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:			
Research and development	13%	26%	29%
Selling, general and administrative	73%	105%	111%
Restructuring	5%	0%	0%
Total operating expenses	91%	131%	140%

Loss from operations	(31)%	(68)%	(80)%
Interest expense	(2)%	0%	(0)%
Interest and other income, net	0%	1%	(2)%
Net loss	(33)%	(67)%	(78)%

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The following table sets forth comparisons of key components of our sales results for the years ended December 31, 2004 and 2003, providing additional information on the sales impact of the consolidation of our acquired specialty access catheter products.

	2004	2003	Growth	%
Domestic sales:				
Radiofrequency ablation products	$ 13,865	$ 13,275	$ 590	4%
Specialty access catheter products	9,747		9,747	
Total domestic sales	$ 23,612	$ 13,275	$ 10,337	78%
International sales:				
Radiofrequency ablation products	$ 3,688	$ 3,332	$ 356	11%
Specialty access catheter products	915		915	
Total international sales	$ 4,603	$ 3,332	$ 1,271	38%
Total radiofrequency ablation sales	$ 17,553	$ 16,607	$ 946	6%
Total specialty access catheter products	10,662		10,662	
Total sales	$ 28,215	$ 16,607	$ 11,608	70%

Years Ended December 31, 2004 and 2003

For the year ended December 31, 2004, sales totaled $28.2 million, an increase of 70% or $11.6 million from $16.6 million in 2003. The merger with Horizon added $10.7 million to our sales, while sales of our radiofrequency ablation products grew $0.9 million or 6% over 2003. Domestic sales of radiofrequency ablation products were 4% higher in 2004 than in 2003. We believe that sales were limited by the impact of training and turnover in our sales group that resulted from the Horizon merger. International sales of radiofrequency ablation products grew 11% over 2003. For the year ended December 31, 2004, domestic sales represented 84% of total sales, compared to 80% in 2003. Radiofrequency ablation products accounted for 62% of sales in 2004, while specialty access catheter products accounted for 38% of sales, although the results of the specialty access catheter products acquired in the Horizon merger reflect only sales made from July 29, 2004 through December 31, 2004.

Cost of goods sold for the year ended December 31, 2004 was $11.2 million as compared to $6.2 million in 2003, resulting in a 60% gross margin for 2004 compared to a 63% gross margin rate in 2003. As with our sales results, the increase in our cost of goods sold was primarily due to the merger with Horizon and inclusion of the results of the acquired specialty access catheter products. Our cost of goods sold during the fourth quarter of 2004 reflected a negative impact of approximately $1.0 million in inefficiencies resulting from the transfer of our radiofrequency product manufacturing operations from our Mountain View, California location to our Manchester, Georgia location. These inefficiencies will likely continue into the second quarter of 2005, because we do not expect to achieve full production volumes or complete training of our manufacturing personnel in Georgia until that point. Our cost of goods sold in 2004 was also affected by amortization of intangibles, including $0.3 million in amortization of capitalized license fees associated with the settlement of our patent litigation dispute with Boston Scientific Corporation and $0.3 million in amortization of a product technology intangible asset recognized as part of the Horizon merger. The amortization expense of the product technology intangible asset will grow to $0.6 million in 2005, as we will amortize the asset for a full year, rather than only five months. We expect such amortization charges to continue through 2016.

Research and development expenses for the year ended December 31, 2004 were $3.8 million as compared to $4.3 million in 2003. This decrease was due to reduced new product development and clinical trial costs. We expect an increase in research expenditures for 2005, driven by developmental charges associated with technical innovation of our products, the expansion of our product line after the Horizon merger and,

to some extent, the implementation of SFAS 123R.

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Selling, general and administrative expenses for the year ended December 31, 2004 were $20.6 million as compared to $17.4 million in 2003. Most of the increase, about $2.6 million, reflects higher sales, marketing and administrative expenses associated with our increased size after the Horizon merger, including $0.7 million in amortization of related intangibles. However, about $0.4 million of the increase was due to expenses associated with merger integration and sales training, and another $0.6 million of the increase was due to legal, audit and consulting expenses associated with compliance with the Sarbanes-Oxley Act of 2002. Our bad debt expense was about $0.4 million lower in 2004 than in 2003, primarily reflecting reduced allowances relating to our domestic distributors. In 2005, we expect selling, general and administrative expenses to increase 8% to 10% as a result of including a full year of the operations acquired from Horizon, compared to only five months in 2004. Also, a further increase will result from implementation of SFAS 123R. We are not now able to precisely quantify the impact of SFAS 123R on our results, but we believe it will significantly increase our selling, general and administrative expenses.

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, primarily in the areas of sales, accounting and operations. We do not expect significant additional restructuring expenses in 2005.

Interest expense for the year ended December 31, 2004 was $0.6 million, compared to zero during the year ended December 31, 2003. The interest expense in 2004 relates to debt assumed in the merger with Horizon, the balance of which was $16.8 million at December 31, 2004. We had no debt throughout 2003. In 2005, despite payments made or to be made on our debt, interest expense on the remaining debt will be incurred for twelve months rather than only five months, as in 2004. For this reason, and because the interest rate on some of our remaining debt is scheduled to increase in 2005, we expect our interest expense to increase to approximately $1.0 million in 2005.

Interest income was essentially zero during the year ended December 31, 2004, down from $0.2 million for the year ended December 31, 2003, because average daily cash balances fell during 2004 as we utilized cash for operations.

Years Ended December 31, 2003 and 2002

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

Cost of goods sold for the year ended December 31, 2003 was $6.2 million as compared to $6.9 million in 2002, resulting in a 63% gross margin for 2003 compared to a 60% gross margin rate in 2002. Cost of goods sold was affected by charges for obsolete inventory that totaled approximately $0.5 million for 2003, down from $0.7 million in 2002. Costs for the first two quarters of 2003 were further increased by temporary price increases of approximately $0.5 million on our vendor sourced ancillary infusion pumps. These temporary charges ceased by June of 2003. Our cost of goods sold in 2003 also included $0.2 million amortization of capitalized license fees associated with the settlement of our patent litigation dispute with Boston Scientific Corporation.

Research and development expenses for the year ended December 31, 2003 were $4.3 million as compared to $5.1 million in 2002. This decrease was due to reduced new product development and clinical trial costs. Also, there were no charges for amortization of deferred

stock-based compensation in 2003, compared to $0.2 million of such charges for 2002.

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

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

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 that were fully repaid as of December 31, 2002. In January of 2003, we raised an additional $8.3 million, net of expenses, through a private placement of our common shares. In November of 2004, we raised an additional $11.1 million, net of expenses, through a second private placement of our common shares. As of December 31, 2004, we had $13.0 million of cash and cash equivalents, $0.9 million of marketable securities and $14.3 million of working capital.

