

David Horn has served as our Vice President, Business Development since September 2001. From February 2000 through November 2000, Mr. Horn held the position of Vice President, Corporate Development for Ventro Corporation. From December 1999 through February 2000, he served as Vice President in the Corporate Finance Department of Morgan Stanley Dean Witter & Co., a financial services corporation. From July 1995 through November 1999, he held the position of Associate in the Corporate Finance Department of Morgan Stanley Dean Witter & Co. Mr. Horn holds an A.B. in Political Economy from Princeton University and an M.B.A. from Stanford University.

Eric Mueninghoff has served as our Vice President, Marketing since March 2001. From February 2000 to February 2001, he served as Director of Global Marketing. From January 1999 to January 2000, Mr. Mueninghoff served as Director of United States Sales. Mr. Mueninghoff joined RITA as National Sales Manager in September 1997. Prior to joining us, Mr. Mueninghoff held the position of National Sales Manager for Aria Technologies, a fiberoptics company, from January 1997 to September 1997. Previously, he held the position of Executive Territory Manager for the Chiron Vision Corporation, an ophthalmic device company, from September 1995 to January 1997. Mr. Mueninghoff holds a B.S. from Illinois State University.

Trent Reutiman has served as our Vice President of U.S. Sales since December 2001. From January 2001 to December 2001, he served as Director of U.S. Sales and from March 2000 to January 2001 he served as a regional sales manager. Prior to joining us, Mr. Reutiman served from March 1998 through March 2000 as a district sales manager with the Cardio Thoracic Systems Division of Guidant Corporation. From October 1996 through February 1998 he was a sales representative for Johnson and Johnson's Cordis division. Mr. Reutiman holds a B.S. in Business Administration from Colorado State University and an M.B.A. from the University of California, Irvine.

Ronald Steckel has served as our Vice President, Operations since June 1998 and was promoted to Senior Vice President, Operations in January 2001. Prior to joining us, Mr. Steckel held various positions at Metra Biosystems, Inc., a medical diagnostics company, including Senior Vice President from July 1996 to June 1998, Vice President, Operations from February 1992 to June 1996 and a consultant from July 1991 to February 1992. Mr. Steckel holds a B.S. in Biology from Blackburn University and an M.B.A. from Lake Forest College.

Kenneth Waters has served as our Senior Vice President, Global Sales since November 2001. From 1993 through November 2001, Mr. Waters held the position of Vice President of Global Sales for the Cardiac Assist Division of Datascope Corporation. Previously, he held other positions with Datascope Corporation, including National Sales Manager, U.S. and Director of Sales, U.S. Mr. Waters

holds a B.S. in Management from Jacksonville State University.

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 2002 and that additional space will be available at commercially reasonable terms to meet future growth requirements. See also Note 5 in the "Notes to Financial Statements" contained elsewhere in this Form 10-K.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings, other than the patent disputes described in "Risk Factors--We are currently involved in a patent interference action and a patent opposition action involving RadioTherapeutics Corporation, and if we do not prevail in these actions, we may be unable to sell the RITA System." The patent interference proceeding is pending before the Board of Patent Appeals and

Interferences of the United States Patent and Trademark Office. On July 16, 1999 the United States Patent and Trademark Office declared interference between a claim of one of our issued patents and claims of a patent application controlled by RadioTherapeutics Corporation. The principal parties in the proceeding are RadioTherapeutics and RITA. The factual basis underlying the claim is the determination by the commissioner of the United States Patent and Trademark Office that our patent and the RadioTherapeutics patent application interfere. In the interference proceeding, RadioTherapeutics seeks to invalidate our patent claim and to establish the patentability of the claims in their patent application. We seek to maintain the priority of our patent claim. On February 26, 2001, the USPTO issued a decision on preliminary motions filed in the patent interference proceeding. The decision found that one of the claims in our United States Patent No. 5,536,267 (claim no. 32) is invalid. We expect to receive final confirmation of that decision later this year. The European opposition is pending before the European Patent Office and was instituted on March 2, 2000. The principal parties are RadioTherapeutics and RITA. The factual basis underlying the claim is the allegation by RadioTherapeutics that our European patent is not valid. In the opposition, RadioTherapeutics seeks to have our patent declared invalid and to have our patent cancelled. We are defending our patent and seek to defend it as issued. On February 7, 2002, the European Patent Office determined that we are entitled to European Patent No. 0777445 which covers radiofrequency ablation technology. The European Patent Office approved 27 claims, despite the opposition proceeding by RadioTherapeutics. In addition to these patent proceedings, we may from time to time become a party to various legal proceedings arising in the ordinary course of our business.

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

Not applicable.

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 2000 and 2001 as reported by the Nasdaq National Market:

	HIGH	LOW
Year ended December 31, 2000.....		
Third quarter.....	$14.38	$8.88
Fourth quarter.....	$12.38	$5.00
Year ended December 31, 2001.....		
First quarter.....	$ 9.50	$2.81
Second quarter.....	$ 5.44	$3.38
Third quarter.....	$ 5.41	$2.66
Fourth quarter.....	$ 6.67	$2.81
Year ended December 31, 2002.....		
First quarter (through February 28, 2002).	$ 6.91	$5.41

On February 28, 2002, the last reported sales price of our common stock on the Nasdaq National Market was $6.11. As of February 28, 2002, there were 111 holders of our common stock. This does not include the number of persons whose stock is in the nominee or "street name" accounts through brokers. The market price of our common stock has been and may continue to be subject to wide fluctuations in response to a number of events and factors, such as quarterly variations in our operating results, announcements of technological innovations or new products by us or our competitors, changes in financial estimates and recommendations by securities analysts, the operating and stock performance of other companies that investors may deem comparable to us, and news reports relating to trends in our markets. These fluctuations, as well as general economic and market conditions, may adversely affect the market price for our common stock.

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

In December 2001, we issued a warrant to purchase 25,000 shares of our common stock in connection with a patent license. In October 2001, we issued a warrant to purchase 25,000 shares of common stock in connection with a severance agreement. Consideration for these warrants was a nominal amount of cash plus the execution of the related agreements. The issuances were 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.

In the year ending December 31, 2000, we issued 412,447 shares of unregistered common stock to our employees pursuant to the exercise of stock options under our 1994 incentive stock plan and our 2000 stock plan. These options were exercised at a weighted average exercise price of $1.14 per share. These issuances were made in reliance upon Rule 701 promulgated under the Securities Act.

On July 26, 2000, we completed our initial public offering of 3,600,000 common shares at a price of $12.00 per share, raising approximately $39.0 million net of underwriting discounts, commissions and other offering costs (see also Note 6 in the "Notes to the Financial Statements" contained elsewhere in this Form 10-K). The managing underwriters were Salomon Smith Barney and Robertson Stephens. As of December 31, 2001, we have fully used the proceeds of the offering to expand sales, marketing, physician and patient awareness programs, to continue product development and clinical research programs, to repay debt and to fund general corporate purposes including working capital, as follows:

Use	Approximate Dollar Amount (in millions)
Permanent working capital	$ 5.0
Repayment of term loans and other debt	$ 4.6
Sales, marketing, research and clinical programs and general corporate purposes	$29.4
TOTAL	$39.0

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 financial statements. Our audited statement of operations for the years ended December 31, 2001, 2000 and 1999 and our audited balance sheet at December 31, 2001 and 2000 are presented elsewhere in this Form 10-K. The unaudited information provided below is in thousands, except for per share data.

	Years ended December 31,				
	2001	2000	1999	1998	1997
Statement of Operations Data:					
Sales	$ 14,791	$ 10,010	$ 4,629	$ 1,137	$ 2
Cost of goods sold	6,132	6,048	2,994	1,523	5
Gross profit (loss)	8,659	3,962	1,635	(386)	(3
Operating expenses:					
Research and development	6,489	5,615	3,931	2,729	2,4
Selling, general and administrative	16,646	12,052	5,452	3,606	2,8
Total operating expenses	23,135	17,667	9,383	6,335	5,3

Loss from operations	(14,476)	(13,705)	(7,748)	(6,721)	(5,6
Interest and other income (expense), net	1,516	898	238	(28)	(1
Net loss	$(12,960)	$(12,807)	$ (7,510)	$ (6,749)	$ (5,8
Net loss per share, basic and diluted	$ (0.90)	$ (1.99)	$ (9.33)	$ (10.10)	$ (11.
Shares used in computing net loss per share, basic and diluted	14,353	6,440	805	668	5

	December 31,				
	2001	2000	1999	1998	1997
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 19,184	$ 40,057	$ 12,153	$ 7,644	$ 1
Working capital	25,478	41,512	12,437	7,560	(2,2
Total assets	35,834	46,270	15,705	9,009	1,0
Long-term obligations, net of current portion	--	180	1,854	--	
Convertible preferred stock and preferred stock warrants	--	--	38,516	28,337	12,4
Common stock and additional paid-in capital	88,474	88,435	3,652	165	
Total stockholders equity (deficit)	32,145	42,647	(26,991)	(20,510)	(14,2

Quarterly Results of Operations:

The following table sets forth selected items from our statements of operations for each of the eight quarters ended December 31, 2001. This data has been derived from unaudited financial statements that, in the opinion of our management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of such information when read in conjunction with our annual audited financial statements and notes thereto appearing elsewhere in this Form 10-K. The operating results for any quarter are not necessarily indicative of results for any future period.

