RITA MEDICAL SYSTEMS INC
Form 10-K
March 31, 2005
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2004

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 000-30959

RITA MEDICAL SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3199149**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

967 N. Shoreline Blvd.

Mountain View, CA 94043

(Address of principal executive offices, including zip code)

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

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

None

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

Common Stock, $0.001 par value

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $51,425,855 as of June 30, 2004, 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. This determination and calculation have been made without taking into account the effect of the merger of the registrant and Horizon Medical Products, Inc. on July 29, 2004.

There were 41,406,634 shares of the registrant s Common Stock issued and outstanding as of January 31, 2005.

Documents Incorporated by Reference

Part III incorporates information by reference from the definitive proxy statement to be filed in connection with the registrant s 2005 annual meeting of stockholders.

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RITA Medical Systems, Inc.

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2003

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Filing Sections

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

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

PART I

Item 1. Business.

We are a diversified medical device oncology company that develops, manufactures and markets innovative products for cancer patients including radiofrequency ablation (RFA) systems for treating cancerous tumors as well as percutaneous vascular ports and specialty access catheters. Founded in 1994 on our core radiofrequency ablation platform, we are a leader in radiofrequency ablation for the treatment of solid cancerous and benign tumors in solid organs. We pioneered radiofrequency technology and have led the market in clinical training and clinical acceptance. In July 2004, we merged with Horizon Medical Products, Inc. (Horizon) in order to add Horizon s specialty access catheter (SAC) product line to our product portfolio. Our SAC products include implantable infusion ports for the delivery of systemic chemotherapy, tunneled central venous catheters, safety needles, PICC lines, dialysis catheters and specialty catheters for the stem cell transplant procedure. We also distribute the Isomed Hepatic Artery Infusion Pump from Medtronic, Inc., for use in delivering high dose regionally delivered chemotherapy.

With our RFA and SAC products lines, our sales and marketing organization targets the same practicing clinicians: the surgical oncologists and interventional radiologists. We believe that the blend of a complex RFA technology with a core SAC product offering strengthens our market position and value to our customers. Our future success and market share growth depends on new product launches, procedure adoption across multiple organs, license and distribution arrangements and possible acquisitions of other synergistic businesses. We believe there is an increasing role for medical devices in the management of cancer whether as an integral part in drug delivery or in the local control of tumors. We intend to continue to build our platform based on our core medical oncology device platform and will endeavor to identify new drug or device treatments which enhance patient care.

Our Business Strategy

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

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

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

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

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

Expand the Application of Our Proprietary Technology to Markets Beyond Liver Cancer. We believe our minimally invasive proprietary technology can be broadly applied to the treatment of other types of cancerous and benign tumors, including tumors in the bone, lung, breast, prostate, uterus and kidney. In 2002 we received FDA clearance for treating painful bone metastases and plan to expand our marketing efforts to capitalize on this opportunity. We plan to build on our extensive clinical experience in liver tumors as well as studies in additional organs to support the extension of our technology to additional applications in the future. We estimate that the market for these additional applications exceeds $1 billion annually.

Increase our Market share in Vascular Access. By means of differentiating the features and benefits of our specialty access ports and catheters, and with the intent of reducing interventions and complications we intend to create additional demand for our existing specialty access products as well as additional products that we ll bring to the market place.

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.

Overview: Radiofrequency Ablation Products

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

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

We have received regulatory clearance for sale in major markets worldwide, including the United States. In March 2000, we became the first radiofrequency ablation company to receive specific Food and Drug Administration (FDA) clearance for unresectable liver lesions in addition to our previous general FDA clearance for the ablation of soft tissue. In October 2002, we again received specific FDA clearance, this time for the palliation of pain associated with metastatic lesions involving bone. Our system is distributed in the United States through our direct sales force and internationally through distribution partners. Since our product launch, we have sold approximately 75,000 disposable devices.

Market Opportunity

Cancer Market

Millions of people throughout the world are afflicted with cancer. According to the American Cancer Society, cancer has surpassed heart disease as the leading annual cause of death in the United States.

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

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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 1,000,000 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% 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 that there are approximately 300,000 annual cases of primary and metastatic liver cancer 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% of these patients will develop metastatic liver tumors. Due to numerous factors, including the absence of viable treatment options, metastatic liver cancer often causes death.

Treatment Options for Liver Cancer

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

Surgery

While surgery is considered by the medical community to be the preferred treatment option to address liver tumors, approximately 70% to 90% 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%; 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.

Systemic chemotherapy causes significant side effects in the majority of patients, including loss of appetite, nausea and vomiting, hair loss and ulcerations of the mouth. In addition, chemotherapy can damage the blood-

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producing cells of the bone marrow, leading to a low blood cell count. As a result, chemotherapy patients have an increased chance of infection, bleeding or bruising after minor cuts or injuries, and fatigue or shortness of breath.

Cryosurgery

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

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

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

Percutaneous Ethanol Injection

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

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

Radiation Therapy

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

Bone Metastases Market and Treatment Options

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

Prospective Future Markets

Breast Cancer: According to the American Cancer Society (ACS), breast cancer is the most common cancer among women, excluding non-melanoma skin cancers. The ACS estimates there are more than 200,000

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new invasive and 55,000 new cases of *in situ* breast cancer annually among U.S. women, resulting in more than 40,000 deaths per year. We estimate that there are 1,000,000 breast cancer cases diagnosed annually worldwide.

