RITA MEDICAL SYSTEMS INC
Form 10-K
March 27, 2001

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, 2000

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 0-30959

RITA MEDICAL SYSTEMS, INC.
(Exact name of registrant as specified in this 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 95035
(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:

Common Stock	Nasdaq National Market

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

Common Stock

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 $15,771,679 as of March 12, 2001, 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 14,370,098 shares of the registrant's Common Stock issued and outstanding as of March 12, 2001.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference from the definitive proxy statement for the 2001 Annual Meeting of Stockholders to be held on June 13, 2001.

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 lung, bone, breast, 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 20,000 disposable devices.

RITA has a broad patent portfolio. As of March 12, 2001, we had 36 issued patents, one notice of allowance and 40 United States and foreign patent applications pending. The issued and allowed 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 three-centimeter ablation, 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.

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;

  - 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; and

  - broaden our market coverage by expanding our domestic direct sales force and international distribution channels.

- 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 lung, bone, breast, prostate 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. Examples of these efforts include:

- further enhancements of ablation technologies; and

- technologies for the improved visualization of tissue during the ablation process.

. Capitalize on the Significant Opportunity in International Markets. Liver cancer is one of the leading causes of death in a number of international markets. We plan to continue to devote substantial clinical and marketing support to existing international distributors and to identify new distributors in additional markets.

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 product offerings.

	Product Name	Description	Year of Introduction	U.S. List Price
Disposable Devices:	Model 30	Creates a 3-centimeter ablation. Compatible with the Model 500 generator.	1997	$900
	Model 70	Creates a scalable 2- to 3-centimeter ablation. Compatible with the Model 500 generator.	1999	$1,100
	StarBurst	Creates a scalable 2- to 3-centimeter ablation. Compatible with the Model 1500 generator.	2000	$1,100
	StarBurst XL	Creates a scalable 3- to 5-centimeter ablation. Compatible with the Model 1500 generator.	2000	$1,440
Generators:	Model 500	50 Watt generator	1997	$30,000
	Model 1500	150 Watt generator	2000	$37,500

Disposable Devices

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

Our disposable devices are available in different array sizes to allow the physician to create a spherical ablation volume of anywhere from two to three or from three to five centimeters. Three centimeters is slightly

smaller than a ping-pong ball. Five centimeters is approximately the size of a billiard ball. In addition, each of the devices is available in 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.

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 generator has 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 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.

In the United States we market our products through a direct sales force of 15 sales representatives and three regional managers. Overseas we market our products through distribution partners. To date, we have entered into agreements with distributors in 21 countries including the major countries in Europe and Asia. RITA has three full-time sales managers who are responsible for directing, supporting and monitoring our international distributors' activities. We plan to selectively expand our United States direct sales force and our network of international distributors in 2001.

Our marketing and sales efforts are directed at placing generators at key cancer centers and other leading medical centers worldwide and then working with those centers' physicians to increase their usage of our disposable devices. We recognize that our predominant source of recurring revenue will be from our disposable devices, which can only be used once a generator is placed. 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 plan to expand public awareness of our products using both marketing materials and a new patient education Internet site.

Clinical Research

To date, there have been over 35 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 45 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.

In the area of unresectable liver tumors there have been over 25 published reports on the use of the RITA system. Of the initial seven reports that included follow-up data, local tumor recurrence rates ranged from 0 percent to 55 percent with an average of 14 percent local recurrence. Serious complications were rare and overall complication rates were low.

In the area of breast tumors, a presentation was made at the Radiological Society of North America annual conference in November 2000. Data were presented from the first ten patients in a feasibility study at the MD Anderson Cancer Center showing that complete tumor destruction had been achieved. Human feasibility studies of lung and bone tumors were initiated in late in 2000, and we plan to complete feasibility work and hope to initiate follow-on safety and efficacy studies in late 2001.