	Quarter Ended							
	Dec. 31, 2001	Sept. 30, 2001	June 30, 2001	Mar. 31, 2001	Dec. 31, 2000	Sept. 30, 2000	June 30, 2000	Mar 2
Net Sales	$ 4,011	$ 3,707	$ 3,769	$ 3,304	$ 3,030	$ 2,712	$ 2,427	$ 1
Gross Profit	2,790	2,235	2,099	1,535	1,279	1,090	933	
Net Loss	$(3,761)	$(3,084)	$(2,993)	$(3,122)	$(3,067)	$(2,956)	$(3,207)	$(3
Net Loss per Share	$ (0.26)	$ (0.21)	$ (0.21)	$ (0.22)	$ (0.22)	$ (0.31)	$ (2.79)	$ (
Shares used in computing net loss per share, basic and diluted	14,514	14,406	14,320	14,167	13,869	9,607	1,150	1

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations and other parts of this Form 10-K contain forward-looking statements that involve risks and uncertainties. Words such as "anticipates", "expects", "intends", "plans", "believes", "seeks", "estimates", and similar expressions identify such forward-looking statements. These statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or forecasted. Factors that might cause such a difference include, but are not limited to, those discussed in the section entitled "Factors That May Affect Future Results" and those appearing elsewhere in this Form 10-K. Readers are cautioned not to place undue reliance on these forward-looking statements that reflect management's analysis only as of the date hereof. We assume no obligation to update these forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements.

Business Overview and Discussion of Known Trends

We develop, manufacture and market minimally invasive products that use radiofrequency energy to treat patients with solid cancerous or benign tumors. From inception in 1994 through 1996, our operations consisted primarily of various start-up activities, including development of technologies central to our business, recruiting personnel and raising capital. In 1997, we began commercial product shipments. In 2001, we commercially launched our StarBurst XLi family of disposable devices and significantly expanded our direct domestic sales organization and our international distribution network.

Our products are sold in the United States through our direct sales force and internationally through distribution partners. For the year ended December 31, 2001, sales in the United States accounted for 54% of our total sales while sales in our international markets accounted for 46% of our total sales. We expect domestic sales to account for an increasing percentage of total sales in future years due to our significant investment in our domestic sales force and because, at least for 2002, our premium-priced Starburst XLi family of disposable needles will only be distributed in the United States. Conversely, we expect reimbursement issues in Europe and Japan to limit sales growth in these regions for the next several years. However, our international operations will continue to represent a significant, if decreasing, portion of our revenue because of the high incidence of primary liver cancer in Asian and European markets.

All of our revenue is derived from the sale of our disposable devices and radiofrequency generators. For the year ended December 31, 2001, 78% of our sales were derived from our disposable devices and 22% were derived from the sale of our generators. We will continue to focus on expanding our base of customer accounts and on increasing usage of our disposable products in our established accounts. As a result, revenue from our higher-margin disposable devices should continue to grow faster than revenue from our generators.

To date, essentially all of our revenue has come from products sold in the treatment of cancerous liver tumors. In 2002, we expect some additional revenue in the fourth quarter to come from the use of the RITA system sold for the treatment of patients with metastatic bone tumors, and nominal revenue at the end of 2002 from sales for the treatment of unresectable lung tumors. We are conducting research and clinical trials in other organs that may lead to additional sources of revenue in the years beyond 2002.

Our manufacturing costs consist of raw materials, including generators

produced for us by third-party suppliers, labor to produce our disposable devices and to inspect incoming, in-process and finished goods, sterilization performed by an outside service provider and general overhead expenses. Gross margins are affected by production volumes, average selling prices, the sales mix of higher-margin disposable devices versus generators and the mix of domestic direct sales versus international sales, which provide for standard distributor discounts. Our gross margin improved in 2001, increasing to 59% from 40% in 2000, in response to the increasing percentages of domestic business and disposable products in our sales mix and lower unit costs driven by higher production volumes. We expect gross margins to continue to improve in the near term primarily as a result of continued improvements in our sales mix and cost factors and also due to the growing acceptance of our premium-priced Starburst XLi line of disposable devices.

For the year ended December 31, 2001, 28% of our operating expenses were related to research and development activities, down from 32% in 2000. We expect our research and development activities to continue to grow more slowly than sales and marketing activities, at least through 2002, as we commit significantly more resources to market development and business expansion efforts. Selling, general and administrative activities represented 72% of our operating expenses for the year, up from 68% in 2000. This increase resulted from investments in the expansion of our domestic sales force and international distribution support activities as well as physician training and patient awareness programs. Also, because our collection periods in Europe have grown longer as a result of difficult economic conditions, we increased our allowance for uncollectible accounts to 11% of gross trade receivables as of December 31, 2001, from 4% at December 31, 2000. This increase further affected growth in administrative expense. While our investments in market growth and business development will continue to grow, we believe the deterioration we experienced in our European collections in 2001 will begin to stabilize as the global economy improves and that the need to increase our allowance for uncollectible accounts will moderate.

Our working capital decreased to $25.5 million at December 31, 2001, from $41.5 million at December 31, 2000, primarily due to cash used to fund operations. However, our investments in accounts receivable and inventory increased during the year. Accounts receivable, net of reserves, were $5.1 million at December 31, 2001, up from $2.4 million at December 31, 2000. This increase was due to our increasing sales volume and to a significant lengthening of collection cycle with our European distributors. Inventory, net of reserves, was $3.6 million at December 31, 2001, up from $1.6 million at December 31, 2000. Inventory growth was driven by increasing sales volume and temporary investments intended to support the market introduction of new products.

In connection with grants of stock options to employees and non-employees, we record deferred stock-based compensation as a component of stockholders' equity. This stock-based compensation is amortized as charges to operations over the vesting periods of the options. We recorded amortization of deferred compensation of $1.4 million for the year ended December 31, 2001. We expect to record additional amortization expense for deferred compensation, in diminishing amounts, through 2004, at which point our existing deferred stock-base compensation will be fully amortized.

We incurred net losses of $13.0 million for the year ended December 31, 2001. As of December 31, 2001, we had an accumulated deficit of $54.4 million. Due to the high costs associated with continued research and development programs, expanded clinical research programs and increased sales and marketing

efforts, we expect to incur net losses for the full year 2002, but losses should diminish through the first three quarters of the year, and we expect to be modestly profitable in the fourth quarter of 2002. Profitability beyond 2002 will depend on our success in expanding product usage in our current market and in developing new markets. To the extent current or new markets do not materialize in accordance with our expectations, our sales and profitability could be lower than expected and we may be unable to achieve or sustain profitability.

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

Critical Accounting Policies

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 Financial Statements included elsewhere in this Form 10-K.

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

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

Litigation costs: In August 2001, we filed a complaint in the United States District Court for the Northern District of California against RadioTherapeutics Corporation. As discussed in Note 5 of our consolidated financial statements appearing elsewhere in this Form 10K, the complaint alleges that RadioTherapeutics' radiofrequency ablation products infringe six of our patents. The litigation costs thereby incurred in defense of our patents, approximately $332,000 as of December 31, 2001, have been capitalized. Amortization of this asset has been matched to the remaining life of the six patents, approximately 11 years. Although we expect a favorable outcome in this matter, an unsuccessful outcome would require an immediate charge to earnings of any remaining unamortized costs. It is probable that additional litigation costs will be capitalized in future periods.

Contingencies: In addition to the complaint described in the preceding paragraph, we are involved in a patent interference proceeding in the United States with RadioTherapeutics Corporation in which the validity of one of our

patents has been called into question. Although we believe we have meritorious defenses, we could be prevented from selling the RITA system or be required to pay license fees and/or royalties on past and future product sales if we do not prevail in this interference proceeding. Further, we are involved in a patent opposition currently pending before the European Patent Office. The principal parties in this opposition are RadioTherapeutics and RITA. RadioTherapeutics seeks to have our only European patent declared invalid. In

February 2002, the European Patent Office determined that we were entitled to this patent, European Patent No. 0777445, but appeals of this decision are likely and a final decision is not expected in this opposition proceeding for several years. If we do not prevail in the opposition proceeding, we could lose our only currently issued patent in Europe.

Both the interference proceeding in the United States and the European opposition proceeding are discussed in Note 5 to our consolidated financial statements contained elsewhere in this form Form 10-K. As of December 31, 2001, it is not possible to estimate additional probable costs for the resolution of these claims. Although we do not currently believe these proceedings will have a material adverse effect on our consolidated financial position, it is possible that future results of operations could be materially affected by rulings that are unfavorable to us.

Revenue recognition: Revenue is recognized upon receipt of a customer purchase order and subsequent product shipment provided no significant obligations remain and collection of the associated receivable is deemed probable. This policy is applied to all of our customers, including our distributors, who have no price protection and no return rights on product purchased. Should changes in conditions or the status of obligations cause us to determine that our criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected. We do not generally engage in "bundling" transactions that would call for the deferral of revenue. Through December 31, 2001, all of our billings have been denominated in US dollars, although we expect relatively minor billings in foreign currencies in future periods.

Results of Operations

The following table sets forth the percentage of net revenue represented by certain items in our Statements of Operations for the years ended December 31, 2001, 2000 and 1999 respectively:

	Years Ended December 31,		
	2001	2000	1999
Sales	100%	100%	100%
Cost of goods sold	41%	60%	65%
Gross profit	59%	40%	35%
Operating expenses:			
Research and Development	44%	56%	85%
Selling, general and administrative	113%	120%	118%

Total operating expenses.....	156%	176%	203%
Loss from operations.....	(98%)	(137%)	(167%)
Interest and other income (expense), net	10%	9%	5%
Net loss.....	(88%)	(128%)	(162%)

Years Ended December 31, 2001 and 2000

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

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

Research and development expenses for the year ended December 31, 2001 were $6.5 million as compared to $5.6 million in 2000. This increase was due to expenses associated with the development of our next-generation technology, increased clinical program spending, and increased spending related to the growth and protection of our patent portfolio. Amortization of deferred stock-based compensation was $465,000 for the year, down from $998,000 in 2000. We expect to continue to make substantial investments in research and development, although research and development expense may fall in 2002 as most of the development costs of the new Starburst Xli disposable device have already been recognized.