In 2004, we began investigating the clinical benefit of RFA as an adjunct to surgical lumpectomy in breast cancer surgery. The aim of our investigation is to demonstrate that RFA can be used to provide an ablated margin in the lumpectomy cavity as a compensation for inadequate surgical margins associated with the gold standard lumpectomy procedure. We believe that as many as 100,000 patients annually can benefit from this procedure, with the potential clinical benefit being the elimination of re-excision operations due to inadequate surgical margins. In the future, we may also attempt to show that this procedure provides similar local tumor control benefits to that of brachytherapy; however we do not have any specific plans at this time to pursue this.

Lung Cancer: According to the ACS, lung cancer is the leading cause of death from cancer in the United States in both men and women, with more than 170,000 new cases of lung cancer expected to be diagnosed in the United States in 2005. The ACS estimates that lung cancer now claims more than 160,000 lives per year in the United States, along with 187,000 lives in the European Union and 55,000 lives in Japan. Again according to the ACS, 50% of lung cancer patients in the United States are non-surgical candidates and over 140,000 of the cases diagnosed in the United States have non-small cell lung cancer (NSCLC). Additionally, autopsy series have demonstrated that lung metastases are present in 20-54% of all patients who die of cancer.

The RITA system has been used in clinical studies to treat NSCLC and metastatic lung cancer patients who were not candidates for surgery. Publications reporting on the results of the clinical studies suggest that the RITA system may provide a safe and useful adjunctive therapy in the management of disease in lung cancer patients. Furthermore, we believe that RFA may be a particularly attractive treatment modality for the approximately 55,000 (US only) Stage III and Stage IV (late stage) NSCLC patients who have fewer treatment options than early stage lung cancer patients do.

Kidney Cancer-Renal Cell Carcinoma: The worldwide incidence of renal cell carcinoma (RCC), the most common type of kidney cancer, is estimated to be in excess of 180,000 cases annually. The ACS estimates that there are now more than 30,000 new cases of kidney cancer diagnosed in the United States annually, one of the highest per capita rates of kidney cancer in the world. There are approximately 90,000 deaths per year associated with renal cell carcinoma (RCC). We estimate that 50% of these patients are RFA amenable.

Surgery is the gold standard for the treatment of this disease, because chemotherapy and radiation therapy yield poor results for kidney cancer patients. Laparoscopic partial nephrectomy has become an increasingly popular surgical intervention, and RFA is being used in combination with this minimally invasive kidney cancer treatment as a tool to provide hemostatis during the resection of RCC cancer. RFA is also being used as a primary therapy for RCC and we believe the early results in the published literature are encouraging.

Our RFA Procedure

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

The physician inserts the RITA disposable needle electrode device into the target body tissue, typically under ultrasound, computed tomography or magnetic resonance imaging guidance. Once the device is inserted, pushing on the handle of the device causes a group of curved wires to be

deployed from the tip of the electrode. When the power is turned on, these wires deliver radiofrequency energy throughout the tumor. In addition, temperature sensors on the tips of the wires measure tissue temperature throughout the procedure. During the procedure, our system automatically adjusts the amount of energy delivered in order to maintain the temperature necessary to ablate the targeted tissue. For a typical five centimeter ablation using our Starburst Xli or

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Starburst XLie disposable device, the ablation process takes approximately ten minutes. When the ablation is complete, pulling back on the handle of the device causes the curved wire array to be retracted into the device so it can be removed from the body. Our disposable device cauterizes the tissue along the needle tract, which we believe kills any residual cancer cells that might be removed from the tumor.

Benefits of the RITA System

The benefits of our system include:

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

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

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

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

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

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

Radiofrequency Ablation Product Technology

Our radiofrequency ablation products are based on proprietary technology 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

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tissue. To effectively ablate tissue, it must be heated to an approximate temperature of 45 to 50°C, or 113 to 122°F.

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

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

Radiofrequency Ablation Products

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

	Product Name	Description	Year of Introduction	U.S. List Price
Disposable Devices:	StarBurst	Creates a scalable 2 to 3 centimeter ablation.	2000	$ 1,100
	StarBurst XL	Creates a scalable 3 to 5 centimeter ablation.	2000	$ 1,440
	StarBurst SDE	Creates a 2 cm ablation, via a side-deployed array.	2003	$ 2,195
	StarBurst Semi-Flex	Creates a scalable 3 to 5 centimeter ablation and has a partially flexible shaft.	2003	$ 2,195
	7 cm Starburst XLie	Creates a scalable 4 to 7 centimeter ablation. Requires an accessory infusion pump for irrigation of saline.	2003	$ 2,495
Generators:	Model 1500X	250 Watt Capable Generator with Field-Software Upgradeability	2002	$ 37,500

RFA Disposable Devices

Our RFA 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. Sales of RFA disposable devices totaled $15.9 million, $14.6 million and $13.1 million in the years ended December 31, 2004, 2003 and 2002, respectively.

Our RFA disposable devices are available in different array sizes to allow the physician to create a spherical ablation volume of anywhere from two to seven centimeters. Three centimeters is slightly smaller than a ping-pong ball. Seven centimeters is approximately the size of a tennis ball. In addition, depending on product line, the devices are available in 10, 12, 15 or 25 centimeter lengths to allow physicians to access tumors that are located more or less deeply within the body. Each RFA disposable device is supplied with one or more ground pads to allow a return path for the flow of radiofrequency energy from the patient back to the generator.

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RFA 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 1500X generators have the ability, using a laptop computer, to display real-time, color-coded graphs of items such as power, and temperature and impedance to aid the user in controlling the system and to collect procedural information for the patient s record. These generators also have the ability to have their software changed in the field through the insertion of a small card containing electronic memory circuits. Sales of our generators totaled $1.6 million, $2.0 million and $4.3 million in the years ended December 31, 2004, 2003 and 2002, respectively.