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, a privately held company, and Radionics, 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 reimbursement codes for open, laparoscopic and percutaneous liver tumor ablation procedures that will apply beginning in 2002. The exact terminology has not been established and will not be known until the 2002 reimbursement codes are published. While the approval of specific reimbursement codes will not require insurance providers to reimburse physicians for procedures using our products, they 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 have generally been successful in obtaining reimbursement for procedures using our products. 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. We are working on a number of enhancements to our existing products that we believe will further improve the ablation process. Our next-generation ablation products are currently under development with a planned market launch in the latter part of 2001.

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 March 12, 2001, we had 36 issued patents, one notice of allowance and 40 United States and foreign patent applications pending. The issued and allowed 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 patents expire 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. None of these incidents resulted in permanent injury or death.

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 March 12, 2001, we had 88 full-time employees, including 30 in sales and marketing, 30 in manufacturing, 16 in research and development and 12 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 March 12, 2001.

Name	Age	Position(s)
Barry Cheskin.....	40	Chief Executive Officer, President and Director
Marilynne Solloway.....	53	Chief Financial Officer and Vice President, Finance and Administration

Daniel Balbierz.....	39	Vice President, Research and Development
Vicki Hacker.....	44	Vice President, Clinical Affairs
Russell Johnson.....	47	Vice President, Business Development
David Martin.....	36	Vice President, Global Sales
Eric Mueninghoff.....	43	Vice President, Marketing
Ronald Steckel.....	47	Senior Vice President, Operations

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.

Marilynne Solloway has served as our Vice President, Finance & Administration and Chief Financial Officer since April 1998. Prior to joining us, from July 1995 to April 1998, Ms. Solloway was self-employed as a consultant and worked with several non-profit organizations. In 1985, she co-founded Menlo Care, Inc., a medical device company. Ms. Solloway held the position of Chief Financial Officer and Director of Menlo Care, Inc. from May 1985 to June 1995. Ms. Solloway holds a B.A. from University of California, Berkeley and an M.B.A. from University of Santa Clara.

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.

Russell Johnson has served as our Vice President, Business Development since January 2001. From July 1998 to January 2001, Mr. Johnson served as our Vice President, Marketing. From March 1999 to March 2000, he also served as our Vice President, Global Sales. Prior to joining us, he founded The Pathfinder Group, a marketing consulting firm servicing emerging medical device companies, and served as President from June 1997 to June 1998. Previously, Mr. Johnson held the position of Director, International Sales of Vista Medical Technologies, Inc., a medical device company, from January 1997 to May 1997 and before that he was the Director, Worldwide Marketing for the Cardiothoracic Surgery Division of Vista Medical Technologies, Inc., from July 1996 to December 1996.

He also held the position of Director of International Marketing for Boston Scientific, a medical device company, from July 1993 to July 1996. Mr. Johnson holds a B.A. from Brown University and an M.B.A. from University of Michigan.

David Martin has served as our Vice President, Global Sales since March 2000. Prior to joining us, he held the position of Director of United States Sales for the Cardiac Surgery division of Guidant Corporation, a medical device company, from November 1999 to March 2000. Previously, Mr. Martin held various positions at CardioThoracic Systems, Inc., a minimally invasive cardiac surgery company, including Director of Sales for the United States from January 1998 to November 1999 and Regional Sales Manager and District Sales Manager Western United States from July 1996 to December 1997. He also held the position of District Manager for Carbomedics, a medical device company, from March 1994 to June 1996. Mr. Martin holds a B.A. from University of California, Santa Barbara and an M.B.A. from University of San Diego.

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.

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.

Item 2. Properties.

We are headquartered in Mountain View, CA, 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. Through October 2000, the Company sublet 6,000 square feet of its space, and as of December 31, 2000 had not fully occupied the entire building. We believe the facility is suitable and adequate to meet our current or forseeable requirements through 2001 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 "Factors that May Affect Future Results--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 its 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. 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 as reported by the Nasdaq National Market:

	Common Stock Price	
	High	Low
Year ended December 31, 2000		
Third quarter (from July 27, 2000)	$14.38	$8.88
Fourth quarter	$12.38	$5.00
Year ended December 31, 2001		
First quarter (through March 12, 2001)	$ 9.88	$3.63

On March 12, 2001, the last reported sales price of our common stock on the Nasdaq National Market was $3.75. As of March 12, 2001, there were 148 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 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 $39.1 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. We intend to use 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. Additionally, we may use the proceeds of the offering to fund the acquisition of complementary businesses, products or technologies, although there are no current agreements or negotiations with respect to any specific transaction.