Selling, general and administrative expenses for the year ended December 31, 2001 were $16.6 million as compared to $12.1 million in 2000. The increase was primarily attributable to the major expansion of our domestic sales organization, additional investments in market development and public relations, and administrative expenses relating to provisions to our allowance for uncollectible accounts. Amortization of deferred stock-based compensation was $349,000 for the year, down from $2,898,000 in 2000. We anticipate that selling, general and administrative expenses will continue to increase as we

expand our sales organization, invest in marketing and public relations and add personnel.

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

Years Ended December 31, 2000 and 1999

For the year ended December 31, 2000, sales totaled $10.0 million, an increase of 116% from $4.6 million in 1999. We experienced growth in both domestic and international markets, with domestic sales increasing 136% and international sales increasing 105% over the previous year. For the year ended December 31, 2000, domestic sales represented 39% of total revenue, as compared to 36% in 1999. We experienced growth in sales of our disposable products and our generators, with disposable product sales increasing 124% and generator sales increasing 102% over the previous year. For the year ended December 31, 2000, disposable sales accounted for 67% of total revenue, as compared to 64% in 1999. Higher unit shipments of generators and disposables resulted from increased physician awareness of our technology, a major expansion of our domestic sales force, increased geographical representation through the appointment of new international distributors and the launch of our Model 1500 generator and StarBurst family of disposable devices.

Cost of goods sold for the year ended December 31, 2000 was $6.0 million as compared to $3.0 million in 1999. The growth in cost of goods sold was attributable primarily to higher material, labor, and overhead costs associated with increased unit shipments. Included in cost of goods sold was amortization of deferred stock-based compensation of $926,000 in the year ended December 31, 2000 as compared to $107,000 in 1999. Excluding the effect of the amortization of deferred stock-based compensation, gross margins improved to 49% in 2000 from 38% in 1999. The improvement was due in part to an increase in average selling prices of our disposable devices, related to the launch of our five-centimeter StarBurst XL electrode. The improvement was

also the result of the increase in higher margin disposable devices as a proportion of total sales. Gross margins also benefited from manufacturing efficiencies attained through higher volume production of our disposable devices.

Research and development expenses for the year ended December 31, 2000 were $5.6 million as compared to $3.9 million in 1999. The expense increase was due to additional personnel, expenses associated with the development of our next-generation technology, increased clinical program spending, increased spending related to the growth and protection of our patent portfolio and increases in the amortization of deferred stock-based compensation. Amortization of deferred stock-based compensation was $998,000 for the year ended December 31, 2000 as compared to $354,000 in 1999.

Selling, general and administrative expenses for the year ended December 31, 2000 were $12.1 million as compared to $5.5 million in 1999. The expense increase was primarily attributable to the major expansion of our domestic sales organization, increased administrative expenses due to added personnel to support our growth in operations, the costs associated with our operation as a public company and increases in the amortization of deferred stock-based

compensation. For the year ended December 31, 2000, we recorded amortization of deferred stock-based compensation of $2.9 million as compared to $530,000 in 1999.

Interest income for the year ended December 31, 2000 was $1.6 million as compared to $446,000 in 1999. The increase in interest income was primarily attributable to earnings on short-term investments made with cash received from our initial public offering of common shares completed in the third quarter of 2000. Interest expense for the year ended December 31, 2000 was $683,000 as compared to $212,000 in 1999. The increase in interest expense for 2000 was attributable to higher average debt outstanding on the loan and security agreement entered into in June 1999. During the third quarter of 2000, we repaid all debt outstanding under our term loans, and during the fourth quarter of 2000, we repaid $500,000 of borrowings under our revolving credit facility, bringing our bank debt outstanding to $833,000 at December 31, 2000.

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 totaled $1.3 million in principal outstanding at December 31, 2000 and $0.2 million at December 31, 2001. As of December 31, 2001, we had $7.3 million of cash and cash equivalents, $11.9 million of marketable securities, $4.4 million in investments intended for resale and $25.5 million of working capital.

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

For the year ended December 31, 2000, net cash used in operating activities was $8.9 million principally due to our net loss and increases in accounts receivable and inventory resulting from higher revenues and increased unit shipments. Our investing activities for the year ended December 31, 2000 were limited to the purchase of property and equipment in the amount of $856,000 and net purchases or sales of short-term investment instruments. For the year ended December 31, 2000, net cash provided by financing activities was $37.6 million, attributable to our initial public offering of common shares, partially offset by borrowings and repayment of debt.

In June 1999, we entered into a loan and security agreement for a loan facility of up to $5.0 million. The facility consisted of two term loans of $1.5 million each and a revolving credit note of up to $2.0 million. As of December 31, 2000, borrowings under the term loans had been completely repaid and we had a balance outstanding of $833,000 on the revolving credit note, bearing interest at 2% over the prime rate. This balance was paid as scheduled in 2001 and the loan facility was cancelled. We have also, from time to time,

financed equipment through capital and operating leases. As of December 31, 2001, our future minimum payments due under capital and operating leases are as follows:

Future minimum capital lease payments	
Payments due in 2002	$ 204
Less imputed interest (including warrants)	(12)
Present value of future minimum capital lease payments	$ 192
Future minimum operating lease payments	
2002	$ 530
2003	533
2004	356
Total of future minimum operating lease payments	$1,419

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

Income Taxes

As of December 31, 2001, we had federal net operating loss carryforwards of approximately $42.7 million and state net operating loss carryforwards of approximately $18.0 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 2010 and 2021, and the state net operating loss carryforwards will expire between 2002 and 2006, 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 8 to "Notes to Financial Statements" appearing elsewhere in this Form 10-K.

Recent Accounting Pronouncements

In July 2001, the Financial Accounting and Standards Board ("FASB") issued Statements of Financial Accounting Standards No. 141 ("SFAS 141"), "Business Combinations," and No. 142 ("SFAS 142"), "Goodwill and Other Intangible Assets." SFAS 141 requires that all business combinations initiated after June 20, 2001 be accounted for under the purchase method. Use of the pooling-of-interests method is no longer permitted. SFAS 142 requires that goodwill no longer be amortized to earnings, but instead be reviewed for

impairment upon initial adoption of the Statement and on an annual basis going forward. The amortization of goodwill will cease upon adoption of SFAS 142. The provisions of SFAS 142 will be effective for fiscal years beginning after December 15, 2001. The Company is required to adopt SFAS 142 in the first quarter of 2002. We believe that adoption of these standards will have no impact on our financial statements.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS No. 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. This Statement supersedes FASB Statement No. 121 and APB 30, however, this Statement retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. This Statement addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Management does not expect the adoption of SFAS No. 144 to have a material impact on the Company's financial position and results of operations.

In May 2000, the Emerging Issues Task Force (EITF) issued EITF Issue No. 00-14, "Accounting for Certain Sales Incentives," addressing the recognition, measurement and income statement classification of sales incentives that a vendor voluntarily offers to its customers, without charge, and which customers may then use in, or exercise as a result of, a single exchange transaction. Sales incentives falling within the scope of EITF Issue No. 00-14 include offers that customers may use to receive a reduction in the price of products or services at the point of sale. In June 2001, the EITF issued EITF Issue No. 00-25, "Vendor Income Statement Characterization of Consideration Paid to a Reseller of the Vendor's Products," addressing whether consideration from a vendor to a reseller is (a) an adjustment to the selling prices of the vendor's products and therefore a deduction from revenue when recognized in the vendor's statement of operations or (b) a cost incurred by the vendor for assets or services received from the reseller and therefore a cost or expense when recognized in the vendor's statement of operations. In September 2001, the EITF issued Issue No. 01-09, "Accounting for Consideration Given by a Vendor to a Customer or a Reseller of the Vendor's Products," which is a codification of EITF Issues No. 00-14, No. 00-25 and also No. 00-22, "Accounting for 'Points' and Certain Other Time or Volume-Based Sales Incentive Offers and Offers for Free Products or Services to be Delivered in the Future." The requirements of EITF Issue No. 01-09, as with the preceding Issues No. 00-14, No. 00-22 and No. 00-25, became effective for annual or interim financial statements dated after December 15, 2001, and include a requirement to reclassify the financial statements of prior periods as necessary to conform with current income statement display standards. No material impact on our financial statements has resulted from the adoption of the above EITF Issues.

Factors That May Affect Future Results

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

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

Because all of our revenue comes from the sale of the RITA system, our

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

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

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

motion in a United States District Court requesting review of the decision. Final determination of the patent interference proceeding may take several years. If the final determination of the United States District Court results in the issuance of patent rights related to the claim to RadioTherapeutics and we were unable to obtain a license to use the relevant patent or successfully modify our disposable device, we could be unable to sell our system and our business could suffer.

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

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

We anticipate that our operating expenses will increase substantially in absolute dollars for the foreseeable future as we expand our sales and marketing, manufacturing, clinical research and product development efforts. In addition, we have charged operating expense to increase our allowance for uncollectible accounts in connection with lengthening collection periods for our accounts in Europe. To become profitable, we must continue to increase our sales. If sales do not continue to grow, we may not be able to achieve or maintain profitability in the future. In particular, we incurred net losses of $13.0 million in 2001, $12.8 million in 2000 and $7.5 million in 1999. At December 31, 2001, we had an accumulated deficit of approximately $54.4 million.