For the year ended December 31, 2004, net cash used in operating activities was $5.6 million principally due to our net loss of $9.3 million, offset by non-cash charges of $2.1 million, including depreciation and amortization, stock-based compensation and provisions to reserves for uncollectible accounts receivable and inventory. Stock-based compensation for 2004 totaled $143,000, primarily from issuance of options to non-employees. Approximately $1.6 million in cash was provided in 2004 by changes in working capital accounts, including $0.7 million in reduced inventory, $0.4 million in reduced prepaid and other current assets, a $0.2 million in reduced accounts receivable and $0.2 million in higher accounts payable and current accrued liabilities. During 2004, $3.2 million was provided by investing activities, with net sales of marketable securities providing $4.9 million offset by $0.7 million used in purchase of property and equipment. Further, the acquisition of Horizon used $1.2 million in cash, the excess of professional service expenses incurred in the merger over Horizon s cash as of the merger date. Financing activities for the year provided $11.6 million in cash, including the $11.1 million we raised in our November 2004 private placement of common stock and $0.7 million related to the issuance of common stock in conjunction with the exercise of stock options. We used $0.3 million to make payments on our debt.

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We have, from time to time, financed equipment through capital and operating leases. Also, in the course of the Horizon merger, we acquired debt, the balance of which was $16.8 million as of December 31, 2004. As of December 31, 2004, we had no future minimum payments due under capital leases. Future minimum payments due under operating leases, including the 2005 operating lease we have entered regarding our new headquarters space in Fremont, California, and debt agreements were as follows (in thousands):

	Operating Leases	Debt	Total
Year ending December 31, 2005	$ 461	$ 7,200	$ 7,661
Year ending December 31, 2006	361	382	743
Year ending December 31, 2007	339	988	1,327
Year ending December 31, 2008	304	8,262	8,566
Year ending December 31, 2009.	308		308
Year ending December 31, 2010 and thereafter	116		116
Total of future minimum operating lease payments	$ 1,889	$ 16,832	$ 18,721

Our capital requirements depend on numerous factors including our research and development expenditures, expenses related to selling, general and administrative operations and working capital to support business growth. Our net cash used in operating activities was $5.6 million for the year ended December 31, 2004. In 2005, we will be required to make $7.2 million in debt payments; $6.5 million of this amount was made in February 2005. Our balance of cash, cash equivalents and marketable securities on December 31, 2004 was $13.9 million. Although it is difficult for us to predict future liquidity requirements with certainty, we believe that our current balances of cash, cash equivalents and marketable securities will satisfy our cash requirements for at least the next 12 months. During or after this period, if cash generated by operations is insufficient to satisfy our liquidity requirements, we may need to sell additional equity or debt securities, obtain an additional credit facility or renegotiate debt repayment terms. 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 us and our stockholders, or that we will be successful in renegotiating debt repayment terms. Failure to obtain sufficient funds on acceptable terms when needed, to make timely debt payments, or to achieve our growth or profitability objectives may require us to curtail operations, perhaps to a significant extent.

Private Placement of Securities

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 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.

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

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Income Taxes

As of December 31, 2004, we had federal net operating loss carryforwards of approximately $103.5 million and state net operating loss carryforwards of approximately $56.6 million, available to offset future regular taxable income. We have fully reserved our deferred tax assets, however, because realization of favorable tax assets in future returns is very uncertain. The federal net operating loss carryforwards will expire between 2008 and 2024, and the state net operating loss carryforwards will expire between 2005 and 2014, 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, Income Taxes, in the Notes to Consolidated Financial Statements appearing elsewhere in this Form 10-K.

Recent Accounting Pronouncements

In March 2004, the FASB issued EITF Issue No. 03-1 (EITF 03-1), The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments which provides new guidance for assessing impairment losses on investments. Additionally, EITF 03-1 includes new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB delayed the accounting provisions of EITF 03-1; however, the disclosure requirements remain effective for annual periods ending after June 15, 2004. We will evaluate the impact of EITF 03-1 once the final guidance is issued.

In November 2004, the Financial Accounting Standards Board issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning in the second quarter of fiscal 2006. We do not believe the adoption of SFAS No. 151 will have a material effect on our consolidated financial position, results of operations or cash flows.

In December 2004, the Financial Accounting Standards Board issued Statement of Accounting Standards (SFAS) No. 123R, Share-Based Payment , which replaces SFAS No. 123. SFAS No. 123R requires public companies to recognize an expense for share-based payment arrangements including stock options and employee stock purchase plans. The statement eliminates a company s ability to account for share-based compensation transactions using APB 25, and generally requires instead that such transactions be accounted for using a fair-value based method. SFAS No. 123R requires an entity to measure the cost of employee services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant, and to recognize the cost over the period during which the employee is required to provide service in exchange for the award. SFAS No. 123R is effective for us in the quarter ending September 30, 2005. Upon adoption of SFAS 123R, companies are allowed to select one of three alternative transition methods, each of which has different financial reporting implications. Management is currently evaluating the transition methods, valuation methodologies and other assumptions for employee stock options in light of SFAS No. 123R. Current estimates of option values using the Black-Scholes method may not be indicative of results from the valuation methodologies we ultimately implement upon adoption of SFAS No. 123R. Although we have not yet fully quantified the impact this standard will have on our financial statements, it is likely that the adoption of SFAS No. 123R will have a material impact on our financial position and results of operations.

Factors That May Affect Future Results

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

We may be unable to integrate our operations successfully and realize all of the anticipated benefits of our merger with Horizon Medical Products.

Our merger with Horizon involves the integration of two companies that previously have operated independently, which is a complex, costly and time-consuming process. The difficulties of combining the companies operations include, among other things:

Coordinating geographically disparate organizations, systems and facilities;

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Integrating personnel with diverse business backgrounds;

Consolidating corporate and administrative functions;

Consolidating research and development, and manufacturing operations;

Coordinating sales and marketing functions;

Retaining key employees; and

Preserving research and development, collaboration, distribution, marketing, promotion and other important relationships of the companies.

The process of integrating our operations with Horizon s has caused and could cause an interruption of, or loss of momentum in, the activities of the combined company s business and the loss of key personnel. The diversion of our management s attention and any delays or difficulties encountered in connection with the integration of our operations with those of Horizon Medical Products could harm our business, results of operations, financial condition or prospects after the merger.

We have identified material weaknesses in our internal control over financial reporting. Failure to remediate these weaknesses could impact the reliability of our financial reporting.

To date, we have identified material weaknesses in our procurement process which did, prior to adjustment, or could otherwise, result in a material misstatement of our annual or interim financial statements. As a result of these material weaknesses, we have determined that we did not maintain effective internal control over financial reporting as of December 31, 2004. See our disclosure in Status of Management s Report on Internal Control over Financial Reporting included under Item 9A for further discussion of these material weaknesses.

Because of the significant delays we have encountered in executing against our internal Section 404 project plan, it is possible that we will not be able to timely deliver the required management report on internal control over financial reporting May 2, 2005. If we are not so able to report by this extended due date, we will no longer be current in our Exchange Act reporting obligations and the liquidity of our common stock for certain of our selling stockholders will be adversely impacted.

In an exemptive order dated November 30, 2004, the Securities and Exchange Commission provided an extension on the due date for management s and the independent registered accounting firm s reports on internal control over financial reporting for certain filers until May 2, 2005. We are eligible for this extended due date and will elect to use it. However, because of the significant delays we have encountered in executing against our internal Section 404 project plan, it is possible that we will not be able to timely deliver the required management report by the extended due date. If we are not able to deliver this report by May 2, 2005, we will no longer be current in our Exchange Act reporting obligations. As a result, selling stockholders would be unable to use any registration statements on Form S-3 and on Form S-8 that we had filed in order for them to sell their shares of our common stock. Furthermore, selling stockholders would be unable to rely upon Rule 144 of the Securities Act in order to sell their shares of our common stock. The liquidity of our common stock for these selling stockholders will be reduced.