Overview: Specialty Access Catheter Products

We manufacture and market specialty access catheter products including implantable ports, hemodialysis catheters, central venous catheters, needle infusion sets, peripherally inserted central venous catheters and other accessories used in vascular procedures.

Vascular Access Ports

Vascular access ports are implantable devices utilized for the central venous administration of a variety of medical therapies and for blood sampling and diagnostic purposes. Central venous access facilitates a more systemic delivery of treatment agents, while mitigating certain of the harsh side effects of certain treatment protocols and eliminating the need for repeated access to peripheral veins. Once implanted in the body, a port can be utilized for up to approximately 2,000 accesses depending upon needle gauge size and the port size. Our vascular access ports are used primarily in systemic or regional short-and long-term cancer treatment protocols that require frequent infusions of highly concentrated or toxic medications (such as chemotherapy agents, antibiotics or analgesics) and frequent blood samplings. Our line of vascular access ports consist of the following families of products: (i) the Vortex family of ports including Vortex VTX, LifePort VTX, TriumphTM VTX and GenesisTM VTX; (ii) LifePort; (iii) Triumph-1; (iv) Infuse-a-Port; (v) OmegaPort; (vi) TitanPort; and (vii) the Vortex MP Port system. Port sales totaled $6.4 million during the August 2004 through December 2004 period in which we reported sales for this and other specialty access products acquired in the Horizon merger. We believe that as a result of our merger with Horizon, we are the second largest supplier of vascular access ports within the United States.

Our Vortex® line of ports is a clear-flow port technology that revolutionizes port design. With its rounded chamber, the Vortex® is designed to have no sludge-harboring corners or dead spaces. This contrasts to conventional ports where squared reservoir design promotes sludge accumulation setting the stage for occlusions and infections. A tangential stem adds to the flow dynamics, which is designed to result in a hyper-cleaning flow process to remove blood deposits and drug residuals. A comparative study on RITA s Vortex® port technology to non-Vortex bodied ports published in the summer 2000 issue of the Journal of Vascular Access Devices, concluded, The design of the Vortex® reservoir appears to contribute to a condition of less build-up of thrombus, and/or drug residuals in the device itself, resulting in fewer complications. This same study reports that patients in the study with the Vortex® port implanted required 56% fewer interventions than those patients with conventional ports. Almost one out of every ten conventional ports failed before the end of therapy requiring surgical removal, whereas none of the Vortex® ports had to be removed prematurely.

Catheters

We also produce and market hemodialysis and apheresis catheters. Hemodialysis catheters are used in the treatment of patients suffering from renal failure who are required to undergo short-term (acute) care or long-term (chronic) hemodialysis, a process involving the removal of waste products from the blood by passing a patient s blood through a dialysis machine. Stem cell apheresis is a protocol for treating certain forms of mid and late-stage cancers, particularly breast cancer. The typical apheresis procedure involves the insertion of a catheter

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into a patient through which (i) blood is withdrawn from the patient, cycled through an apheresis machine in which stem cells (cells which perform a key role in the body s immune system) are removed from the blood and the blood is reinfused into the body, (ii) high doses of chemotherapy agents, as well as antibiotics and blood products, are administered to the patient over extended periods of time, and (iii) the previously removed stem cells are subsequently reintroduced into the patient. Our catheters are used primarily in hemodialysis and apheresis procedures. Our catheters include the following families of products: (i) Circle C chronic and acute hemodialysis catheters, including the LifeJet and LifeJet F-16 chronic hemodialysis catheters; (ii) long-term triple lumen central venous catheters; (iii) peripherally inserted central venous catheters and (iv) the LifeValve Platinum central venous catheter. We expect that our specialty hemodialysis and apheresis families of catheters will continue to benefit from unique designs, allowing some of the highest flow rates available in the market.

The LifeGuard Safety Infusion Set, launched in 2002 and used to infuse our ports, complements our port and specialty access catheter products. The unique, intuitive design was developed with the input of clinicians to provide safer needle placements, and the needles low profile design is intended to allow clinicians to easily dress the site. We believe that the ease of use and visual confirmation of safety is ideal in the clinical setting.

Also, under a distribution agreement with Medtronic, Inc., we sell Medtronic s IsoMed constant flow infusion system for the delivery of chemotherapy agents for use in hepatic arterial infusion therapy for patients with colorectal and/or liver cancer in the treatment of hepatic arterial infusion and malignant pain.

Sales and Marketing

We have a geographically diverse customer base which includes the United States, Europe and Asia. Our customers include surgical oncologists, hepatobiliary surgeons, liver transplant surgeons, laparoscopists and interventional radiologists. We also target patient referral sources, including colorectal surgeons, radiation oncologists and medical oncologists.

In the United States, we market our products through a direct sales force consisting of 34 field representatives and 8 managers. We also utilize two domestic distributors. Overseas, we market our products through distribution partners, including distributors in all the major countries in Europe and Asia, supported by four full-time field representatives.

Our sales and marketing efforts regarding RFA products 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 from our RFA products will be from our disposable devices, which can only be used once a generator is placed. Most of our generators are sold to our customers at a discount from list price, and we have also established a variety of programs, including volume discount and preferred customer discount programs, to facilitate generator placement.

We plan to continue to drive physician adoption of radiofrequency ablation as a therapy 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. We also offer programs to assist our customers in marketing the benefits of the RITA system to referring clinical oncologists and colorectal surgeons. In addition, because cancer treatment options are often affected by patient choice, we are expanding public awareness in this area through a patient education Internet site that focuses on liver cancer.