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

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

We compete directly with two companies in the domestic and international markets: RadioTherapeutics Corporation, a division of Boston Scientific Corporation, and Radionics, Inc., a division of Tyco Healthcare, which is a division of Tyco International. Boston Scientific Corporation and Tyco International are publicly traded companies with substantially greater resources than we have. Both RadioTherapeutics and Radionics sell products that use radiofrequency energy to ablate soft tissue.

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

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

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

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

If we are unable to protect our intellectual property rights, we may lose market share to a competitor and our business could suffer.

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

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

business could suffer.

If we are sued for patent infringement, we could be prevented from selling our products and our business could suffer.

We are aware of the existence of patents held by competitors in our market, which could result in a patent lawsuit against us. In the event that we are subject to a patent infringement lawsuit and if the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be prevented from selling our products unless we could obtain a license or were able to redesign the product to avoid infringement. If we were unable to obtain a license or successfully redesign our system, we may be prevented from selling our system and our business could suffer.

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

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

- the challenge of managing international sales without direct access to the end customer;
- the risk of inventory build-up by our distributors which could negatively impact sales in future periods;
- obtaining reimbursement for procedures using our devices in some foreign markets;
- the burden of complying with complex and changing foreign regulatory requirements;
- longer accounts receivable collection time;
- significant currency fluctuations, which could cause our distributors to reduce the number of products they purchase from us because the cost of our products to them could increase relative to the price they could charge their customers;
- reduced protection of intellectual property rights in some foreign countries; and
- contractual provisions governed by foreign laws.

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

We are substantially dependent on a limited number of significant distributors in our international markets, and if we lose these distributors and fail to attract additional distributors, our international revenues could decline. ITX Corporation, formerly known as Nissho Iwai Corporation, is our primary distributor in Asia. It accounted for 31 percent of our international revenues for the year ended December 31, 2001 and 48 percent of our international revenues in 2000. M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, accounted for 17 percent of our international revenues

for the year ended December 31, 2001 and 17 percent of our international revenues for 2000. Because international revenues accounted for 46 percent of our total revenues for the year ended December 31, 2001 and these two distributors represented 48 percent of that total, the loss of either distributor or a significant decrease in unit purchases by either distributor could cause revenues to decline substantially. If we are unable to attract additional international distributors, our international revenues may not grow.

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

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

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

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

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

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

Physicians, hospitals and other health care providers may be reluctant to purchase our products if they do not receive substantial reimbursement for the cost of the procedures using our products from third-party payors, such as Medicare, Medicaid and private health insurance plans. Although we were notified in February 2002 by the American Medical Association that specific reimbursement codes for radiofrequency ablation of liver tumors have been established, they reserve the right to reverse this decision. In this case, we would be required to reapply for a specific code. This process is time consuming and costly and may require us to provide extensive supporting scientific, clinical and cost-effectiveness data for our products to the American Medical Association. Even though we were successful in establishing a new code, a payor still may not reimburse adequately for the procedure or product. In addition, there is no specific reimbursement code for radiofrequency ablation of tumors

in other organs. Further, we believe the advent of fixed payment schedules has made it difficult to receive reimbursement for disposable products, even if the use of these products improves clinical outcomes. Fixed payment schedules typically permit reimbursement for a procedure rather than a device. If physicians believe that our system will add cost to a procedure but will not add sufficient offsetting economic or clinical benefits, physician adoption could be slowed.

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

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

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

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

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

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

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

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

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

It is critical to our sales effort to train a sufficient number of physicians and to instruct them properly in the procedures that utilize our

products. We have established formal physician training programs and rely on physicians to devote adequate time to understanding how and when our products should be used. If physicians are not properly trained, they may misuse or ineffectively use our products. This may result in unsatisfactory patient outcomes, patient injury and related liability or negative publicity that could have an adverse effect on our product sales.

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

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

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

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

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

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

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

To be successful, we must manufacture our products in substantial quantities

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

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

Because there is only one supplier that provides us with a component that we include in our disposable devices, a disruption in the supply of this component could negatively affect revenues. This supplier is the only source of this component. If we were unable to remedy a disruption in supply of this component within twelve

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

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

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

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

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

Sales of our products outside the United States are subject to foreign regulatory requirements that vary from country to country. The time required to

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

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

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

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

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

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

Because our executive officers and directors, and their respective affiliates, own approximately 28 percent of our outstanding common stock, these stockholders may, as a practical matter, be able to exert significant influence over matters requiring approval by our stockholders, including the election of

directors and the approval of mergers or other business combinations. This concentration of voting stock could have the effect of delaying or preventing a change in control.

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

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

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

Our exposure to interest rate risk at December 31, 2001 is related to our investment portfolio; we have no interest rate sensitive borrowings as of that date. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. Floating rate investments may produce less income than expected if interest rates fall, and floating rate borrowings 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 2001 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.

Item 8. Consolidated Financial Statements and Supplementary Data.

RITA Medical Systems, Inc.

Index to Consolidated Financial Statements

Report of Independent Accountants

To the Stockholders and Board of Directors
of RITA Medical Systems, Inc.

In our opinion, the consolidated financial statements listed in the accompanying index appearing under Item 14 on page 55, present fairly, in all material respects, the financial position of RITA Medical Systems, Inc. and its subsidiaries at December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 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, CA
January 23, 2002

RITA MEDICAL SYSTEMS, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	Decem
	2001
ASSETS	
Current assets:	
Cash and cash equivalents	$ 7,297
Marketable securities	11,887
Accounts receivable, net of allowance for doubtful accounts of $629 at December 31, 2001 and $103 at December 31, 2000	5,056
Inventories, net	3,645
Prepaid assets and other current assets	1,282
Total current assets	29,167
Long term marketable securities	4,353
Property and equipment, net	1,934
Other assets	380
Total assets	$ 35,834

LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable	$ 822
Accrued liabilities	2,675
Current portion of revolving term loan	--
Current portion of capital lease obligations	192
Total current liabilities	3,689
Capital lease obligations, net of current portion	--
Total liabilities	3,689
Commitments and contingencies (Note 5)	
Stockholders' equity:	
Preferred stock, $0.001 par value:	
Authorized: 2,100 shares at December 31, 2001 and 2,000 shares at December 31, 2000	
Issued and outstanding: No shares at December 31, 2001 and December 31, 2000	--
Common stock, $0.001 par value:	
Authorized: 100,000 shares at December 31, 2001 and December 31, 2000	
Issued and outstanding: 14,591 shares at December 31, 2001 and 13,970 shares at December 31, 2000	15
Additional paid-in capital	88,459
Deferred stock-based compensation	(1,905
Stockholder notes receivable	(99
Accumulated other comprehensive income	70
Accumulated deficit	(54,395
Total stockholders' equity	32,145
Total liabilities and stockholders' equity	$ 35,834

See accompanying notes

RITA MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)

	Years Ended December		
	2001	2000	1
Sales	$ 14,791	$ 10,010	$
Cost of goods sold (including stock-based compensation of $558, $926, and $107 in 2001, 2000 and 1999, respectively)	6,132	6,048	
Gross profit	8,659	3,962	

Operating Expenses:			
Research and Development (including stock-based compensation of $465, $998 and $354 in 2001, 2000 and 1999 respectively)	6,489	5,615	
Selling, general and administrative (including stock-based compensation of $349, $2,898 and $530 in 2001, 2000 and 1999 respectively)	16,646	12,052	
Total operating expenses	23,135	17,667	
Loss from operations	(14,476)	(13,705)	(
Interest income	1,610	1,585	
Interest expense	(86)	(683)	
Other income (expense), net	(8)	(4)	
Net loss	(12,960)	(12,807)	(
Other comprehensive income (expense):			
Change in unrealized gain (loss) on marketable securities	57	20	
Comprehensive loss	$(12,903)	$(12,787)	$(
Net loss per common share, basic and diluted	$ (0.90)	$ (1.99)	$
Shares used in computing net loss per share, basic and diluted	14,353	6,440	

See accompanying notes

RITA MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands)

	Common Stock		Additional	Deferred	Stockholder	Accumulated Other Comprehensive
	Shares Issued	Amount $	Paid-in Capital $	Stock-based Compensation $	Note Receivable $	Gain/(Loss) $
Balances, December 31, 1998	778	$ 1	$ 1,538	$ (933)	$ --	$ 2
Stock options exercised	149	--	92	--	(73)	--
Stock compensation	--	--	28	--	--	--
Deferred stock-based compensation	--	--	1,993	(1,993)	--	--
Amortization of deferred stock-based compensation	--	--	--	991	--	--
Change in unrealized gain on marketable securities	--	--	--	--	--	(9)
Net loss	--	--	--	--	--	--
Balances, December 31, 1999	927	1	3,651	(1,935)	(73)	(7)