As of December 31, 2000, of the $39.1 million in net proceeds from our offering we had applied the net proceeds as follows:

Use	Approximate Dollar Amount (in millions)
Permanent working capital	$ 5.0
Repayment of term loans and other debt	$ 3.5
Sales, marketing, research and clinical programs and general corporate purposes	$ 6.9
TOTAL:	$15.4

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. Quarterly data is derived from unaudited statements that, in the opinion of 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. The operating results for any quarter are not necessarily indicative of results for any future period. Our audited

statements of operations for the years ended December 31, 2000, 1999 and 1998 and our audited balance sheet at December 31, 2000 and 1999 are presented elsewhere in this Form 10-K. The information provided below is in thousands, except for per share data.

	Years Ended December 31,				
	2000	1999	1998	1997	1996
Statement of Operations Data:					
Sales	$ 10,010	$ 4,629	$ 1,137	$ 220	$ --
Cost of goods sold	6,048	2,994	1,523	589	--
Gross profit (loss)	3,962	1,635	(386)	(369)	--
Operating expenses:					
Research and development	5,615	3,931	2,729	2,486	2,214
Selling, general and administrative	12,052	5,452	3,606	2,829	1,732
Total operating expenses	17,667	9,383	6,335	5,315	3,946
Loss from operations	(13,705)	(7,748)	(6,721)	(5,684)	(3,946)
Interest and other income (expense), net	898	238	(28)	(176)	(24)
Net loss	$(12,807)	$ (7,510)	$ (6,749)	$ (5,860)	$(3,970)
Net loss per share, basic and diluted	$ (1.99)	$ (9.33)	$ (10.10)	$ (11.02)	$ (7.74)
Shares used in computing net loss per share, basic and diluted	6,440	805	668	532	513

	December 31,				
	2000	1999	1998	1997	1996
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 40,057	$ 12,153	$ 7,644	$ 147	$ 3,791
Working capital	41,512	12,437	7,560	(2,276)	3,329
Total assets	46,270	15,705	9,009	1,082	4,592
Long-term obligations, net of current portion	180	1,854	--	17	40
Convertible preferred stock and preferred stock warrants	--	38,516	28,337	12,492	12,331
Common stock and additional paid-in capital	88,435	3,652	165	56	8
Total stockholders equity (deficit)	42,647	(26,991)	(20,510)	(14,275)	(8,501)

Quarterly Results of Operations:

	Quarter Ended							
	Mar. 31, 2000	June 30, 2000	Sept. 30, 2000	Dec. 31, 2000	Mar. 31, 1999	June 30, 1999	Sept. 30, 1999	Dec. 31, 1999
Sales	$ 1,841	$ 2,427	$ 2,712	$ 3,030	$ 837	$ 1,062	$ 1,197	$ 1,533
Gross Profit	659	933	1,090	1,279	147	444	400	644
Net Loss	$(3,578)	$(3,207)	$(2,956)	$(3,067)	$(1,858)	$(1,663)	$(1,678)	$(2,311)
Net Loss per Share	$ (3.52)	$ (2.79)	$ (0.31)	$ (0.22)	$ (2.39)	$ (2.11)	$ (2.09)	$ (2.73)
Shares used in computing net loss per share, basic and diluted	1,017	1,150	9,607	13,869	779	789	803	848

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.