Our sales and marketing efforts for our SAC product line emphasize the importance of increasing market share by having physicians switch from our competitors products to our Vortex® port systems. We believe that a direct, targeted, and focused strategy supported by our clinically proven SAC technology will achieve this result.

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We intend to leverage our established relationships with leading physicians and prominent cancer centers from our RFA therapy to promote our Vortex Ports and the rest of our SAC product line. We will also continue to develop products for implanters that are easy to use, with features that are designed to expedite implant procedures; such as suture anywhere capabilities and the FluoroMax high radiopacity catheter technology.

Competition

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

RadioTherapeutics Corporation, a division of Boston Scientific Corporation, and Radionics, a division of Tyco Healthcare, which is a division of Tyco International, are the two companies whose products compete directly with our RFA products 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. Furthermore, several other companies, such as Vivant Medical, Inc. and Microsulis Limited, are developing microwave technologies for the treatment of tumor ablation. Vivant Medical has an FDA 510(k) clearance for soft tissue ablation.

We believe the principal competitive factors in our markets for RFA products 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.

The markets for our specialty access catheter product lines are also highly competitive. We face substantial competition from a number of other manufacturers and suppliers of vascular access ports, dialysis and apheresis catheters and related ancillary products, including companies with greater research, manufacturing and financial resources than we have. One of our primary competitors in the market for SAC products in the United States and overseas is Bard Access Systems, a division of C.R. Bard, Inc (Bard). Bard is a publicly traded company with substantially greater resources than we have.

We believe the principal competitive factors in our markets for SAC products are:

product quality and reliability;

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product line diversity;

customer service;

relationships; and

price.

Third-Party Reimbursement

During the past several years, the major third-party payors of hospital services (Medicare, Medicaid, private healthcare indemnity insurance and managed care plans) have substantially revised their payment methodologies to contain healthcare costs. These cost pressures are leading to increased emphasis on the price and cost-effectiveness of any treatment regimen and medical device. In addition, third-party payors, such as governmental programs, private indemnity insurance and managed care plans which are billed by hospitals for such healthcare services, are increasingly negotiating the prices charged for medical products and services and may deny reimbursement if they determine that a device was not used in accordance with cost-effective treatment methods as determined by the payor, was experimental or was used for an unapproved application. There can be no assurance that in the future, hospital purchasing decisions or third party reimbursement levels will not adversely affect our profitability. Furthermore, establishing reimbursement for any new technology is a challenge in the current environment of cost containment and managed care. Currently, hospitals and physicians in the United States are reimbursed for open, laproscopic and percutaneous radiofrequency ablation liver procedures using procedural diagnosis codes as well as CPT codes approved by the American Medical Association. Medicare has also established payment levels for the physician, inpatient hospital and outpatient hospital settings associated with the codes. Private payor reimbursement from the top national organizations, including Blue Cross and Blue Shield plans, has also been established.

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

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

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

Clinical Research and Product Development

Our clinical research staff regularly works with clinicians and medical and academic institutions in the development of new technologies and the evaluation and testing of our products. These relationships are valuable in generating data necessary for regulatory compliance. Our research and development efforts are currently focused on the extension of our radiofrequency ablation product technology to address tumors of the breast, kidney and lung, and initial results of our lung, kidney and breast clinical investigations have been published or presented. We also continue to develop new catheter and port products featuring improved performance and lower cost.

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We believe that we have a strong base of proprietary design, development and manufacturing capabilities. We have particular expertise in the core research and development areas relevant to the production of new disposable electrode devices and computer controlled radiofrequency ablation systems. We are working on a number of enhancements to our existing ablation products that we believe will further improve their ease of use and performance across a broad array of applications.

Patents and Proprietary Technology

We believe that a key element of our competitive advantage depends on our ability to develop and maintain the proprietary aspects of our technology. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws to protect our intellectual property. As of December 31, 2004, we had 58 issued patents worldwide and 58 United States and foreign patent applications pending in the field of radiofrequency ablation. The issued patents cover, among other things, deployable multi-array electrode technology and temperature feedback technology. These patents expire between 2012 and 2022.

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

Our merger with Horizon resulted in acquisition of 25 issued and 2 pending patents covering our specialty access catheter product lines. The issued patents cover, among other things, port reservoir technology, valved catheter technology and needle safety technology. These patents expire between 2006 and 2022.

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 (PMA). 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. Approval of a PMA generally requires several years:

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 RFA products to be marketed for the ablation of soft tissue. In March 2000, we received a specific 510(k) clearance from the FDA for the partial or complete ablation of nonresectable liver lesions. In October 2002, we received another specific 510(k) clearance, this time for the palliation of pain associated with metastatic lesions involving bone in patients who have failed or are

not candidates for standard pain therapy. While we have been successful to date in obtaining regulatory clearance of our products through the 510(k) notification process, if the FDA concludes that any product does not meet the requirements for 510(k) clearance, then a premarket approval would be required and the time required for obtaining regulatory approval would be significantly lengthened.

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

The FDA regulates the labeling, advertising, and distribution of our products, including promotional communications outside conventional marketing materials. Our marketing materials are consistent with the FDA s clearance for our device products. However, the FDA evaluates other activities and if it concludes that promotional communications for our products fall outside the clinical conditions cleared for our products, it may cause them to consider our products to be in violation of the FDC Act.