Conversion of preferred stock to common stock	8,911	9	38,505	--	--	
Issuance of common stock, net	3,600	3	38,716	--	--	
Stock options and warrants exercised	532	1	460	--	(91)	
Deferred stock-based compensation	--	--	7,089	(7,089)	--	
Amortization of deferred stock-based compensation	--	--	--	4,822	--	
Change in unrealized gain on marketable securities	--	--	--	--	--	20
Net loss	--	--	--	--	--	--
Balances, December 31, 2000	13,970	14	88,421	(4,202)	(164)	13
Issuance of common stock, net	89	--	324	--	--	
Stock options and warrants exercised	551	1	406	--		
Cancellation of common stock	(19)	--	(31)		31	
Issuance of common stock warrants for services received			264			
Deferred stock-based compensation	--	--	(925)	925		
Amortization of deferred stock-based compensation	--	--	--	1,372		
Forgiveness of stockholder note receivable, net					34	
Change in unrealized gain on marketable securities	--	--	--	--	--	57
Net loss	--	--	--	--	--	--
Balances, December 31, 2001	14,591	$15	$88,459	$(1,905)	$ (99)	$70

See accompanying notes

RITA MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 3		
	2001	2000	199
Cash flows from operating activities:			
Net loss	$(12,960)	$(12,807)	$(7,
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	1,018	1,019	
Issuance of common stock for services received	--	--	
Issuance of common stock warrants for services received	264	--	
Allowance for doubtful accounts	526	49	

Provision for obsolete inventories	137	17	
Amortization of stock-based compensation	1,372	4,822	
Changes in operating assets and liabilities:			
Accounts receivable	(3,145)	(1,338)	(
Inventory	(2,144)	(809)	(
Prepaid and other current assets	(459)	(323)	
Accounts payable and accrued liabilities	1,177	472	
Net cash used in operating activities	(14,214)	(8,898)	(6,
Cash flows from investing activities:			
Purchase of property and equipment	(1,648)	(856)	(
Purchase of short-term investments	(15,114)	(32,295)	(7,
Maturities of short-term investments	30,650	10,020	4,
Purchase of long-term investments	(4,337)	--	
Capitalization of patent litigation costs	(332)	--	
Notes receivable and other assets	6	6	
Net cash provided by (used in) investing activities	9,225	(23,125)	(3,
Cash flows from financing activities:			
Proceeds from issuance of common stock	731	39,087	
Proceeds from issuance of preferred stock	--	--	9,
Proceeds from long-term debt	--	1,500	1,
Payments on long-term debt	--	(3,000)	
Proceeds from revolving term loan	25	800	
Payments on revolving term loan	(858)	(500)	
Payments on capital lease obligations	(288)	(255)	(
Net cash provided by (used in) financing activities	(390)	37,632	11,
Net increase (decrease) cash and cash equivalents	(5,379)	5,609	1,
Cash and cash equivalents at beginning of year	12,676	7,067	5,
Cash and cash equivalents at end of year	$ 7,297	$ 12,676	$ 7,
Supplemental disclosures of cash flow information:			
Cash paid for taxes	$ 8	$ 6	$
Cash paid for interest	75	460	
Supplemental disclosures of noncash financing activities:			
Issuance of preferred stock warrants in connection with long term debt.	--	--	
Equipment purchased under capital leases	--	319	

See accompanying notes

RITA Medical Systems, Inc.

Notes to Financial Statements

NOTE 1: FORMATION AND BUSINESS OF THE COMPANY

RITA Medical Systems, Inc. (formerly ZoMed International, 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 a family of 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 subsidiary, RITA Medical Systems Netherlands, BV. Intercompany transactions and accounts have been eliminated.

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. 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 and accounts receivable. Cash and cash equivalents are deposited in demand and money market accounts in three financial institutions in the United States and one financial institution in the Netherlands. 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 based on the expected collectibility of individual accounts. Provisions to the allowance for doubtful accounts were approximately $535,000, $50,000 and $27,000 for the years ended December 31, 2001, 2000 and 1999, respectively. Charges against the allowance were approximately $9,000, $1,000 and $2,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

Cash and cash equivalents

All highly liquid investments with original maturities of ninety days or less from the date of purchase are considered to be cash equivalents.

Marketable securities

The Company's marketable securities are categorized as available-for-sale, as defined by Statement of

Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Marketable securities with original maturities greater than three months and less than one year are classified as short-term investments. Marketable securities with original maturities greater than one year are classified as long-term investments. Unrealized holding gains and losses are reflected as a net amount in a separate component of stockholders equity (deficit) until realized. For the purpose of computing realized gains and losses, cost is identified on a specific identification basis.

Fair Value of Financial Instruments

The carrying amounts of some of the Company's financial instruments including cash and cash equivalents, accounts receivable and accounts payable approximate fair value due to their short maturities. Based on borrowing rates currently available to the Company for loans with similar terms, the carrying value of its debt obligations approximates fair value.

Inventories

Inventories are stated at the lower of cost (determined on a first-in, first-out basis) or market. The Company records provisions to write down its inventory for estimated obsolescence or unmarketable inventory equal to the difference between the cost of the inventory and its estimated market value based upon assumptions about future market demand and market conditions. If future demand or market conditions are less favorable than currently expected, additional inventory provisions may be required. Provisions to the allowance for excess and obsolete inventory were approximately $355,000, $139,000 and $144,000 for the years ended December 31, 2001, 2000 and 1999 respectively. Charges against the allowance were approximately $218,000, $122,000 and $39,000 for the years ended December 31, 2001, 2000 and 1999 respectively.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation and amortization. Depreciation and amortization of property and equipment is computed using the straight-line method over the estimated useful lives of the respective assets as follows:

Machinery and equipment	1 to 5 years
Computers and software	3 to 5 years
Furniture and fixtures	5 years

Leasehold improvements are amortized over their estimated useful lives, or the remaining lease term, whichever is shorter, using the straight-line method. Upon sale or retirement, the asset's cost and related accumulated depreciation are removed from the accounts and any related gain or loss is reflected in operations.

RITA Medical Systems, Inc.

Notes to Financial Statements--(Continued)

Long-lived assets

The Company periodically assesses the impairment of its long-lived assets in accordance with the provisions of SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." An impairment review is performed whenever events or changes in circumstances indicate that the carrying value of the Company's long-lived assets may not be recoverable. Indicators which could trigger an impairment review include, but are not limited to, significant underperformance relative to past or planned operating results, significant changes in the strategy for the overall business, significant negative industry trends and/or a significant decline in the stock price of the Company for a sustained period of time. When it is determined, based on one or more of these indicators, that the carrying value of the Company's long-lived assets may not be recoverable, impairment is measured using the projected discounted cash flow method and charged to operations.

Intangible assets

Litigation costs incurred in defense of the Company's patent positions have been capitalized and are carried at cost less accumulated amortization. Amortization of these costs is computed using the straight-line method over the remaining life of the related patents, which was approximately 11 years as of December 31, 2001.

Revenue recognition

Revenue is recognized upon receipt of a customer purchase order and subsequent product shipment, provided no significant obligations remain and collection of the associated receivable is deemed probable. This policy is applied to all the Company's customers, including distributors, who have no price protection or return rights on product purchased.

Research and Development

Research and development costs are expensed as incurred. Research and development costs consist of direct and indirect internal costs related to specific projects as well as fees paid to other entities that conduct certain research activities on behalf of the Company.

Advertising

Advertising production costs are expensed as incurred. Media for print placement costs are expensed in the period the advertising appears. Total advertising and promotional expenses were approximately $169,000, $100,000 and $48,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

Income Taxes

Income taxes are accounted for using the liability method under which deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using 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 amount expected to be realized. Provisions to the allowance were approximately $3,419,000, $3,038,000 and $2,485,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

Accounting for stock-based compensation

The Company accounts for stock-based employee compensation arrangements in accordance with provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB No. 25"). Financial Accounting Standards Board Interpretations ("FIN") No. 28, "Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans" and complies with the disclosure provisions of Statements of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123").

Under APB No. 25, compensation expense is based on the difference, if any, on the date of the grant between the fair value of the Company's stock and the exercise price. SFAS No. 123 defines a "fair value" based method of accounting for an employee stock option or similar equity instruments. The pro forma disclosures of the difference between compensation expense included in net loss and the related cost measured by the fair value method are presented in Note 7.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Task Force Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services."

Net loss per share

Basic earnings per share is calculated based on the weighted-average number of common shares outstanding during the period less the weighted average number of any common shares subject to repurchase by the Company. Diluted earnings per share further includes the dilutive effect of common stock equivalents consisting of stock options, warrants and shares issuable upon conversion of preferred stock provided that the inclusion of such securities is not antidilutive; the Company has reported net losses since its inception and therefore excludes such potentially dilutive securities from its calculation of diluted earnings per share.

The reconciliation of total outstanding common shares to shares used in determining net loss per share is as follows (in thousands):

	Years ended December 31,		
	2001	2000	1999
Net loss, basic and diluted	$12,960	$12,807	$7,510
Weighted-average shares of common stock outstanding	14,419	6,514	805
Less: weighted-average shares subject to repurchase	66	74	--

Weighted-average shares used in basicand diluted net loss per share	14,353	6,440	805

RITA Medical Systems, Inc.