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We will be heavily dependent on the RITA system and our line of specialty access catheters in order to achieve our sales goals and our profitability targets. Failure to achieve and grow market acceptance for either product line could harm our business.

The majority of our sales will come from the sale of the RITA system and our line of specialty access catheters. Our financial performance will depend upon physician adoption and patient awareness of these products. If we are unable to convince physicians to use these products, we may not be able to generate sales because we do not have alternative products.

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

We incurred net losses of $9.3 million in 2004, $11.1 million in 2003, $13.5 million in 2002, $13.0 million in 2001, $12.8 million in 2000 and $7.5 million in 1999. At December 31, 2004, we had an accumulated deficit of $88.3 million. To become profitable we must increase our sales and continue to limit the growth of our operating expenses. If our sales do not grow, or if expenses grow excessively, we may not be able to achieve or maintain profitability in the future.

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.

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

In the market for specialty access catheters and ports, we compete directly with C.R. Bard Inc. C.R. Bard is a publicly traded company with substantially greater resources than we have.

We are also aware of several companies in international markets that sell products that compete directly with ours. These companies are affecting our international market share and may erode that share in the future. In addition, one of these companies, Berchtold Corporation, has received FDA clearance for using radiofrequency energy to ablate soft tissue.

Alternative therapies could prove to be superior to the RITA radiofrequency ablation system or implantable vascular products, and physician adoption of our products could be negatively affected.

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

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

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

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

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

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

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

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

- the challenge of managing international sales without direct access to the end customer;
- lower average selling prices for our products, due to distributor discounts;

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;

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- significant currency fluctuations, which could cause our distributors to reduce the number of products they purchase from us because the cost of our products to them could increase relative to the price they could charge their customers;

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

- contractual provisions governed by foreign laws.

We are substantially dependent on two distributors in our international markets, and if we lose either distributor or if either distributor significantly reduces its product demand, our international and total sales 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 sales could decline. ITX Corporation, formerly known as Nissho Iwai Corporation, is our primary distributor in Asia. Although it accounted for only 7% of our international sales in 2004, it accounted for 21% of our international sales in 2003. M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, accounted for 19% of our international in 2004 and 22% of our international sales in 2003. International sales accounted for 16% of our total sales in 2004, and these two distributors represented 26% of that total. For the year ended December 31, 2003, international sales accounted for 20% of our total sales and these distributors represented 43% of that total. The loss of either distributor or a significant decrease in unit purchases by either distributor could cause our sales to decline substantially. If we are unable to attract additional international distributors, our international and total sales may not grow.

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

We sell our products in international markets and selected domestic markets through third-party distributors over whom we have limited control, and, if they fail to adequately support our products, our sales could decline. In the past, we have terminated agreements with distributors and although we contracted with replacement distributors, we expended significant time and resources in doing so, and our sales in the affected markets suffered during the transition period that lasted approximately nine months. If our distributors or we terminate other distributor agreements, we could incur similar or more burdensome expenses, we could expend significant time and resources in finding replacement distributors, and our sales could decrease during any related transition period.

We are aware that some of our distributors have built up inventory of our products. As a result, future sales to these distributors could be negatively impacted. Sales to our Japanese distributor in 2004 and 2003 and to a domestic distributor in the three months ended September 30, 2004 were so affected. In addition, while our distributors have no price protection and may only return undamaged products per our return policies, if we permit the return of products in excess of our provision for returns, we will have to adjust our revenues relating to these products. This may also impact our revenue recognition policy on future distributor sales.

In 2002, we significantly increased our allowance for doubtful accounts to address the risk associated with longer collection periods that have arisen principally with our European distributors. Although the deterioration we experienced in international collections in 2002 stabilized in 2003, and remained stable in 2004, we may encounter new difficulties with collections that require further increases in our allowance for doubtful accounts in the future, and we may require specific accounts to post letters of credit or pay in advance to minimize our credit risk. Further, we may, in the future, terminate relationships with some of the domestic distributors utilized by Horizon prior to the merger, making collection of accounts receivable with these customers difficult. We believe our allowance for doubtful accounts sufficiently reflects this possibility, but additional provisions to the allowance for doubtful accounts are could be required. Additional future increases in our allowance for doubtful accounts would reduce our profits.

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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. If our distributors or we are unable to either obtain the required reimbursement codes or develop an effective strategy to resolve the reimbursement issue, physicians in foreign markets may be unwilling to purchase our products, negatively impacting our international revenues.

Our business is dependent upon reimbursement from government programs, such as Medicare and Medicaid, and we may face limitations on such third-party reimbursement, which could harm our operating results.

In the United States, our products are purchased primarily by hospitals and medical clinics, which then bill various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans, for the healthcare services provided to patients. Government agencies, private insurers and other payors determine whether to provide coverage for a particular procedure and reimburse hospitals for medical treatment at a fixed rate based on the diagnosis-related group, or DRG, established by the United States Centers for Medicare and Medicaid Services, or CMS. The fixed rate of reimbursement is based on the procedure performed and is unrelated to the specific devices used in that procedure. If a procedure is not covered by a DRG, payors may deny reimbursement. In addition, third-party payors may deny reimbursement if they determine that the device used in a treatment was unnecessary, inappropriate or not cost-effective, experimental or used for a non-approved indication.

There can be no assurance that reimbursement for implantation of our vascular access ports and catheter products will continue at current levels, or that future reimbursement policies of third-party payors will not adversely affect our ability to sell our vascular products on a profitable basis. Failure by hospitals and other users of our products to obtain reimbursement from third-party payors, or changes in government and private third-party payors policies toward reimbursement for procedures employing our products, would have a material adverse effect on our business, results of operations and financial condition.

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

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

We are subject to, and may in the future 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 are and may in the future be subject to product liability lawsuits. 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.

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

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

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

Our stock price is likely to fluctuate owing to market uncertainty about our ability to successfully integrate the operations of Horizon and manage our cash during the process of integration. Our stock price may also fluctuate for a number of other reasons including:

our ability to repay debt;

our ability to successfully commercialize our products;

our ability to comply with Section 404 of the Sarbanes-Oxley Act of 2002;

conclusions that our internal control over financial reporting are ineffective;

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

quarterly fluctuations in our results of operations;

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

product liability claims;

regulatory developments regarding us or our competitors;

acquisitions or strategic alliances by us or our competitors;

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

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

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

We have limited experience manufacturing our disposable devices in substantial quantities, and if we are unable to hire sufficient additional personnel or to purchase additional equipment or are otherwise unable to meet customer demand, our business could suffer. Also, we are consolidating our manufacturing operations at our Manchester, Georgia location, and, prior to September 30, 2004, personnel at that location had essentially no experience in manufacturing our radiofrequency ablation disposable devices.

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

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will need to hire additional personnel and may need to purchase additional equipment. If we are unable to sufficiently staff and equip our manufacturing operations, particularly considering our plans to consolidate our manufacturing operations in our Manchester, Georgia location by the second quarter of 2005, or are otherwise unable to meet customer demand for our products, our business could suffer.

We will relocate our headquarters to a new facility in 2005. We will incur moving expenses, and if we become unable to meet customer demand through disruption of manufacturing operations, our business could suffer.