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 a result, we are subject to inspection by the FDA and the California Departments of Heath and Safety for compliance with good manufacturing practices, and other applicable equivalents, including labeling and the adulteration and misbranding provisions of the FDC Act. Specifically, our manufacturing processes are required to comply with the FDA s 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. We have filed medical device reports with the FDA for our RFA products 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 are also subject to regulations and product registration requirements in many of the foreign countries in which we sell our products in the areas of product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. The time required to obtain marketing approval or clearance required by foreign countries may be longer or shorter than that required for FDA approval or clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements. Either our distributors or we have received registrations and approvals to market certain of our products in international markets that include the European Economic Area, Japan, Korea, Canada, Australia, New Zealand, and other countries.

The European Union has promulgated rules, under the Medical Devices Directive, or MDD, which require medical devices to bear the CE mark . The CE mark is an international symbol of adherence to quality assurance standards. We obtained MDD certification in December 1996. We received our ISO9001/EN46001 recertification in January 2000 of our Mountain View, California facility and have instituted all the systems necessary to meet the Medical Device Directive, thus acquiring the ability to affix the CE mark to our devices and export our devices to any EC-member country. New devices may be required to meet additional requirements before we affix the CE mark. Our Manchester, Georgia facility is also certified as an ISO 9001 medical device manufacturer and is similarly in conformance with the European Medical Device Directive for sale of products in Europe.

Manufacturing

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

manufactured in our Mountain View, California facility throughout 2004, but these operations will be transferred to our Manchester, Georgia facility by the second quarter of 2005. Our Manchester facility also produces our complete line of ports, infusion sets,

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hemodialysis catheters, other miscellaneous catheters, and dialysis accessories, except for a peripherally inserted central venous catheter line and certain product accessories. Some component parts are produced for us by other manufacturers.

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. Our Manchester, Georgia facility is also certified as an ISO 9001 medical device manufacturer and is similarly in conformance with the European Medical Device Directive for sale of products in Europe. GMP regulations may also apply to 3rd party manufacturers depending on the type of component they manufacture for us.

Corporate History, Headquarters and Available Information

We were incorporated in California on January 6, 1994 and reincorporated in Delaware on May 9, 2000. Our principal executive offices are located at 967 N. Shoreline Blvd. Mountain View, California 94043. Our telephone number at that location is (650) 314-3400 and our website is *www.ritamedical.com*. We make our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports, proxy statements and other information available free of charge on our website as soon as reasonably practicable after we file these reports with the Securities and Exchange Commission. These filings are also accessible on the SEC s website at www.sec.gov. The public may read and copy any materials we filed with the SEC at the SEC s Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information for the Public Reference Room by calling the SEC at 1-800-SEC-0330.

Employees

As of January 31, 2005 we had 182 full-time employees, including 58 in sales and marketing, 83 in manufacturing, 21 in research and development and 20 in general and administrative functions. From time to time, we also employ independent contractors to support our organization.

Item 2. Properties.

We are headquartered in Mountain View, California, where we lease one building with approximately 18,000 square feet of office, research and development and manufacturing space. The lease is noncancellable and expires in April 2005. Effective April 2005, our headquarters location will be moving to Fremont, California, where we will lease one building with approximately 14,500 square feet of office, research and development space. Our lease on the Fremont, California facility is also noncancellable and expires in April 2010. Our principle manufacturing facility is one building of approximately 60,000 square feet located in Manchester, Georgia. This facility also includes office and research and development space and is leased through 2010. We also lease approximately 3,000 square feet of administrative office space in Atlanta, Georgia; this lease expires in 2007. We believe these facilities are suitable and adequate to meet our current or foreseeable requirements at least through 2005 and that additional or alternative space will be available at commercially reasonable terms to meet future growth requirements.

Item 3. Legal Proceedings.

We are now and may in the future become a party to legal proceedings arising in the ordinary course of business. Such matters generally involve complex questions of fact and law and could involve significant costs and the diversion of resources to defend. Additionally, the results of

litigation are inherently uncertain, and an adverse outcome is at least reasonably possible. We are unable to estimate the range of possible loss from such future litigation or other legal proceedings and no amounts have been provided for such matters in the accompanying consolidated financial statements.

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

Not applicable.

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is traded on the Nasdaq National Market under the symbol RITA . We commenced trading on July 27, 2000. The following table shows the high and low closing sales prices of our common stock by quarter for 2003 and 2004, and through January 31, 2005, as reported by the Nasdaq National Market:

	HIGH	LOW
Year ended December 31, 2003		
First quarter	$ 5.71	$ 4.03
Second quarter	$ 4.40	$ 2.70
Third quarter	$ 3.59	$ 2.48
Fourth quarter	$ 4.94	$ 3.02
Year ended December 31, 2004		
First quarter	$ 5.91	$ 4.15
Second quarter	$ 6.88	$ 3.75
Third quarter	$ 4.34	$ 2.95
Fourth quarter	$ 4.05	$ 2.47
First quarter of 2005, through January 31, 2005	$ 3.87	$ 2.95

On January 31, 2005, the last reported sales price of our common stock on the Nasdaq National Market was $3.16. The market price of our common stock has been and may continue to be subject to wide fluctuations in response to a number of events and factors, such as quarterly variations in our operating results, announcements of technological innovations or new products by us or our competitors, changes in financial estimates and recommendations by securities analysts, the operating and stock performance of other companies that investors may deem comparable to us, and news reports relating to trends in our markets. These fluctuations, as well as general economic and market conditions, may adversely affect the market price for our common stock. As of January 31, 2005, there were 177 holders of our common stock, excluding persons whose stock is in nominee or street name accounts through brokers.