Notes to Financial Statements--(Continued)

The following numbers of shares represented by options and warrants (prior to application of the treasury stock method), shares subject to repurchase and convertible preferred stock (on an as-if converted basis) were excluded from the computation of diluted net loss per share as their effect was antidilutive (in thousands):

	Years ended December 31,		
	2001	2000	1999
Effect of common stock equivalents:			
Unvested common stock subject to repurchase	66	74	--
Options outstanding	2,438	1,890	1,483
Warrants outstanding	19	186	217
Shares resulting from the conversion of the:			
Series A convertible preferred stock	--	557	958
Series B convertible preferred stock	--	824	1,415
Series C convertible preferred stock	--	648	1,113
Series D convertible preferred stock	--	185	318
Series E convertible preferred stock	--	2,986	3,746
Total common stock equivalents excluded from the computation of earnings per share as their effect was antidilutive	2,523	7,350	9,250

Recent accounting pronouncements

In July 2001, the Financial Accounting and Standards Board ("FASB") issued Statements of Financial Accounting Standards No. 141 ("SFAS 141"), "Business Combinations," and No. 142 ("SFAS 142"), "Goodwill and Other Intangible Assets." SFAS 141 requires that all business combinations initiated after June 20, 2001 be accounted for under the purchase method. Use of the pooling-of-interests method is no longer permitted. SFAS 142 requires that goodwill no longer be amortized to earnings, but instead be reviewed for impairment upon initial adoption of the Statement and on an annual basis going forward. The amortization of goodwill will cease upon adoption of SFAS 142. The provisions of SFAS 142 will be effective for fiscal years beginning after December 15, 2001. The Company is required to adopt SFAS 142 in the first quarter of 2002. We believe that adoption of these standards will have no impact on our financial statements.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS No. 144"), "Accounting for the Impairment or Disposal of

Long-Lived Assets," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. This Statement supersedes FASB Statement No. 121 and APB 30, however, this Statement retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. This Statement addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Management does not expect the adoption of SFAS No. 144 to have a material impact on the Company's financial position and results of operations.

In May 2000, the Emerging Issues Task Force (EITF) issued EITF Issue No. 00-14, "Accounting for Certain Sales Incentives," addressing the recognition, measurement and income statement classification of sales incentives that a vendor voluntarily offers to its customers, without charge, and which customers may then use in, or exercise as a result of, a single exchange transaction. Sales incentives falling within the scope of EITF Issue No. 00-14 include offers that customers may use to receive a reduction in the price of products or services at the point of sale. In June 2001, the EITF issued EITF Issue No. 00-25, "Vendor Income Statement Characterization

of Consideration Paid to a Reseller of the Vendor's Products," addressing whether consideration from a vendor to a reseller is (a) an adjustment to the selling prices of the vendor's products and therefore a deduction from revenue when recognized in the vendor's statement of operations or (b) a cost incurred by the vendor for assets or services received from the reseller and therefore a cost or expense when recognized in the vendor's statement of operations. In September 2001, the EITF issued Issue No. 01-09, "Accounting for Consideration Given by a Vendor to a Customer or a Reseller of the Vendor's Products," which is a codification of EITF Issues No. 00-14, No. 00-25 and also No. 00-22, "Accounting for 'Points' and Certain Other Time or Volume-Based Sales Incentive Offers and Offers for Free Products or Services to be Delivered in the Future." The requirements of EITF Issue No. 01-09, as with the preceding Issues No. 00-14, No. 00-22 and No. 00-25, became effective for annual or interim financial statements dated after December 15, 2001, and include a requirement to reclassify the financial statements of prior periods as necessary to conform with current income statement display standards. No material impact on our financial statements has resulted from the adoption of the EITF Issues above.

NOTE 3: BALANCE SHEET COMPONENTS

Marketable Securities (in thousands):

The cost and fair value of available-for-sale securities at December 31, 2001 were as follows:

Securities with original maturities 91 days to 1 year:	Cost Value	Unrealized Gain/(Loss)	Fair Value
Corporate Notes.....	$ 3,420	$ 23	$ 3,443

Market Auction Preferred	2,300	--	2,300
US Government Agency Notes	6,113	31	6,144
	$11,833	$ 54	$11,887

Securities with original maturities greater than 1 year:	Cost Value	Unrealized Gain/(Loss)	Fair Value
Corporate Notes	$ 1,550	$ 26	$ 1,576
Foreign Debt Securities	2,787	(10)	2,777
	$ 4,337	$ 16	$ 4,353

Securities with original maturities greater than one year have been reported as long-term investments.

The cost and fair value of available-for-sale securities at December 31, 2000 were as follows:

Securities with original maturities 91 days to 1 year:	Cost Value	Unrealized Gain/(Loss)	Fair Value
Corporate commercial paper	$15,290	$(2)	$15,288
Corporate notes	12,078	15	12,093
	$27,368	$13	$27,381

Inventories (in thousands):

	December 31, 2001	2000
Raw materials	$1,017	$ 404
Work in progress	377	203
Finished goods	2,251	1,031
	$3,645	$1,638

Property and equipment (in thousands):

	December 31,	
	2001	2000
Computer equipment and software	$ 867	$ 594
Furniture and fixtures	187	90
Leasehold improvements	740	207
Machinery and equipment	3,275	2,531
	5,069	3,422
Less: accumulated depreciation and amortization	(3,135)	(2,167)
	$ 1,934	$ 1,255

Property and equipment includes approximately $636,000 of machinery, equipment and other assets under capital lease at both December 31, 2001 and December 31, 2000. Accumulated amortization of assets under capital lease totaled approximately $443,000 at December 31, 2001 and $324,000 at December 31, 2000.

Other Assets (in thousands):

	December 31,	
	2001	2000
Capitalized patent defense litigation costs	$332	$--
Deposits	46	46
Other non-current assets	8	14
	386	60
Less: accumulated amortization	(6)	--
	$380	$60

Accrued Liabilities (in thousands):

	December 31,	
	2001	2000
Payroll and related expenses	$1,177	$ 864
Accrued vacation	277	197
Accrued legal expenses	247	23
Product received but not yet invoiced	217	52
Other accrued liabilities	757	759
	$2,675	$1,895

====== ======

RITA Medical Systems, Inc.

Notes to Financial Statements--(Continued)

NOTE 4: DEBT

Notes Payable

In June 1999, the Company entered into a loan and security agreement for a loan facility of up to $5,000,000, consisting of two term loans of $1,500,000 each and a revolving term loan of up to $2,000,000. In connection with this agreement, the Company issued warrants to purchase 85,091 shares of its then authorized Series E preferred stock (Note 6).

As of December 31, 1999, the Company had drawn down the initial term loan of $1,500,000. In February 2000, the Company drew down the second term loan of $1,500,000. Both term loans were repaid in full in September 2000.

As of December 31, 2000, the Company had borrowed approximately $833,000 under the revolving term loan. This loan was completely repaid as of June 30, 2001, and the loan facility was cancelled.

NOTE 5: COMMITMENTS AND CONTINGENCIES

Capital lease

In September 1998, the Company entered into a three year capital lease agreement and was permitted to borrow up to $1,000,000 for equipment deliverable no later than March 31, 2000. In conjunction with this lease agreement, the Company issued warrants which are now exchangeable for 10,909 of its common shares at $4.58 per share. As of December 31, 2001, future minimum payments under this capital lease agreement are as follows (in thousands):

Payments due in 2002	$204
Less imputed interest (including warrants)	(12)
Present value of future minimum lease payments	$192

Operating Leases

The Company leases manufacturing and office space under a 60 month noncancelable operating lease terminating in August 2004. The base rent will increase according to the CPI formula as stipulated in the lease agreement. Under the terms of the lease, the Company is responsible for property taxes, insurance and maintenance costs. The Company sublet a portion of its facilities through October, 2000. Rent expense, net of sublease income, was approximately $475,000, $323,000 and $296,000 for the years ended December 31, 2001, 2000 and 1999 respectively. Future minimum annual rental payments are as follows (in thousands):

2002	$ 530
2003	533
2004	356
	$1,419

Contingencies

In July 1999, the United States Patent and Trademark Office declared an interference involving us, which was provoked by RadioTherapeutics Corporation, a competitor of ours, in which the validity of a patent claim previously issued to us is being called into question. The claim being questioned is one of a number of issued patent claims that cover the curvature of the array at the tip of our disposable devices. In February 2001, the USPTO issued a decision on preliminary motions filed in the patent interference proceeding. The decision found that one of the claims in our United States Patent No. 5,536,267 (claim no. 32) is invalid. We expect to receive final confirmation of that decision later this year. In the event that the decision is confirmed, we plan to file a motion in a United States District Court requesting review of the decision. Final determination of the patent interference proceeding may take several years. If the final determination of the United States District Court results in the issuance of patent rights related to the claim to RadioTherapeutics and we were unable to obtain a license to use the relevant patent or successfully modify our disposable device, we could be unable to sell our system and our business could suffer.

The Company is also involved in a patent opposition action pending before the European Patent Office. This opposition was instituted on March 2, 2000. The principal parties are RadioTherapeutics and RITA. The factual basis underlying the claim is the allegation by RadioTherapeutics that our European patent is not valid. In the opposition, RadioTherapeutics seeks to have our patent declared invalid and to have our patent cancelled. We are defending our patent and seek to defend it as issued. On February 7, 2002, the European Patent Office determined that we are entitled to European Patent No. 0777445 which covers radiofrequency ablation technology. The European Patent Office approved 27 claims. A final decision is not expected in this proceeding for several years. If we do not prevail in the opposition proceeding, we could lose our only currently issued patent in Europe.

In August 2001 the Company filed a complaint in the United States District Court for the Northern District of California against RadioTherapeutics Corporation. This complaint, which is distinct from the patent interference proceeding described above, alleges that RadioTherapeutics' radiofrequency ablation products infringe six different patents held by the Company. As of December 31, 2001, the Company has capitalized approximately $332,000 in litigation costs incurred in defense of its patent positions (see Notes 2 and 3).

NOTE 6: STOCKHOLDERS' EQUITY

Stock split

On May 1, 2000, the board of directors approved a 3-for-5 reverse stock split of the common and then outstanding preferred stock. Stockholders' approval of the reverse stock split was obtained on June 20, 2000. All share and per share amounts in the accompanying financial statements have been adjusted retroactively.