We are planning to relocate our headquarters facility in April 2005, and to complete transition of our manufacturing operations to our Manchester, Georgia location by that time. In so doing, we will incur normal and customary moving costs and may experience an interruption in our manufacturing operations. If we become unable to meet customer demand for our products, our business could suffer.

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

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

We are dependent on one supplier as our only source of an accessory device used in conjunction with our Starburst XLi and Xlie lines of disposable devices, and any disruption in the supply of this device could negatively affect our sales.

In the past, we have experienced shortages in the supply of accessory infusion pumps used in conjunction with our Starburst Xli and Starburst Xlie lines of disposable radiofrequency devices. We currently have one supplier for our accessory infusion pumps and, although we believe this supplier to be reliable, future disruptions in supply are possible. In that event, our business could suffer through lower sales or higher costs.

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

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

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

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

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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 RFA products have not received approval in Japan. Any failure to obtain necessary regulatory approvals for our new products in foreign countries could negatively affect revenues.

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

Unless we are exempt, we must obtain the appropriate FDA approval or clearance before we can sell a new medical device in the United States. Obtaining this approval or clearance can be a lengthy and time-consuming process. To date, all of our products have received clearances from the FDA through premarket notification under Section 510(k) of the Federal Food, Drug and Cosmetic Act. However, if the FDA requires us to submit a new premarket notification under Section 510(k) for modifications to our existing products, or if the FDA requires us to go through a lengthier, more rigorous examination than we now expect, our product introductions or modifications could be delayed or canceled which could cause our revenues to be below expectations. The FDA may determine that future products will require the more costly, lengthy and uncertain premarket approval process. In addition, modifications to medical device products cleared via the 510(k) process may require a new 510(k) submission. We have, in the past, made minor modifications to the RITA system and to our implantable vascular products. 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 or our implantable vascular products until the FDA has cleared new 510(k) submissions for these modifications, or it may require us to recall previously sold products. In addition, we intend to request additional label indications, such as approvals or clearances for the ablation of tumors in additional organs, including lung, uterus and breast, for our current products. The FDA may either deny these requests outright, require additional extensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of approval or clearance. Therefore, obtaining necessary approvals or clearances for these additional applications could be an expensive and lengthy process. In addition, in the course of the FDA process leading to clearance or approval for a new indication, the FDA may request an advisory panel meeting or meetings to discuss the clinical data, the appropriate study design or other criteria for clearance or approval. In the event that the advisory panel advises FDA that the clinical data are inadequate or the study design or other criteria are inappropriate, and the FDA concurs, the FDA clearance or approval process could be lengthened and anticipated revenues from that new indication would be delayed.

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

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

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

assumption of liabilities of the acquired company.

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

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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. Failure to obtain sufficient funds on acceptable terms when needed or to make timely debt payments may require us to curtail operations, perhaps to a significant extent.

Our executive officers and directors could exert significant influence over matters requiring stockholder approval.

Our executive officers and directors, and their respective affiliates, own approximately 4% of our outstanding common stock as of January 31, 2005. These stockholders may, as a practical matter, be able to exert significant influence over matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. This concentration of voting stock could have the effect of delaying or preventing a merger or acquisition or other change of control that a stockholder may consider favorable.

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

Our exposure to interest rate risk at December 31, 2004 and December 31, 2003 is related to our investment portfolio. We had no interest rate sensitive borrowings as of December 31, 2004 or December 31, 2003, although as of December 31, 2004, we have borrowings with interest rates that will increase by fixed amounts as of certain dates during 2005. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. Floating rate investments may produce less income than expected if interest rates fall, and floating rate borrowings, should we acquire any, will lead to additional interest expense if interest rates increase. Due in part to these factors, our future investment income may fall short of expectations, and our interest expense may be above our expectations. Further, we may suffer losses in investment principal if we are forced to sell securities that have declined in market value due to changes in interest rates.

We invest our excess cash in debt instruments of the United States government and its agencies and in high quality corporate issuers. The average contractual duration of our investments in 2004 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.

Our outstanding long-term debt is fixed rate and not subject to rate fluctuation, although our Senior Notes feature scheduled rate increases in January and July of 2005. The fair value of our debt will increase or decrease as interest rates decrease or increase, respectively.

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

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Item 8. Consolidated Financial Statements and Supplementary Data.

RITA Medical Systems, Inc.

Index to Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm on Financial Statements

To the Stockholders and Board of Directors

of RITA Medical Systems, Inc.:

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of RITA Medical Systems, Inc. and its subsidiaries at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 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 the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 28, 2005

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RITA MEDICAL SYSTEMS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2004	**2003**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,978	$ 3,780
Marketable securities	880	4,822
Accounts and note receivable, net of allowance for doubtful accounts and sales returns of $1,237 at December 31, 2004 and $1,117 at December 31, 2003	6,410	2,990
Inventories	7,126	2,192
Prepaid and other current assets	792	1,028
Total current assets	28,186	14,812
Long term marketable securities.		933
Long term note receivable, net of collection allowance of $61 at December 31, 2004 and $45 at December 31, 2003	177	338
Property and equipment, net	1,966	1,089
Goodwill	91,339	
Intangible assets	30,600	4,814
Other assets	41	47
Total assets	$ 152,309	$ 22,033
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,572	$ 1,124
Accrued liabilities	4,159	1,802
Current portion of long term debt	7,200	
Total current liabilities	13,931	2,926
Long term debt, net of current portion	9,632	
Other long term liabilities	90	23
Total liabilities	23,653	2,949
Commitments and contingencies (Note 5)		
Stockholders equity:		
Preferred stock, $0.001 par value:		
Authorized: 2,000 shares at December 31, 2004		
Issued and outstanding: No shares at December 31, 2004 and 2003		
Common stock, $0.001 par value:		
Authorized: 150,000 shares at December 31, 2004		
Issued and outstanding: 41,350 shares at December 31, 2004 and 17,975 shares at December 31, 2003	41	18

Additional paid-in capital	216,893	98,037
Accumulated other comprehensive income (loss)	(2)	2
Accumulated deficit	(88,276)	(78,973)
Total stockholders equity	128,656	19,084
Total liabilities and stockholders equity	$ 152,309	$ 22,033

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

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RITA MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share data)

	Years Ended December 31,		
	2004	2003	2002
Sales	$ 28,215	$ 16,607	$ 17,393
Cost of goods sold (including stock-based employee compensation of $42 in 2002)	11,200	6,166	6,908
Gross profit	17,015	10,441	10,485
Operating expenses:			
Research and development (including stock-based employee compensation of $216 in 2002)	3,787	4,294	5,052
Selling, general and administrative (including stock-based employee compensation of $26, $0 and $196 in 2004, 2003 and 2002, respectively)	20,637	17,418	19,366
Restructuring charges	1,309		
Total operating expenses	25,733	21,712	24,418
Loss from operations	(8,718)	(11,271)	(13,933)
Interest income	46	201	473
Interest expense	(604)		(12)
Other expense, net	(27)	(9)	(27)
Net loss	(9,303)	(11,079)	(13,499)
Other comprehensive loss:			
Change in unrealized loss on marketable securities	(4)	(5)	(63)
Comprehensive loss	$ (9,307)	$ (11,084)	$ (13,562)
Net loss per common share, basic and diluted	$ (0.35)	$ (0.63)	$ (0.91)
Shares used in computing net loss per common share, basic and diluted	26,465	17,647	14,890