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

On November 24, 2004, we entered into Stock and Warrant Purchase Agreements, with SF Capital Partners Ltd., BayStar Capital, Walker Smith Capital (and its affiliates) and Capital Ventures International. Pursuant to the terms of the Purchase Agreements, we sold an aggregate of 4,363,634 shares of its unregistered common stock at a per share price of $2.75 and warrants to purchase an aggregate of 3,272,724 shares of its common stock which are initially exercisable at a price of $4.00 per share, netting approximately $11.1 million after issuance fees and expenses. The issuance was deemed to be exempt from registration under the Securities Act of 1933 in reliance upon Section 4(2) thereof as transactions by an issuer not involving any public offering. On January 21, 2005, our Registration Statement on Form S-3/A, which registered the shares of common stock and the shares of common stock issuable upon exercise of the warrants to SF Capital Partners Ltd., Baystar Capital, Walker Smith Capital (and its affiliates) and Capital Ventures International, became effective. We are required to keep this registration statement effective until the earlier of (i) the date when the selling stockholders have sold all the shares of common stock and the shares of common stock issuable upon exercise of the warrants pursuant to the registration statement, (ii) the date on which all of the shares may be sold pursuant to Rule 144 under the Securities Act of 1933, as amended or (iii) November 24, 2006.

The disclosure required by Item 201(d) of Regulation S-K is incorporated by reference to the definitive proxy statement for our 2005 Annual Meeting of Stockholders to be filed with the SEC pursuant to Regulation

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14A no later than 120 days after the end of the fiscal year covered by this report, or the Proxy Statement, under the caption *Equity Compensation Plan Information*.

Item 6. Selected Financial Data.

You should read the following selected financial data in conjunction with our financial statements and related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this Form 10-K. The annual data presented below is derived from our audited consolidated financial statements. Our audited consolidated statement of operations for the years ended December 31, 2004, 2003 and 2002 and our audited consolidated balance sheet at December 31, 2004 and 2003 are presented elsewhere in this Form 10-K. The information provided below is in thousands, except for per share data. The merger with Horizon in July 2004 has affected the selected financial data for the year ended December 31, 2004 and as of December 31, 2004, making comparisons with prior periods difficult.

	Years ended December 31,				
	2004	2003	2002	2001	2000
Statement of Operations Data:					
Sales	$ 28,215	$ 16,607	$ 17,393	$ 14,791	$ 10,010
Cost of goods sold	11,200	6,166	6,908	6,132	6,048
Gross profit	17,015	10,441	10,485	8,659	3,962
Operating expenses:					
Research and development	3,787	4,294	5,052	6,489	5,615
Selling, general and administrative	20,637	17,418	19,366	16,646	12,052
Restructuring charges	1,309				
Total operating expenses	25,733	21,712	24,418	23,135	17,667
Loss from operations	(8,718)	(11,271)	(13,933)	(14,476)	(13,705)
Interest expense	(604)		(12)	(86)	(683)
Interest and other income, net	19	192	446	1,602	1,581
Net loss	$ (9,303)	$ (11,079)	$ (13,499)	$ (12,960)	$ (12,807)
Net loss per common share, basic and diluted	$ (0.35)	$ (0.63)	$ (0.91)	$ (0.90)	$ (1.99)
Shares used in computing net loss per common share, basic and diluted	26,465	17,647	14,890	14,353	6,440

	December 31,				
	2004	2003	2002	2001	2000
Balance Sheet Data:					

Cash, cash equivalents and marketable securities, current and long term	$ 13,858	$ 9,535	$ 12,835	$ 23,537	$ 40,057
Working capital	14,255	11,886	16,066	25,478	41,512
Total assets	152,309	22,033	24,166	35,834	46,270
Long-term obligations, net of current portion	9,722	23			180
Common stock and additional paid-in capital	216,934	98,055	88,540	88,474	88,435
Total stockholders equity	128,656	19,084	20,603	32,145	42,647

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

Business Overview

We develop, manufacture and market innovative products for cancer patients, including radiofrequency ablation systems for treating cancerous tumors as well as percutaneous vascular and spinal access systems. In 2001, we commercially launched our StarBurst XLi family of disposable devices and significantly expanded our direct domestic sales organization and our international distribution network. In 2002, the XLi family of disposable devices gained wide acceptance with our customers in the United States. In 2003, we introduced our next generation in infusion technology, the Xli-Enhanced (Xlie) disposable device. The Xlie device builds upon our established infusion expertise, making the ablation process easier and more efficient.

On July 29, 2004, we completed a merger with Horizon Medical Products, Inc. Horizon operated as a specialty medical device company focused on manufacturing and marketing vascular products, particularly oncology product lines including implantable vascular ports, tunneled catheters and stem cell transplant catheters used in cancer treatment protocols. Each Horizon common stockholder received 0.4212 of a share of our common stock for each share of Horizon common stock held. We thereby issued approximately 18.7 million shares of its common stock to acquire all issued and outstanding shares of Horizon common stock, and further assumed all outstanding Horizon options and warrants that, upon exercise, will result in the issuance of approximately 3.9 million shares of our common stock. The fair value of shares we issued was approximately $91.6 million based on a price per share of $4.896, our average closing price the day the proposed merger was announced (May 13, 2004), the two business days preceding the announcement and the two business days following the announcement. The fair value of options and warrants, all of which were fully vested when we assumed them, was determined to be approximately $15.3 million using the Black-Scholes valuation model. Costs incurred to effect the merger and included as a component of purchase price were $2.4 million. The total purchase price was approximately $109.3 million. The fair value of assets acquired, net of liabilities assumed, was approximately $18.0 million, resulting in goodwill of $91.3 million. We believe the merger will lead to higher sales and greater profitability than either or both of the pre-merger companies on a standalone basis due to a larger, more effective sales group, consolidation of manufacturing resulting in lower product costs, and reduced administrative expenses.