Overview

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 2000, we commercially launched our Model 1500 generator and StarBurst 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, 2000, sales in the United States accounted for 39% of our total sales while sales in our international markets accounted for 61% of our total sales. We expect that a significant portion of our revenue will continue to come from international operations 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, 2000, 67% of our

sales were derived from our disposable devices and 33% were derived from the sale of our generators. Placement of generators at hospitals is necessary for customers to use our disposable devices, and we continue to focus on expanding our base of customer accounts. We are also continuing to focus on increasing usage of our disposable products at our established accounts, and we expect that a significant proportion of our revenues will continue to be derived from the sale of our higher-margin disposable devices.

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 and average selling prices. In addition, margins are affected by the sales mix of disposable devices versus generators and the mix of domestic direct sales versus international sales, which provide for standard distributor discounts.

For the year ended December 31, 2000, 32% of our operating expenses were related to research and development activities, while 68% of our operating expenses were related to selling, general and administrative activities. We expect to continue to devote significant resources to product development and clinical research programs. We also expect to continue to devote the majority of our operating expenses to selling, general and administrative activities, particularly to our sales and marketing efforts. These efforts include the expansion of our domestic sales force and our international distribution support activities as well as physician training and patient awareness programs.

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 $4.8 million for the year ended December 31, 2000. We expect to record additional amortization expense for deferred compensation in future periods.

We incurred net losses of $12.8 million for the year ended December 31, 2000. As of December 31, 2000, we had an accumulated deficit of $41.4 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 continue to incur net losses for the near future.

Our future growth depends on expanding product usage in our current market and finding new large markets in which we can leverage our core technologies of applying radiofrequency energy to treat cancerous and benign tumors. To the extent our current or new markets do not materialize in accordance with our expectations, our sales could be lower than expected.

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.

Results of Operations

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 by 136% and international sales increasing by 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 by 124% and generator sales increasing by 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 devises, 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 the $1.8 million debt outstanding under a revolving credit facility.

Years Ended December 31, 1999 and 1998

For the year ended December 31, 1999, sales totaled $4.6 million, an increase of 307% from $1.1 million in 1998. We experienced growth in both domestic and international markets, with domestic sales increasing by 136% and international sales increasing by 533% over the previous year. For the year ended December 31, 1999, domestic sales represented 36% of total revenue, as compared to 59% in 1998. We experienced growth in sales of our disposable products and our generators, with disposable product sales increasing by 379% and generator sales increasing by 222% over the previous year. For the year ended December 31, 2000, disposable sales accounted for 64% of total revenue, as compared to 52% in 1999. Higher unit shipments of generators and disposables resulted from increased physician awareness of our technology, product improvements, expansion of our domestic sales force and increased geographical coverage in international markets including Japan.

Cost of goods sold for the year ended December 31, 1999 was $3.0 million as compared to $1.5 million in 1998. The growth in cost of goods sold was attributable primarily to the expansion of our manufacturing operations, increased quality assurance programs and 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 $107,000 in the year ended December 31, 1999 as compared $25,000 in 1998. Excluding the effect of the amortization of deferred stock-based compensation, gross margins improved to 38% in 1999 from a loss of 32% in 1998. The improvement was primarily due to manufacturing efficiencies attained through higher volume production of our disposable devices.

Research and development expenses for the year ended December 31, 1999 were $3.9 million as compared to $2.7 million in 1999. The expense increase was attributable primarily to the hiring of additional

personnel, expenses associated with the development of our second-generation disposable devices, expenses associated with 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 $354,000 in 1999 as compared to $186,000 in 1998.

Selling, general and administrative expenses for the year ended December 31, 1999 were $5.5 million as compared to $3.6 million in 1998. The increase in selling expenses resulted primarily from the addition of domestic field sales personnel as well as sales management personnel to support international distribution efforts. In addition, in 1999 we loaned generators to a group of prestigious medical centers that agreed to provide references on our system to other hospitals, and selling expenses for 1999 included depreciation charges related to the generators placed at these medical centers. General and administrative expenses increased due to added personnel to support our growth in operations. For the year ended December 31, 1999, we recorded amortization of deferred stock-based compensation of $530,000 as compared to $192,000 in 1998.