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

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RITA MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands)

	Common Stock							
	Shares Issued	Amount	Additional Paid-in Capital	Deferred Stock-based Compensation	Stockholder Notes Receivable	Accumulated Other Compre-hensive Income	Accumulated Deficit	Total Stockholders Equity
Balances, December 31, 2001	14,591	$ 15	$ 88,459	$ (1,905)	$ (99)	$ 70	$ (54,395)	$ 32,145
Issuance of common stock	125		421					421
Stock options and warrants exercised	466		1,130					1,130
Cancellation of common stock	(27)		(15)		15			
Revaluation of common stock warrant			(19)					(19)
Deferred stock-based compensation			(1,451)	1,451				
Amortization of deferred stock-based compensation				454				454
Forgiveness of stockholder note receivable					34			34
Change in unrealized gain on marketable securities						(63)		(63)
Net loss							(13,499)	(13,499)
Balances, December 31, 2002	15,155	15	88,525		(50)	7	(67,894)	20,603
Issuance of common stock	2,126	2	8,605					8,607
Stock options exercised	714	1	1,028					1,029
Cancellation of common stock	(20)		(20)		20			
Revaluation of common stock warrant			(101)					(101)
Forgiveness of stockholder note receivable					30			30
Change in unrealized gain on marketable securities						(5)		(5)
Net loss							(11,079)	(11,079)
Balances, December 31, 2003	17,975	18	98,037			2	(78,973)	19,084
Issuance of common stock	4,427	5	11,285					11,290
Issuance of common stock in conjunction with acquisition	18,704	18	91,560					91,578
Issuance of stock options and warrants in conjunction with acquisition			15,322					15,322
Stock options exercised	244		546					546
Stock compensation expense			143					143
Change in unrealized gain on marketable securities						(4)		(4)
Net loss							(9,303)	(9,303)
Balances, December 31, 2004	41,350	$ 41	$ 216,893	$	$	$ (2)	$ (88,276)	$ 128,656

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

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RITA MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,		
	2004	2003	2002
Cash flows from operating activities:			
Net loss	$ (9,303)	$ (11,079)	$ (13,499)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	2,597	1,713	1,401
Loss on disposal of property and equipment	23	275	
Issuance and revaluation of common stock warrants for services received		(101)	(19)
Stock compensation expense	143		454
Allowance for doubtful accounts	(694)	(99)	865
Provision for obsolete inventories	40	551	670
Changes in operating assets and liabilities, net of assets and liabilities acquired:			
Accounts and note receivable	221	(190)	1,534
Inventories	742	778	(546)
Prepaid and other current assets	441	(33)	287
Accounts payable and accrued liabilities	236	(637)	66
Deferred maintenance revenue	(9)	23	
Net cash used in operating activities	(5,563)	(8,799)	(8,787)
Cash flows from investing activities:			
Purchase of property and equipment	(662)	(1,003)	(893)
Purchases of marketable securities	(698)	(12,787)	(1,604)
Sales and maturities of marketable securities	5,568	15,424	11,684
Net cash used in acquisition of Horizon Medical Products, Inc.	(1,150)		
Capitalization of patent litigation costs		(621)	(1,802)
Acquisition of intangibles		(2,650)	
Note receivable, other assets and other long term liabilities	150	142	(516)
Net cash provided by (used in) investing activities	3,208	(1,495)	6,869
Cash flows from financing activities:			
Principle payments on debt	(283)		
Proceeds from issuance of common stock, net of issuance costs	11,836	9,636	1,551
Payments on capital lease obligations			(192)
Net cash provided by financing activities	11,553	9,636	1,359
Net increase (decrease) in cash and cash equivalents	9,198	(658)	(559)
Cash and cash equivalents at beginning of year	3,780	4,438	4,997
Cash and cash equivalents at end of year	$ 12,978	$ 3,780	$ 4,438

Supplemental disclosures of cash flow information:			
Cash paid for taxes	$ 39	$ 9	$ 27
Cash paid for interest	$ 572	$	$ 12
Supplemental disclosure of non-cash investing and financing activities:			
Non-cash net assets acquired in acquisition	$ 16,712	$	$

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

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: FORMATION AND BUSINESS OF THE COMPANY

RITA Medical Systems, Inc. (the Company) was incorporated in January 1994. The Company is engaged in developing, manufacturing and marketing innovative products that use radiofrequency energy to treat patients with solid cancerous or benign tumors. On July 29, 2004, the Company completed a merger with Horizon Medical Products, Inc. (Horizon). From that date, the Company has also been engaged in the manufacture and marketing of specialty access catheters. The Company s products include radiofrequency generators, disposable needle electrode devices that deliver controlled thermal energy to targeted tissue, implantable ports, venous catheters, stem cell catheters and kidney dialysis catheters.

NOTE 2: BUSINESS COMBINATION

On July 29, 2004, the Company merged with Horizon in a transaction accounted for under the purchase method of accounting. The combined companies will continue to operate under the name RITA Medical Systems, Inc. The merger was pursued and completed because the management groups and stockholders of each company believe the combined entity will achieve higher sales and profitability than either or both of the pre-merger companies on a stand-alone basis. These factors contributed to a purchase price in excess of the fair value of Horizon s net tangible and intangible assets acquired and, as a result, the Company has recorded goodwill in connection with this transaction.

Each Horizon common stockholder received 0.4212 of a share of the Company s common stock for each share of Horizon common stock held. The Company 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 the Company s common stock. The fair value of shares issued by the Company was approximately $91.6 million based on a price per share of $4.896, the Company s 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 assumed by the Company was determined to be approximately $15.3 million using the Black-Scholes valuation model. Costs incurred to effect the merger 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.

The allocation of purchase price was as follows (in thousands):

Current assets	$ 10,666
Property and equipment	1,312
Intangible assets	27,309
Goodwill	91,339
Other assets	6
Current liabilities	(11,337)

Debt	(9,928)
Other long term liabilities	(81)
Purchase consideration	$ 109,286

The merger was completed on July 29, 2004 and none of Horizon s results of operations prior to that date are included in the Company s condensed consolidated statements of operations for the twelve months ended December 31, 2004. However, the Company has prepared pro forma financial information showing sales and net loss for the combined entity for the years ended December 31, 2004, 2003 and 2002, respectively, as if the

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

merger occurred as of the beginning of those periods. This unaudited pro forma financial information is not intended to represent or be indicative of the consolidated results of operations of the Company that would have been reported had the acquisition been completed as of the dates presented and should not be taken as representative of the future consolidated results of operations or financial condition of the Company (in thousands, except per share amounts):

	Years ended December 31,		
	2004	2003	2002
		Unaudited	
Sales	$ 44,079	$ 44,582	$ 39,105
Net loss	$ (13,853)	$ (12,748)	$ (40,640)
Net loss per common share, basic and diluted	$ (0.37)	$ (0.35)	$ (1.21)

Restructuring costs of $1,309,000, consisting entirely of severance related to the termination of employees to eliminate certain duplicative activities, were incurred in the year ended December 31, 2004 (see Note 12, Restructuring).