Management relies on certain statistical measurements to assess trends in sales growth and the effectiveness of our selling strategies. The following table, derived from our Consolidated Statements of Operations and other unaudited data for the years ended December 31, 2004, 2003 and 2002, sets forth some of these measurements:

	Years ended December 31,		
	2004	2003	2002
Total sales (in thousands)	$ 28,215	$ 16,607	$ 17,393
Percentage of sales: United States	84%	80%	74%
Percentage of sales: International	16%	20%	26%
Percentage of sales: Radiofrequency products	62%	100%	100%
Percentage of sales: Specialty access catheters	38%	0%	0%
Gross margin	60%	63%	60%

Consolidation of Horizon s results did not begin until the closing date of the merger, July 29, 2004. Therefore, the percentages shown for historical periods are not indicative of future results. In particular, the percentage of sales attributable to specialty access products is expected to be higher in future years that reflect twelve months of specialty access product results.

Prior to completion of the Horizon merger, our products were sold in the United States exclusively through our direct sales force and internationally through distribution partners. Horizon, in contrast, made use of domestic distribution partners in selected areas of the United States. Since completion of the merger, we have begun to

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distribute our radiofrequency ablation products through two of these domestic distribution partners. However, direct sales will remain our predominant mode of domestic distribution for the foreseeable future.

Our sales in the United States are more profitable than our sales in international markets because direct selling, which avoids distributor discounts, permits higher average selling prices for our products. Accordingly, we have made significant investments in our domestic sales force in an effort to increase sales growth in the United States, and we introduced our premium-priced Starburst Xli and Xlie families of disposable needles in this region earlier than in Europe or other regions. These actions have resulted in a growing percentage of sales derived from the domestic market. The merger with Horizon should permit wider and even more efficient coverage of the domestic market, further strengthening this trend. In contrast, our international markets in Europe and Japan have relatively more restrictive reimbursement conditions than those in the United States, which combined with our distributor discounts, limit our average selling prices in these markets. We expect 2005 sales growth in the United States to continue to outpace international growth because we believe the principle impact of the Horizon merger will be upon the domestic market and because introduction of premium products to our international distributors will have a relatively small impact on growth due to pricing limitations.

Prior to completion of the Horizon merger, essentially all of our sales came from the sale of our disposable devices and radiofrequency generators used in the treatment of cancerous liver tumors. The merger with Horizon expanded our product offering and has resulted in additional sales, primarily from the specialty access catheter and port product lines used in cancer treatment protocols. Going forward, we expect that nearly 95% of our sales will be derived from our RFA and SAC disposable products, with the balance of our sales coming from hardware products. During the third quarter of 2004, integration of the two sales groups required training that adversely impacted sales growth. However, sales in the fourth quarter of 2004 returned to historically normal rates. We believe that in 2005 the broader product line and larger sales group resulting from the merger will enable us to increase the efficiency of our selling effort.

Our manufacturing costs consist of raw materials, including generators and ancillary hardware components produced for us by third-party suppliers, labor to produce our disposable devices and to inspect incoming, in-process and finished goods, sterilization performed by an outside service provider and general overhead expenses. Our manufacturing costs are volume-dependent, and our unit costs should decrease as our production volumes increase. The ongoing integration of our manufacturing operations in our Manchester, Georgia location should result in lower costs in the future from the use of less expensive labor and economies of scale. We also believe we have the opportunity to reduce the cost of our vendor-supplied hardware products through higher order volumes or product redesign. Besides manufacturing costs, our cost of goods sold for 2004 and 2003 reflects amortization of intangible assets relating to product technology acquired in the merger and the 2003 settlement of patent litigation. We expect these amortization charges to continue through 2016. Further, our cost of goods sold also includes provisions to our reserve for obsolete inventory. Technology in our marketplace has evolved rapidly and we have, from time to time, recognized relatively high expenses related to obsolete inventory as our product line has changed. We may experience similar product changes and related obsolete inventory provisions in the future.

Our gross margins reflect our selling prices, our domestic / international mix percentages, our product mix percentages, our production volumes, the costs we pay for vendor manufactured product and our provisions for obsolete inventory. Our gross margin for the 2004 was 60%, compared to a 2003 gross margin of 63%. Historically, the gross margin rate for our specialty access catheter products has been lower than that of our radiofrequency ablation products. Also, amortization of our product technology related intangible assets will negatively impact cost of goods sold. We expect that our future gross margins will be somewhat lower than our historical gross margin rates because of inclusion of these products and expenses in our results.

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In addition to the selling statistics discussed above, management relies on certain measurements to assess the effectiveness of our operations. The following tables sets forth some of these measurements, derived from our Consolidated Statements of Operations for the three years ended December 31, 2004, 2003 and 2002 and our Consolidated Balance Sheets as of December 31, 2004 and 2003.