Interest income for the year ended December 31, 1999 was $446,000 as compared to $342,000 in 1998. The increase in interest income was primarily due to earnings on higher average cash balances due to the timing of our private placement financings. Interest expense for the year ended December 31, 1999 was $212,000 as compared to $359,000 in 1998. Interest expense for 1998 included

interest and warrant amortization associated with bridge loans obtained in 1997 and 1998. Interest expense for 1999 included interest and warrant amortization associated with a loan and security agreement entered into in June 1999.

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, which totaled $1.3 million in principal outstanding at December 31, 2000. As of December 31, 2000, we had $12.7 million of cash and cash equivalents, $27.4 million of marketable securities and $41.5 million of working capital.

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 the borrowing 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 consists 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, we had a balance outstanding of $833,000 on the revolving credit note, which bears interest at 2% over the prime rate and is due on June 30, 2001. All borrowings under the term loans, totaling approximately $3.0 million, were repaid as of December 31, 2000.

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, 2000, we had federal net operating loss carryforwards of approximately $33.1 million and state net operating loss carryforwards of approximately $19.6 million, available to offset future regular taxable income. The federal net operating loss carryforwards will expire between 2010 and 2020, and the state net operating loss carryforwards will expire between 2001 and 2005, 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 June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards ("SFAS") No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 133 establishes new standards of accounting and reporting for derivative instruments and hedging activities. SFAS No. 133 requires that all derivatives be recognized at fair value in the statement of financial position, and that the corresponding gains or losses be reported either in the statement of operations or as a component of comprehensive income, depending on the type of relationship that exists. To date, we have not engaged in derivative or hedging activities. We will adopt SFAS No. 133, as required, in fiscal year 2001, and expect no material impact on our financial statements thereby.

In March 2000, the FASB issued Interpretation No. 44, or FIN 44, "Accounting for Certain Transactions Involving Stock Compensation," which is an interpretation of Accounting Principal Board No. 25. this interpretation clarifies:

- the definition of employee for purposes of applying Opinion 25, which deals with stock compensation issues;
- the criteria for determining whether a plan qualifies as a noncompensatory plan;
- the accounting consequence of various modifications to the terms of a previously fixed stock option or award; and
- the accounting for an exchange of stock compensation awards in a business combination.

This interpretation is effective July 1, 2000, but there are conclusions in this interpretation that cover specific events that occur after either December 15, 1998, or January 12, 2000. To the extent that this interpretation covers events occurring during the period after December 15, 1998, or January 12, 2000, but before the effective date of July 1, 2000, the effects of applying this interpretation are recognized on a prospective basis from July 1, 2000. The adoption of FIN 44 did not have a material impact on our financial statements.

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. 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. 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 $12.8 million in 2000, $7.5 million in 1999 and $6.7 million in 1998. At December 31, 2000, we had an accumulated deficit of approximately $41.4 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 privately held company, and Radionics, Inc., a division of Tyco International, a publicly traded company with substantial resources. Both RadioTherapeutics and Radionics sell products that use radiofrequency energy to ablate soft tissue. In 1998, RadioTherapeutics entered into a distribution arrangement with Boston Scientific Corporation, a publicly traded company with substantially greater resources than we have.

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 48 percent of our international revenues for the year ended December 31, 2000 and 63 percent of our international revenues in 1999. 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, 2000 and 22 percent of our international revenues for 1999. Because international revenues accounted for 61 percent of our total revenues for the year ended December 31, 2000 and these two distributors represented 65 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.

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. Hospitals using our products are currently reimbursed based on established general reimbursement codes. Because there is no specific reimbursement code for physicians performing procedures using the RITA system, physicians need to submit a patient case history and data supporting the applicability of our system to the patient's condition in order to obtain reimbursement.