NOTE 3: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

Liquidity

As of December 31, 2004, the Company s total assets were $152.3 million, total liabilities were $23.7 million, working capital was $14.3 million and cash, cash equivalents and marketable securities totaled $13.9 million. Current and anticipated demand for the Company s products as well as procurement and production affect the need for capital. Changes in these or other factors could have a material impact on capital requirements and may require the Company to raise additional capital. While the Company believes that its existing cash resources, including marketable securities, will be sufficient to fund its operating needs for the next twelve months, additional financing may be required for the Company s currently envisioned long term needs. If the Company needs to raise additional financing, it will seek to sell additional equity or debt securities, obtain an additional credit facility or renegotiate debt repayment terms. There can be no assurance that any additional financing will be available

on terms acceptable to the Company, or at all. In addition, future equity financings could result in dilution to shareholders, and future debt financings could result in certain financial and operational restrictions. Failure to obtain sufficient funds on acceptable terms when needed, to make timely debt payments, or to achieve our growth or profitability objectives may require us to curtail operations, perhaps to a significant extent.

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include those required in the assessment of allowances for sales returns, doubtful accounts and for potentially excess and obsolete inventory. Actual results could differ from those estimates.

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Concentration of credit risk and other risks and uncertainties

The Company s products include components subject to rapid technological change. Certain components used in the manufacture of some of our products have relatively few alternative sources of supply and establishing additional or replacement suppliers for such components cannot be accomplished quickly. The Company has been constrained by supply issues in the past, but was not affected by supply constraints as of December 31, 2004. While the Company has ongoing programs to minimize the adverse effect of such changes and considers technological change in estimating its reserves, such estimates could change in the future.

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, marketable securities, accounts receivable and notes receivable. Cash and cash equivalents are deposited in demand and money market accounts in four financial institutions in the United States, one financial institution in the Netherlands and one financial institution in France. Deposits held with financial institutions may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses on its deposits of cash, cash equivalents or marketable securities.

The Company extends credit to its customers, which are primarily comprised of accounts of private companies in the United States, Europe and Asia. The Company performs ongoing credit evaluations of its customers financial conditions and generally requires no collateral. The Company maintains an allowance for doubtful accounts receivable and/or notes receivable based on the expected collectibility of individual accounts. For the year ended December 31, 2004, the Company increased its allowance for doubtful accounts by approximately $1,436,000, the amount of Horizon s allowance for doubtful accounts as of the merger date of July 29, 2004. Subsequently, the Company reduced its allowance for doubtful accounts by approximately $694,000 due to collections of previously reserved amounts. For the year ended December 31, 2003, the Company reduced its allowance for doubtful accounts by approximately $99,000. For the year ended December 31, 2002 a provision of $902,000 was made to the allowance for doubtful accounts. Charges against the allowance were approximately $606,000, $233,000 and $37,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Reclassifications

Certain prior year balances have been reclassified to conform to current year presentation. In the Company s annual reports for the year ended December 31, 2003 and all prior years, investments in variable rate debt obligations featuring interest rate reset intervals of less than 90 days were classified as cash equivalents. In the current year, such investments have been reclassified as current marketable securities in the Company s Consolidated Balance Sheets as of December 31, 2003. Also, the Company s Consolidated Statements of Cash Flows for the years ended December 31, 2003 and 2002 have been modified from past presentation to give effect to purchases and sales or maturities of such securities in the determination of net cash provided by (used in) investing activities. For the year ended December 31, 2003, net cash used in investing activities decreased by $1,650,000. For the year ended December 31, 2002, net cash provided by investing activities decreased by $150,000. The Company s Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2004, 2003 and 2002 were not affected by this reclassification.

Cash and cash equivalents

All highly liquid investments with original maturities of ninety days or less from the date of purchase, if not restricted, are considered to be cash equivalents. The Company has classified approximately $87,000 and $117,000 in restricted cash accounts as other current assets as of December 31, 2004 and 2003, respectively.

Marketable securities

The Company s marketable securities are categorized as available-for-sale. Marketable securities with original maturities greater than three months and remaining maturities of no more than one year are classified as

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

short-term investments. Also, the Company s holdings of investment grade variable debt obligations, which are asset-backed and categorized as available-for sale, are classified as short-term investments. The Company s investments in these variable rate securities are recorded at cost, which approximates fair value because the periodic reset of their interest rates eliminates or greatly reduces realized or unrealized holding gains or losses on such securities. Further, variable rate securities are highly liquid despite the long term nature of the stated contractual maturities. Marketable securities with remaining maturities greater than one year are classified as long-term investments. Unrealized holding gains and losses are reflected as a net amount in a separate component of stockholders equity until realized. For the purpose of computing realized gains and losses, cost is identified on a specific identification basis.

Fair Value of Financial Instruments

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

Inventories

Inventories are stated at lower of cost or market value. Cost is determined using standard cost, which approximates actual costs on a first-in, first-out basis. Market value is determined as the lower of replacement cost or net realizable value. The Company records provisions to write down its inventory for estimated obsolescence or unmarketable inventory equal to the difference between the cost of the inventory and its estimated market value based upon assumptions about future market demand and market conditions. If future demand or market conditions are less favorable than currently expected, additional inventory provisions may be required. For the year ended December 31, 2004, the Company increased its reserve for excess and obsolete inventory by approximately $1,693,000, the amount of Horizon s reserve for excess and obsolete inventory as of the merger date of July 29, 2004. Provisions to the reserve for excess and obsolete inventory were approximately $40,000, $551,000 and $733,000 for the years ended December 31, 2004, 2003 and 2002, respectively. Charges against the reserve were approximately $1,043,000, $277,000 and $63,000 for the years ended December 31, 2004, 2003 and 2002, respectively, as a result of disposals of the related inventory.

Property and Equipment

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

Machinery and equipment	1 to 5 years

Computers and software	3 to 5 years
Furniture and fixtures	5 years

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

Long-lived assets

The Company periodically assesses the impairment of its long-lived assets, including its intangible assets, in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. An impairment review is performed whenever events or

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

changes in circumstances indicate that the carrying value of the Company s long-lived assets may not be recoverable. Indicators which could trigger an impairment review include, but are not limited to, significant underperformance relative to past or planned operating results, significant changes in the strategy for the overall business, significant negative industry trends and/or a significant decline in the stock price of the Company for a sustained period of time. When it is determined, based on one or more of these indicators, that the carrying value of the Company s long-lived assets may not be recoverable, the impairment is measured using the projected discounted cash flow method and charged to operations.

Intangible assets and Goodwill

All of the Company s intangible assets are amortized using the straight-line method. The amortization periods of our intangible assets as of December 31, 2004 are as follows:

Capitalized patent defense litigation costs	9	years
Capitalized patent license agreements	5-10	years
Customer relationships	15	years
Product technology	12	years
Trademarks	10	years
Isomed distribution contract	4	years
Loan closing costs	7	months
Non-compete contracts	1	month

The Company s merger with Horizon resulted in goodwill, the excess of purchase price over the fair value of assets acquired, of $91.3 million. The Company accounts for goodwill under 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 the Company s case, operating in one business segment, the fair value of the reporting unit is equal to 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. The Company tests 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. No impairment of goodwill has been determined to exist as of December 31, 2004.

Revenue recognition

Product-related 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 reasonably assured. This policy is applied to all the Company s customers.

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. A provision for returns is made in the period that the related sales are recorded as a reduction against revenue. Revenue related to service contracts is deferred and recognized ratably over the terms of underlying contracts. Service contract terms range from 12 to 36 months.