Initial public offering of common stock

On July 26, 2000, the Company completed its initial public offering of 3,600,000 shares of common stock at a price of $12.00 per share, raising approximately $39.1 million net of underwriting discounts, commissions and other offering costs. Upon closing of the offering, all of the Company's then outstanding convertible preferred stock converted into approximately 8.9 million shares of common stock.

Warrants

In connection with its September 1998 capital lease arrangement, the Company issued warrants which are now exchangeable for 10,909 common shares at $4.58 per share. These warrants expire in September 2006. Their aggregate fair value of $31,273, based on the Black-Scholes valuation model, has been reflected as a discount on the lease obligation and has been fully amortized as of December 31, 2001.

In connection with its 1999 loan and security agreement, the Company issued warrants to purchase 85,091 shares of its then authorized Series E preferred shares at a price of $4.58 per share. Their fair value of $231,646, based on the Black-Scholes valuation model, was charged to operations in 2000. The holder completed a net issue exercise in January 2001, converting all of the warrants into 52,591 shares of the Company's common stock.

In October 2001, the Company issued a warrant to a former employee under the terms of the employee's separation agreement. The warrant is exchangeable for 25,000 shares of the Company's common stock at a price of $3.10 per share and expires in March 2003. Its aggregate fair value of $34,568, based on the Black-Scholes valuation model, has been charged to operations.

In December 2001, the Company issued a warrant to BEKL Corporation under the terms of a clinical data and patent license agreement. The warrant is exchangeable for 25,000 shares of the Company's common stock at a price of $6.10 per share and expires in December 2006. Its aggregate fair value of $109,553 as of December 31, 2001, based on the Black-Scholes valuation model, has been charged to operations. The fair value of this warrant will be reassessed periodically, and adjusting entries will be recorded, until it is exercised or expires. Further, BEKL Corporation will be awarded additional performance based warrants in the future based on achievement of milestones in the clinical data and patent license agreement. In December 2001, the Company accrued a $119,910 charge to operations, representing the Black-Scholes fair value of a second warrant the Company expects to issue to BEKL Corporation in 2002.

RITA Medical Systems, Inc.

Notes to Financial Statements--(Continued)

NOTE 7: STOCK OPTIONS

Stock Options: 1994 Incentive Stock Plan

Under the 1994 Incentive Stock Plan, options were granted to employees and non-employees at prices determined by the board of directors to be not lower than 85% of the fair market value of the common stock for non-statutory stock options or 100% of the fair market value of the common stock for incentive stock options. (For individuals who at the time of grant owned stock representing more than 10% of the voting power of all classes of outstanding stock, options were granted at prices not lower than 110% of the fair value of the common stock for both non-statutory and incentive stock options.) Options granted under this plan become exercisable and vest on a cumulative basis at the discretion of the board of directors and generally expire ten years from the date of grant. The Company's board of directors has determined that no future grants will be made under this plan. Activity under this plan has been as follows (in thousands, except per share data):

		Options Outstanding		
	Shares Available	Shares	Aggregate Price	Weighted Average Exercise Price
Balances, December 31, 1998...	315	1,360	$1,084	$0.80
Options granted.....	(406)	406	404	1.00
Options exercised.....	--	(149)	(92)	0.62
Options canceled.....	156	(155)	(145)	0.94
Balances, December 31, 1999...	65	1,462	1,251	0.86
Additional shares reserved.	900	--	--	--
Options granted.....	(914)	914	2,172	2.38
Options exercised.....	--	(412)	(468)	1.14
Options canceled.....	120	(122)	(261)	2.14
Balances, December 31, 2000...	171	1,842	2,694	1.46
Options exercised.....	--	(499)	(407)	0.82
Options canceled.....	--	(220)	(455)	2.07
Shares removed from plan...	(171)	--	--	--
Balances, December 31, 2001...	--	1,123	$1,832	$1.63

RITA Medical Systems, Inc.

Notes to Financial Statements--(Continued)

Stock Options: 2000 Director's Stock Option Plan

Under the 2000 Director's Stock Option Plan, shares of common stock have been reserved for issuance to non-employee directors. Option grants have been and will continue to be made at the fair market value of the common stock on the date of the grant. Options granted under this plan become exercisable and vest on a cumulative basis at the discretion of the board of directors and generally expire ten years from the date of grant. Activity under this plan has been as follows (in thousands, except per share data):

		Options Outstanding		
	Shares Available	Shares	Aggregate Price	Weighted Average Exercise Price
Balances, December 31, 1999	--	--	$ --	$ --
Shares reserved	500	--	--	--
Balances, December 31, 2000	500	--	--	--
Options granted	(35)	35	175	5.01
Balances, December 31, 2001	465	35	$175	$5.01

Stock Options: 2000 Stock Plan

The 2000 Stock Plan provides for the grant of incentive stock options to employees and non-statutory stock options and stock purchase rights to employees and consultants. A total of 2,000,000 common shares were originally reserved for issuance under this plan at its creation in 2000 and 500,000 additional common shares were reserved for issuance during 2001. Automatic increases to the shares available for issuance will occur on the first day of each fiscal year through 2010 in the amount of the lesser of 1,000,000 shares, 7% of the Company's outstanding common stock on the last day of the preceding fiscal year, or a lower number as determined by the board of directors. Incentive stock options granted under this plan must have an exercise price of at least 100% of the fair market value of the common stock on the date of the grant, and at least 110% of the fair market value of the common stock if the options are awarded to an employee who holds more than 10% of the total voting power of all classes of the Company's stock. Options granted under this plan become exercisable and vest on a cumulative basis at the discretion of the board of directors and generally expire ten years from the date of grant. Activity under the 2000 Stock Plan has been as follows (in thousands, except per share data):

	Options Outstanding	
		Weighted Average

	Shares Available	Shares	Aggregate Exercise Price	Exercise Price
Balances, December 31, 1999.....	--	--	$ --	$ --
Shares reserved.....	2,000			
Options granted.....	(151)	151	1,569	10.39
Balances, December 31, 2000.....	1,849	151	1,569	10.39
Additional shares reserved.....	500	--	--	--
Options granted.....	(1,423)	1,423	6,426	4.52
Options canceled.....	75	(75)	(485)	6.47
Balances, December 31, 2001.....	1,001	1,499	$7,510	$ 5.01

RITA Medical Systems, Inc.

Notes to Financial Statements--(Continued)

Stock Options: Options outstanding and exercisable

Options outstanding, from all plans, and exercisable as of December 31, 2001 are as follows by exercise price ranges (in thousands, except per share data):

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Outstanding	Weighted-Average Exercise Price
$0.50 to $1.00	777	6.90 years	$0.92	647	$0.91
$1.67 to $3.10	386	7.47 years	$2.33	123	$1.67
$3.20 to $3.55	474	9.25 years	$3.27	47	$3.35
$3.75 to $5.00	428	9.18 years	$4.29	69	$4.26
$5.01 to $11.63	592	8.43 years	$7.62	151	$8.03
	2,657	8.11 years	$3.58	1,037	$2.37

2000 Employee Stock Purchase Plan

The Company's 2000 employee stock purchase plan was adopted in the second quarter of 2000. A total of 650,000 common shares have been reserved for issuance under this plan. Automatic increases will occur on the first day of 2002, 2003 and 2004 in amounts equal to the lesser of 650,000 shares, 4% of the Company's outstanding common stock on the last day of the preceding year, or such lesser number that board of directors determines. This plan permits employees to purchase common shares at a price equal to the lower of 85% of the fair market value of the common stock at the beginning of each offering period or the end of each offering period. Employee purchases are nonetheless limited to 15% of eligible cash compensation, and other restrictions regarding the

amount of annual purchases also apply.

Stock-based compensation

The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123 ("SFAS No.123"), "Accounting for Stock-Based Compensation." Had compensation cost for the incentive stock plans been determined based on the fair value at the grant date for awards during 2001, 2000 and 1999, consistent with the provisions of SFAS No. 123, the Company 's pro forma net loss and pro forma net loss per share would have been as follows (in thousands, except per share data):

	Years ended December 31,		
	2001	2000	1999
Net loss, as reported	$(12,960)	$(12,807)	$(7,510)
Net loss, pro forma	$(14,079)	$(13,353)	$(7,589)
Net loss per share, as reported, basic and diluted	$ (0.90)	$ (1.99)	$ (9.33)
Net loss per share, pro forma, basic and diluted	$ (0.98)	$ (2.07)	$ (9.43)

Such pro forma disclosure may not be representative of future compensation cost because options vest over several years and additional grants are anticipated each year.

The weighted average fair values of options granted during 2001, 2000 and 1999 were $4.53, $2.32 and $0.14 respectively.

Prior to the Company's initial public offering, the value of each option grant was estimated using the minimum value method. The value of each option grant was estimated on the date of grant using the Black-Scholes method with the following weighted assumptions:

	Years ended December 31,		
	2001	2000	1999
Volatility	80%	75%	0%
Risk-free interest rate	4.54%	6.51%	5.54%
Expected life	5 years	5 years	5 years
Expected dividends	0%	0%	0%

During 2001, 2000 and 1999, the Company recorded a total of approximately $8.2 million of deferred stock-based compensation in accordance with APB No. 25, SFAS No. 123 and EITF 96-18, related to options granted to employees and

non-employees. For options granted to non-employees during 2001, 2000 and 1999, the Company determined fair value using the Black-Scholes option pricing model with the following assumptions: expected volatility of 75%, 50% and 50%, respectively, a risk-free interest rate of 5.75% and deemed values of common stock between $1.00 and $6.98 per share. Stock compensation expense is being recognized in accordance with FIN 28 over the vesting periods of the related options, generally four years. The Company recognized stock compensation expense of approximately $1,372,000, $4,822,000 and $991,000 for the years ended December 31, 2001, 2000 and 1999 respectively.