Each payor then determines whether and to what extent to reimburse for a medical procedure or product. Payors may refuse to provide reimbursement for procedures covered by general codes because the applicability of the code must be determined on a case-by-case basis. Although we have been notified by the American Medical Association Coding Committee that specific reimbursement codes for radiofrequency ablation of liver tumors will be established in 2002, 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 if we were successful in establishing a new code, a payor still may not reimburse adequately for the procedure or product. In addition, 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 extremely competitive and is expected to continue to be highly 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.

One third-party supplier currently manufactures, to our specifications, one of the generators we sell. There is only one other third-party contractor who we have used who could readily assume this manufacturing function. Two third-party suppliers produce the other generator we sell. 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 29 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 and Delaware law contain provisions that could discourage a takeover or prevent or delay a merger that stockholders believe is favorable for the company.

Our amended and restated certificate of incorporation and bylaws contain provisions that could delay or prevent a change in control of our company. Some of these provisions:

- authorize the issuance of preferred stock, which can be created and issued by the board of directors without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of common stock;

- provide for a classified board of directors; and

. prohibit stockholder action by written consent.

In addition, the provisions of Section 203 of Delaware General Corporate Law govern us. These provisions may prohibit large stockholders, in particular those owning 15 percent or more of our outstanding voting stock, from merging or combining with us. These and other provisions in our amended and restated certificate of incorporation and bylaws and under Delaware law could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

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

Our exposure to interest rate risk at December 31, 2000 is related to our investment portfolio and our borrowings. 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 2000 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.

At December 31, 2000, we had a revolving credit facility of $833,000 outstanding that bears interest at 2% above the prime rate.

All of our sales and purchases are denominated in United States dollars. Therefore, we do not believe that we currently have any significant direct foreign currency exchange rate risk.

Item 8. Financial Statements and Supplementary Data.

Please see pages F-1 through F-19.

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

None.

PART III

The proxy statement for our 2001 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."

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
+3.2	Amended and Restated Certificate of Incorporation of RITA Medical Systems, Inc., a Delaware corporation.
+3.4	Amended and Restated Bylaws of RITA Medical System, Inc.
+10.1	Sixth Amended and Restated Shareholder Rights Agreement dated May 26, 2000 by and among 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 directors.
+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.
*+10.12	Distribution Agreement with ITX Corporation (formerly Nissho Iwai Corporation) for Japan dated December 1, 1997.
*+10.13	Distribution Agreement with ITX Corporation (formerly Nissho Iwai Corporation) for South 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.
**10.17	Distribution Agreement with MDH s.r.l. Forniture Ospedaliene for Italy dated December 12, 2000.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Accountants.
24.1	Power of Attorney (See signature page).

\+ Incorporated by reference to our registration statement on Form S-1 (File No. 333-36160) initially filed with the SEC on May 3, 2000.

* 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.

(b) Reports on Form 8-K

None.

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.

RITA MEDICAL SYSTEMS, INC.

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

Date: March 27, 2001

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Barry Cheskin and Marilynne Solloway, 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 27, 2001
/s/ Marilynne Solloway Marilynne Solloway	Chief Financial Officer (Principal Financial and Accounting Officer)	March 27, 2001
/s/ Vincent Bucci Vincent Bucci	Director	March 27, 2001
/s/ Janet Effland Janet Effland	Director	March 27, 2001
/s/ John Gilbert John Gilbert	Director	March 27, 2001
/s/ Scott Halsted	Director	March 27, 2001

Scott Halsted		
/s/ Gordon Russell	Director	March 27, 2001
Gordon Russell		

RITA Medical Systems, Inc.

Index to Financial Statements

Report of Independent Accountants

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

In our opinion, the accompanying balance sheets and the related statements of operations and comprehensive loss, of stockholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of RITA Medical Systems, Inc. at December 31, 2000 and 1999, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2000 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.