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Research and Development

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

Advertising

Advertising production costs are expensed as incurred. Media for print placement costs are expensed in the period the advertising appears. Total advertising and promotional expenses were approximately $85,000, $71,000 and $119,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Income Taxes

Income taxes are accounted for using the liability method under which deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

Accounting for stock-based compensation

During the year ended December 31, 2002, the Company adopted SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. The Company accounts for stock-based employee compensation arrangements in accordance with provisions of Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees. Financial Accounting Standards Board Interpretations (FIN) No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans and complies with the disclosure provisions of SFAS No. 123, Accounting for Stock-Based Compensation.

Under APB Opinion No. 25, compensation expense is based on the difference, if any, on the date of the grant between the fair value of the Company s common stock and an option s exercise price. SFAS No. 123 defines a fair value based method of accounting for an employee stock option or similar equity instruments.

The following table illustrates the effect on net loss and net loss per common share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation (in thousands, except per share amounts):

	Years ended December 31,		
	2004	2003	2002
Net loss, as reported	$ (9,303)	$ (11,079)	$ (13,499)
Add: Stock-based employee compensation expense included in reported net loss	26		454
Deduct: Total stock-based employee compensation determined under fair value based method for all awards	(2,021)	(1,914)	(2,274)
Pro forma net loss.	$ (11,298)	$ (12,993)	$ 15,319
Basic and diluted net loss per common share:			
As reported	$ (0.35)	$ (0.63)	$ (0.91)
Pro forma	$ (0.43)	$ (0.74)	$ (1.03)

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

This determination of pro forma net loss and pro forma net loss per common share utilizes the weighted average per share fair values of options granted during 2004, 2003 and 2002, which were $2.47, $1.87 and $4.10 respectively. The value of each option grant was estimated on the date of grant using the Black-Scholes valuation model with the following weighted average assumptions:

	Years ended December 31,		
	2004	2003	2002
Volatility	78%	75%	79%
Risk-free interest rate	3.55%	3.16%	3.93%
Expected life	5 years	5 years	5 years
Expected dividends	0%	0%	0%

The corresponding assumptions for the 2000 Employee Stock Purchase Plan were as follows:

	Years ended December 31,		
	2004	2003	2002
Volatility	60%	70%	79%
Risk-free interest rate	1.10%	2.95%	3.29%
Expected life	0.7 years	1.3 years	0.7 years
Expected dividends	0%	0%	0%

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

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force (EITF) Issue No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Under EITF Issue No. 96-18, the fair value of the equity instrument is calculated using the Black-Scholes valuation model each reporting period with charges amortized to the results of operations over the instrument s vesting period.

Net loss per share

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

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

	Years ended December 31,		
	2004	**2003**	**2002**
Net loss, basic and diluted	$ (9,303)	$ 11,079	$ 13,499
Weighted-average shares of common stock outstanding	26,465	17,651	14,923
Less: weighted-average shares subject to repurchase		4	33
Weighted-average shares used in basic and diluted net loss per common share	26,465	17,647	14,890

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	December 31,		
	2004	2003	2002
Effect of potential common stock:			
Unvested common stock subject to repurchase			28
Options outstanding	7,273	2,675	2,725
Warrants outstanding	3,350	25	25
Total potential common stock excluded from the computation of earnings per common share	10,623	2,700	2,778

Recent accounting pronouncements

In March 2004, the FASB issued EITF Issue No. 03-1 (EITF 03-1), The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments which provides new guidance for assessing impairment losses on investments. Additionally, EITF 03-1 includes new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB delayed the accounting provisions of EITF 03-1; however, the disclosure requirements remain effective for annual periods ending after June 15, 2004. The Company will evaluate the impact of EITF 03-1 once the final guidance is issued.

In November 2004, the Financial Accounting Standards Board issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning in the second quarter of fiscal 2006. The Company does not believe the adoption of SFAS No. 151 will have a material effect on its consolidated financial position, results of operations or cash flows.

In December 2004, the Financial Accounting Standards Board issued Statement of Accounting Standards (SFAS) No. 123R, Share-Based Payment , which replaces SFAS No. 123. SFAS No. 123R requires public companies to recognize an expense for share-based payment arrangements including stock options and employee stock purchase plans. The statement eliminates a company s ability to account for share-based compensation transactions using APB 25, and generally requires instead that such transactions be accounted for using a fair- value based method. SFAS No. 123R requires an entity to measure the cost of employee services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant, and to recognize the cost over the period during which the employee is required to provide service in exchange for the award. SFAS No. 123R is effective for the Company in the quarter ending September 30, 2005. Upon adoption of SFAS 123R, companies are allowed to select one of three alternative transition methods, each of which has different financial reporting implications. Management is currently evaluating the transition methods, valuation methodologies and other assumptions for employee stock options in light of SFAS No. 123R. Current estimates of option values using the Black-Scholes method may not be indicative of results

from valuation methodologies ultimately implemented the Company upon adoption of SFAS No. 123R. Although the Company has not yet fully quantified the impact this standard will have on its financial statements, it is likely that the adoption of SFAS No. 123R will have a material impact on the Company s financial position and results of operations.

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 4: BALANCE SHEET COMPONENTS

Marketable securities (in thousands):

The cost and fair value of available-for-sale securities at December 31, 2004 were as follows:

Short term marketable securities	Cost Value	Unrealized Gain	Fair Value
Corporate notes	$ 507	$ (1)	$ 506
United States government agency notes	375	(1)	374
	$ 882	$ (2)	$ 880

The cost and fair value of available-for-sale securities at December 31, 2003 were as follows:

Short term marketable securities	Cost Value	Unrealized Gain	Fair Value
Corporate notes	$ 2,221	$	$ 2,221
United States government agency notes	1,000	1	1,001
Market auction preferred	1,600		1,600
	$ 4,821	$ 1	$ 4,822

Long term marketable securities	Cost Value	Unrealized Gain	Fair Value
Corporate notes (maturing in 2005)	$ 539	$ 2	$ 541
United States government agency notes (maturing in 2005)	393	(1)	392
	$ 932	$ 1	$ 933

Inventories (in thousands):

	December 31,	
	2004	**2003**
Raw materials	$ 2,776	$ 719
Work in progress	682	214
Finished goods	3,668	1,259
	$ 7,126	$ 2,192

Property and equipment, net (in thousands):

	December 31,	
	2004	**2003**
Computer equipment and software	$ 1,464	$ 1,202
Furniture and fixtures	413	195
Leasehold improvements	1,289	794
Machinery and equipment	5,223	4,261
	8,389	6,452
Less: accumulated depreciation and amortization	(6,423)	(5,363)
	$ 1,966	$ 1,089

Depreciation expense was approximately $1,074,000, $1,203,000 and $1,262,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Intangible assets (in thousands):

	December 31, 2004			December 31, 2003		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Capitalized patent defense litigation costs	$ 2,755	$ (593)	$ 2,162	$ 2,755	$ (351)	$ 2,404
Capitalized patent license agreements	2,650	(561)	2,089	2,650	(240)	2,410
Intangible assets recorded at merger with Horizon:						
Customer relationships	16,600	(461)	16,139			
Product technology	6,900	(239)	6,661			
Trademarks	3,000	(125)	2,875			
Isomed distribution contract	700	(73)	627			
Loan closing costs	73	(32)	41			
Non-compete contracts	36	(30)	6			
	$ 32,714	$ (2,114)	$ 30,600	$ 5,405	$ (591)	$ 4,814

The capitalized patent defense litigation costs relate to the Company s suit against RadioTherapeutics, a division of Boston Scientific Corporation. This suit was settled in April 2003 and no additional costs have been capitalized since that date.