NOTE 8: INCOME TAXES

The tax effects of temporary differences that give rise to significant portions of deferred tax assets are as follows (in thousands):

	December 31,	
	2001	2000
Net operating loss carryforwards	$ 15,582	$ 12,951
Capitalized startup and research and development costs	456	333
Research and development credit	878	813
Other	1,021	421
Total deferred tax assets	17,937	14,518
Less valuation allowance	(17,937)	(14,518)
	$ --	$ --

At December 31, 2001 the Company had federal and state net operating loss carryforwards of approximately $42.7 million and $18.0 million respectively, available to offset future taxable income. The Company's federal and state operating loss carryforwards expire between 2010 and 2021 and between 2002 and 2006 respectively, if not utilized.

Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has placed a valuation allowance against its deferred tax assets. At such time as it is determined that it is more likely than not that the deferred tax assets are realizable, the valuation allowance will be reduced.

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 a company. In the event the Company has a change in ownership, utilization of the carryforwards could be restricted.

NOTE 9: RELATED PARTY TRANSACTIONS

In August 1994, the Company entered into a cross-license agreement (the "Agreement") with VIDAMed (a company whose founder was also one of the founders of the Company) whereby the Company granted VIDAMed and exclusive royalty-free license to use the Company's technology for certain applications. In return, VIDAMed granted the Company an exclusive license to use VIDAMed's technology for certain applications. The Company is required to pay a royalty of 2.5% of net sales on products developed incorporating the VIDAMed technology. This obligation terminates on the earlier of ten years from the effective date of the Agreement or when payments by the Company to VIDAMed total $500,000. To date the Company has made no payments under this agreement.

During 1999, the Company entered into a nonrecourse promissory note arrangement with an officer and director of the Company. The full balance of $72,888 plus accrued interest was repaid during 2000.

During 2000, the Company entered restricted stock purchase agreements and related promissory note arrangements with five officers of the Company, one of whom is also a director. The Company sold a total of 98,376 common shares to these individuals at a price of $1.67 per share. Consideration was in the form of signed, full recourse promissory notes bearing interest at the rate of 8% compounded semiannually and collateralized by the common shares sold. The notes will be forgiven at the rate of 25% of the loan amount on each January 1 from 2001 through 2004 for those individuals still employed with the Company. Any unforgiven amounts will be due and payable on March 31, 2005 or immediately upon an employee's termination from the Company. On January 1, 2001, 25% of the loan amount was forgiven as scheduled. During 2001, two of the officers terminated their employment with the Company; their unvested restricted shares and related notes payable were cancelled as of their termination dates. At December 31, 2001, at total of 54,936 restricted shares remained outstanding.

During the years 2001, 2000 and 1999, and from time to time prior to 1999, the Company has received professional services relating to the administration of its clinical trials from a firm in which one of the Company's directors serves as an officer. The Company has recognized expenses relating to the services received from this firm of approximately $109,000, $13,000 and $87,000 for the years ended December 31, 2001, 2000 and 1999 respectively.

NOTE 10: SEGMENT INFORMATION

The Company operates in one business segment. The Company sells its products and systems directly to customers in the United States, Europe and Asia.

Sales for geographic regions reported below are based upon the customers' locations. Following is a summary of the geographic information related to revenues, long-lived assets and information related to significant customers for the years ended December 31, 2001, 2000 and 1999 (in thousands, except percentage data):

	Years Ended December 31,		
	2001	2000	1999
Sales:			
United States	$ 8,032	$ 3,940	$1,669
Italy	1,137	1,003	646
Japan	1,879	2,924	1,420
Other	3,743	2,143	894
Total	$14,791	$10,010	$4,629

RITA Medical Systems, Inc.

Notes to Financial Statements--(Continued)

	Years Ended December 31,		
	2001	2000	1999
Long-lived assets:			
United States	$1,802	$1,054	$613
Europe	132	201	262
Total	$1,934	$1,255	$875

	Years Ended December 31,		
	2001	2000	1999
Significant customers: Revenue			
Customer A	14%	29%	41%
Customer B	8%	10%	14%

	December 31,	
	2001	2000
Significant customers: Accounts Receivable		
Customer A	11%	22%
Customer B	14%	16%
Customer C	17%	14%
Customer D	5%	4%

NOTE 11: EMPLOYEE BENEFIT PLAN

The Company sponsor's a 401(k) defined contribution plan covering all employees. Contributions made by the Company are determined annually by the board of directors. To date, there have been no company contributions to the plan.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

PART III

The definitive proxy statement for our 2002 Annual Meeting of Stockholders, when filed, pursuant to Regulation 14A of the Securities Exchange Act of 1934, will be incorporated by reference into this Form 10-K pursuant to General Instruction G (3) of Form 10-K and will provide the information required under Part III (Items 10-13), except for the information with respect to our executive officers, which is included in "Item 1. Business--Executive Officers of the Registrant."

PART IV

Item 14.Exhibits, Financial Statement Schedules and Reports on Form 8-K.

(a) The following documents are filed as part of this report:

(1) Financial Statements and Report of PricewaterhouseCoopers, LLP

(2) Exhibits are incorporated herein by reference or are filed in accordance with item 601 of Regulation S-K.

Number	Description
+2.1	Form of Agreement and Plan of Merger between the Registrant and RITA Medical Systems, Inc., a Delaware corporation.
+3.2	Amended and Restated Certificate of Incorporation of RITA Medical Systems, Inc., a Del corporation.
+3.4	Amended and Restated Bylaws of RITA Medical System, Inc.
++4.1	Preferred Shares Rights Agreement, dated as of July 31, 2001, between RITA Medical Sys Inc. and U.S. Stock Transfer Corporation, including the Certificate of Designation, of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B an respectively.
+10.1	Sixth Amended and Restated Shareholder Rights Agreement dated May 26, 2000 by and amon the Registrant and certain security holders.
+10.2	1994 Incentive Stock Plan (as amended) and form of option agreement.

+++10.3	2000 Stock Plan and form of option agreement.
#+++10.4	2000 Directors' Stock Option Plan and form of option agreement.
+10.5	2000 Employee Stock Purchase Plan and form of subscription agreement.
+10.6(a)	Master Lease Agreement with Brown Mountain View Joint Venture dated July 12, 1994 and extension of Master Lease Agreement dated May 12, 1999.
+10.7	Form of Indemnification Agreement between the Registrant and its officers and director
#+10.8	Employment Agreement with Barry Cheskin dated March 21, 1997.
#+10.9	Employment Agreement with Ronald Steckel dated May 26, 1998.
#+10.10	Employment Agreement with David Martin dated February 11, 2000.
#+10.11	Form of Change of Control Agreement entered into between the Company and it officers.
*+10.13	Distribution Agreement with Nissho Iwai Corporation (now named ITX Corporation) for So Korea dated March 12, 1999.
*+10.15	Manufacturing Agreement with Plexus Corporation dated February 17, 2000.
*+10.16	Manufacturing Agreement with Apical Instruments, Inc. dated February 23, 2000.

Number	Description
++++10.18*	Amendment of Distribution Agreement with Nissho Iwai Corporation (now named ITX Corporation) for Japan dated May 11, 2001.
**10.19	Distribution Agreement with MDH s.r.l. Forniture Ospedaliene for Italy dated Decembe 2001.
10.20	Separation Agreement with David Martin dated November 5, 2001.
10.21	Separation Agreement with Russell Johnson dated June 29, 2001.
10.22	Amendment to Master Lease Agreement with Brown Mountain View Joint Venture dated June 4, 2001.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Accountants.
24.1	Power of Attorney (See Signature Page).

---

* Confidential treatment granted with respect to certain portions of this Exhibit.

** Material has been omitted pursuant to a request for confidential treatment and such material has been filed separately with the SEC.

\+ Incorporated by reference to our registration statement on Form S-1 (File

No. 333-36160) initially filed with the SEC on May 3, 2000.

++ Incorporated by reference to our Registration Statement on Form 8-A (File No. 000-30959) filed with the SEC on August 7, 2001.

+++ Incorporated by reference to our report on Form 10-Q (File No. 000-30959) filed with the SEC on November 14, 2001.

++++ Incorporated by reference to our report on Form 10-Q (File No. 000-30959) filed with the SEC on August 8, 2001.

Management contract or compensatory plan or arrangement.

(b) No reports on Form 8-K were filed during the year ended December 31, 2001.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 28, 2002

RITA MEDICAL SYSTEMS, INC.

By: /s/ BARRY CHESKIN
Barry Cheskin
President, Chief Executive Officer and Director

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Barry Cheskin and Donald Stewart, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ BARRY CHESKIN Barry Cheskin	President, Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2002
/s/ DONALD STEWART Donald Stewart	Chief Financial Officer and Vice President, Finance and Administration (Principal	March 28, 2002

	Financial and Accounting Officer)	
/s/ VINCENT BUCCI Vincent Bucci	Director	March 28, 2002
/s/ JANET EFFLAND JANET EFFLAND	Director	March 28, 2002
/s/ JOHN GILBERT John Gilbert	Director	March 28, 2002
/s/ SCOTT HALSTED Scott Halsted	Director	March 28, 2002
/s/ GORDON RUSSELL Gordon Russell	Director	March 28, 2002