	Years ended December 31,		
	2004	2003	2002
Research and development expense	$ 3,787	$ 4,294	$ 5,052
Selling, general and administrative expense	20,637	17,418	19,366
Restructuring charges	1,309		
Total operating expenses	$ 25,733	$ 21,712	$ 24,418

	December 31,	
	2004	2003
Cash and cash equivalents	$ 12,978	$ 3,780
Marketable securities, current and long term	880	5,755
Total cash and marketable securities	$ 13,858	$ 9,535

If we are to become profitable, we must continue to manage our operating expenses. Our operating expenses consist of product development costs, clinical trial expenses, patent litigation expenses, sales and marketing expenses related to our selling efforts in the United States, Europe and Asia, and administrative expenses, including the costs associated with our status as a public company, professional service expenses and our provisions for uncollectible accounts. Changes in these expenses are determined by the breadth of our new product development portfolio, the number of headcount we maintain in our selling and administrative functions, the scope of our marketing efforts, the costs we incur in defense of our patents and intellectual property rights and the extent to which credit issues and economic conditions constrain our ability to collect our receivables.

Research spending in 2004 was $3.8 million, or 12% lower than in 2003. Research spending in 2005 is expected to increase modestly, driven by programs aimed at technical innovation of our radiofrequency ablation products and the introduction of new implantable ports and access catheters.

Selling, general and administrative in 2004 was $20.6 million, about $3.2 million higher than in 2003. The primary reasons for the increase were the consolidation of Horizon results and expenses incurred in the integration of the two companies. Also, the merger resulted in recognition of intangible assets relating to trademarks, customer relationships and our distribution contract with Medtronic, amortization of which will result in charges to selling, general and administrative expense of $1.4 million to $1.6 million per year through 2014. We further note significant costs related to compliance with the Sarbanes-Oxley Act of 2002. However, headcount reductions, particularly in the domestic sales groups, were begun in the third quarter of 2004. These headcount reductions should result in expense levels for the combined company lower than the sum of expenses for the two companies prior to the merger. We incurred restructuring expenses of $1.3 million during the year ended December 31, 2004, consisting of severance related to the termination of employees to eliminate certain duplicative activities.

In addition to management of our operating expenses, we must continue to conserve our cash. Our combined total of cash, cash equivalents and marketable securities was $13.9 million as of December 31, 2004, compared to $9.5 million at December 31, 2003. Our net cash used in operating activities for the year ended December 31, 2004 was $5.6 million. We had approximately $16.8 million in short term and long term debt as of December 31, 2004. We paid $6.5 million of our outstanding debt, plus accrued interest, in February 2005. We may in the future need to raise additional cash through borrowing or sale of equity securities or to renegotiate the payment terms of our debt.

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We incurred a net loss of $9.3 million for year ended December 31, 2004 compared to $11.1 million for the year ended December 31, 2003. Prior to considering the impact of the adoption of Statement of Accounting Standards (SFAS) No. 123R, Share-Based Payment, we believed that the efficiencies achieved by our merger with Horizon and continued growth in sales of our products would permit us to achieve profitability for the year ended December 31, 2005. We have not yet been able to determine the impact of SFAS No. 123R on our future results, but we expect to incur significant charges as a result of adoption of the standard. Profitability further depends on, among other things, our success in expanding product usage in our current markets and in developing new markets, as well as the successful integration of Horizon s operations. To the extent current or new markets do not materialize in accordance with our expectations, our sales could be lower than expected and we may be unable to achieve or sustain profitability.

Critical Accounting Policies and Estimates

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

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

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

Revenue recognition: Revenue is recognized upon receipt of a customer purchase order and subsequent product shipment provided no significant obligations remain and collection of the associated receivable is deemed reasonably assured. Except for our two distributors in the United States, our customers have no price protection and may only return undamaged product within thirty days of purchase. Our two distributors in the United States have no price protection, but it is our policy for these two customers to swap new product for undamaged returned product within 90 days of purchase, subject to a limit of 5% of their purchases in our preceding fiscal quarter. Based on our historical rate of product returns, we maintain a reserve for projected future product returns; provisions to this reserve are accounted for as a deduction from current period sales. Should changes in conditions, including the rate of product returns, or the status of obligations cause us to determine that our criteria for revenue recognition are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected. Payments for maintenance services are usually prepaid and the related maintenance revenue is deferred and recognized ratably over the service contract term. Service contract terms range from 12 to 36 months. Through December 31, 2004, all of our billings have been denominated in U.S. dollars, although we expect relatively minor billings in foreign currencies in future periods.

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

Goodwill and other intangible assets: We account for our goodwill under Statement of Financial Accounting Standards (SFAS) No. 142, Goodwill and Other Intangible Assets. The SFAS No. 142 goodwill impairment model is a two-step process. First, it requires a comparison of the book value of net assets to the fair value of the reporting units that have goodwill assigned to them. In our case, operating in one business segment, the fair value of the reporting unit is equal to our market capitalization. If fair value is determined to be less than book value, a second step is performed to compute the amount of the impairment. Recoverability of the asset is measure by comparison of the asset s carrying amount to future net undiscounted cash flows the asset is expected to generate. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the projected discounted future net cash flows arising from the asset. We test goodwill for impairment during the third quarter of every fiscal year, and when an event occurs or circumstances change such that it is reasonably possible that impairment exists. Events that could, in the future, result in impairment include, but are not limited to, sharply declining sales for a significant product or in a significant geographic region.

Impairment of Long Lived Assets: We review long lived assets whenever events or changes in business conditions indicate that these carrying values may not be recoverable in the ordinary course of business. When such an event occurs, our management determines whether there has been impairment by comparing the anticipated undiscounted future net cash flows to the related asset s carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset.

Results of Operations

The following table sets forth the percentage of sales represented by certain items in our Consolidated Statements of Operations for the years ended December 31, 2004, 2003 and 2002:

	Years ended December 31,		
	2004	**2003**	**2002**
Sales	100%	100%	100%
Cost of goods sold	40%	37%	40%
Gross profit	60%	63%	60%
Operating expenses:			