PricewaterhouseCoopers LLP
San Jose, California
February 8, 2001

BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2000	1999
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,676	$ 7,067
Marketable securities	27,381	5,086
Accounts receivable, net of allowance for doubtful accounts of $103 at December 31, 2000 and $54 at December 31, 1999	2,437	1,149
Inventories, net	1,638	845
Prepaid assets and other current assets	823	616
Total current assets	44,955	14,763
Property and equipment, net	1,255	875
Other assets	60	67
Total assets	$ 46,270	$ 15,705
LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 425	$ 892
Accrued liabilities	1,895	956
Revolving term loan	833	--
Current portion of term loan	--	312
Current portion of capital lease obligations	290	166
Total current liabilities	3,443	2,326
Long-term notes payable	--	1,091
Revolving term loan	--	532
Capital lease obligations, net of current portion	180	231
Total liabilities	3,623	4,180
Commitments and contingency (Note 5)		
Preferred stock and preferred stock warrants:		
Convertible preferred stock, $0.001 par value: Authorized: no shares at December 31, 2000 and 15,166 shares at December 31, 1999 Issued and outstanding: no shares at December 31, 2000 and 8,580 shares at December 31, 1999	--	37,911
Preferred stock warrants	--	605
Total preferred stock and preferred stock warrants	--	38,516
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value: Authorized: 2,000 shares at December 31, 2000		
Common stock, $0.001 par value: Authorized: 100,000 shares at December 31, 2000 and 30,000 shares at December 31, 1999 Issued and outstanding: 13,970 shares at December 31,		

2000 and 927 shares at December 31, 1999	14	1
Additional paid-in capital	88,421	3,651
Deferred stock-based compensation	(4,202)	(1,935)
Stockholder notes receivable	(164)	(73)
Accumulated other comprehensive income (loss)	13	(7)
Accumulated deficit	(41,435)	(28,628)
Total stockholders' equity (deficit)	42,647	(26,991)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 46,270	$ 15,705

See accompanying notes

RITA MEDICAL SYSTEMS, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share data)

	Years Ended December 31,		
	2000	1999	1998
Sales	$ 10,010	$ 4,629	$ 1,137
Cost of goods sold (including stock-based compensation of $926, $107 and $25 in 2000, 1999 and 1998, respectively)	6,048	2,994	1,523
Gross profit (loss)	3,962	1,635	(386)
Operating Expenses:			
Research and development (including stock-based compensation of $998, $354 and $186 in 2000, 1999 and 1998, respectively)	5,615	3,931	2,729
Selling, general and administrative (including stock-based compensation of $2,898, $530 and $192 in 2000, 1999 and 1998, respectively)	12,052	5,452	3,606
Total operating expenses	17,667	9,383	6,335
Loss from operations	(13,705)	(7,748)	(6,721)
Interest income	1,585	446	342
Interest expense	(683)	(212)	(359)
Other income (expense), net	(4)	4	(11)
Net loss	(12,807)	(7,510)	(6,749)
Other comprehensive income (expense):			
Change in unrealized gain (loss) on marketable securities	20	(9)	2
Comprehensive loss	$(12,787)	$(7,519)	$(6,747)
Net loss per common share, basic and diluted	$ (1.99)	$ (9.33)	$(10.10)

Shares used in computing net loss per share, basic and diluted	6,440	805	668

See accompanying notes

RITA MEDICAL SYSTEMS, INC.

STATEMENTS OF STOCKHOLDERS' DEFICIT
For the years ended December 31, 2000, 1999 and 1998

(in thousands)

	Common Stock		Additional Paid-in Capital	Deferred Stock-based Compensation	Stockholder Note Receivable	Accumulated Other Comprehensive Loss	Accumul Defic
	Shares Issued	Amount					
Balances, January 1, 1998	578	$ 1	$ 112	$ (18)	$ --	$--	$(14,3
Issuance of common stock	4	--	2	--	--	--	-
Stock options exercised	196	--	106	--	--	--	-
Deferred stock-based compensation	--	--	1,318	(1,318)	--	--	-
Amortization of deferred stock-based compensation	--	--	--	403	--	--	-
Change in unrealized gain on marketable securities	--	--	--	--	--	2	-
Net loss	--	--	--	--	--	--	(6,7
Balances, December 31, 1998	778	1	1,538	(933)	--	2	(21,1
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	-						