The capitalized patent license agreements relate to the settlement of the Company s suit against RadioTherapeutics and of suits brought against the Company by Boston Scientific Corporation and several related parties. In April 2003, the Company capitalized $2,650,000 in payments made to acquire patent license agreements from Boston Scientific and the other opposing litigants.

Intangible assets acquired at fair value in the merger with Horizon include unamortized loan closing costs related to a debt repayment date extension negotiated by Horizon in March 2003, and unamortized costs of a non-compete agreement to which the Company acquired rights. The Company carries these intangible assets at their acquired fair value less accumulated amortization.

Valuation of the fair value of Horizon s net assets resulted in assignment of a portion of the purchase price to intangible assets related to acquired trademarks, product technology, customer relationships and a distribution contract. The Company carries these assets at their fair value as of the acquisition date of July 29, 2004, less accumulated amortization.

Aggregate amortization expense for the year ended December 31, 2004, and estimated amortization expense for each of the five years ended December 31, 2005 through 2009 is as follows (in thousands):

Aggregate amortization expense:	
For the twelve months ended December 31, 2004	$ 1,523
Estimated amortization expense:	
For the twelve months ended December 31, 2005	$ 2,744
For the twelve months ended December 31, 2006	$ 2,738
For the twelve months ended December 31, 2007	$ 2,723
For the twelve months ended December 31, 2008	$ 2,647
For the twelve months ended December 31, 2009	$ 2,457

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accrued liabilities (in thousands):

	December 31,	
	2004	**2003**
Payroll and related expenses	$ 2,170	$ 687
Accrued vacation	280	226
Accrued legal and audit expenses	491	183
Accrued sales and franchise taxes	403	41
Other accrued liabilities	815	665
	$ 4,159	$ 1,802

Deferred maintenance revenue (in thousands):

Revenue for maintenance contracts is recognized on a pro-rata basis over the period of the applicable maintenance contract, ranging from 12 to 36 months. Costs are recognized as incurred. Changes in the Company s deferred maintenance revenue during the year ended December 31, 2004 were as follows:

	December 31,	
	2004	**2003**
Balance, beginning of year	$ 45	$
Add: maintenance contract billings	15	48
Less: Revenue recognized	(30)	(3)
Balance, end of year	30	45
Less: current portion	(16)	(22)
Deferred maintenance revenue, less current portion	$ 14	$ 23

For the years ended December 31, 2004 and 2003, the current portion of deferred maintenance revenue is included in accrued liabilities and the long-term portion of deferred maintenance revenue is included in other long-term liabilities.

Debt

As part of the merger with Horizon, the Company assumed the following debts:

Senior Subordinated Convertible Notes (the Senior Notes) were originally issued by Horizon in March 2002. At July 29, 2004, the date of the Horizon merger, $14,763,000 of the Senior Notes remained due. As of December 31, 2004, the same $14,763,000 was due under the Senior Notes. Of this amount, $6,501,000 was to have come due in July 2005, but was prepaid in February 2005. The balance of $8,262,000 will come due in July 2008. The Senior Notes bear interest, payable quarterly, at 6.0% per annum. As of December 31, 2004, the interest rate on the Senior Notes will increased to 8% per annum on January 29, 2005 and will increase to 14% per annum on July 29, 2005. The Company may prepay the Senior Notes without a penalty prior to their respective maturity dates. See Note 13 Subsequent Events for Further Discussion on the Senior Notes.

A Junior Promissory Note (the Junior Note) payable to a major financial institution was originally executed by Horizon in April 2002. At July 29, 2004, the date of the Horizon merger, $1,640,000 of the Junior Note remained due. At December 31, 2004, $1,527,500 was due under the Junior Note. The Junior Note bears interest at a rate of 6% per annum, is payable monthly and matures in March 2007. The monthly principal payment is $22,500 until maturity at which time a balloon payment of $920,000 is due.

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A note payable for the Stepic business purchase (the Stepic Note) was executed by Horizon in 1998. At July 29, 2004, the date of the Horizon merger, $710,542 of the Stepic Note remained due. At December 31, 2004, $541,658 was due under the Stepic Note. The Stepic Note bears interest at 8% and calls for monthly interest and principal payments of approximately $38,000. The Stepic Note is scheduled to be fully repaid in March 2006.

None of the Company s note agreements are collateralized. The principal covenants of the note agreements relate to events of default which include, but are not limited to, failure to pay an obligation when due, breach of any covenant which remains uncured for 15 days, bankruptcy and a change of control. Generally, upon an event of default, the holders of a majority of the aggregate principal amount of the notes outstanding may declare the unpaid principal and interest on the notes immediately due and payable.

Future maturities of debt outstanding as of December 31, 2004 are as follows (in thousands):

	Outstanding as of December 31, 2004	Amounts due in the years ended December 31, 2005	2006	2007	2008
Senior Notes	$ 14,763	$ 6,501	$	$	$ 8,262
Junior Note	1,528	270	270	988	
Stepic Note	541	429	112		
Total	$ 16,832	$ 7,200	$ 382	$ 988	$ 8,262

NOTE 5: COMMITMENTS AND CONTINGENCIES

Litigation

The Company is now and may in the future become involved in litigation relating to claims arising from the ordinary course of business. Management is not currently aware of any matters that will have a material adverse effect on the financial position, results of operations or cash flows of the Company.

Operating Leases

As of December 31, 2004, the Company had commitments under operating leases for its facilities in Mountain View, California, Manchester, Georgia and Atlanta, Georgia, as well as for office and other equipment. All of the facility leases are non-cancelable. The leases pertaining to the Manchester, Georgia facility expire in 2010. The lease pertaining to the Atlanta, Georgia facility expires in 2007. The lease on the Company s office facility in Mountain View, California expires in April 2005. During the first quarter of 2005, the Company leased office space in Fremont, California (See Note 13, Subsequent Events). The lease on the Fremont, California facility is also non-cancelable and expires in 2010. Rent expense was approximately $597,000, $539,000 and $529,000 for the years ended December 31, 2004, 2003 and 2002 respectively.

Future minimum payments under operating leases, including the new lease on the Fremont, California facility, are as follows (in thousands):

Year ending December 31, 2005	$ 461
Year ending December 31, 2006	361
Year ending December 31, 2007	339
Year ending December 31, 2008	304
Year ending December 31, 2009	308
Year ending December 31, 2010 and thereafter	116
Total of future minimum operating lease payments	$ 1,889

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 6: STOCKHOLDERS EQUITY

Private placement of common shares

As part of the November 24, 2004, Stock and Warrant Purchase Agreements, the Company 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.

In January of 2003, the Company issued 2,045,453 shares of unregistered common stock at a price of $4.40 per share, netting approximately $8.3 million after issuance fees and expenses. The issuance was deemed to be exempt from registration under the Securities Act.

Warrants

In December 2001, the Company issued a warrant to BEKL Corporation under the terms of a clinical data and patent license agreement. The warrant is exercisable for 25,000 shares of the Company s common stock at a price of $6.10 per share and expires in 2006. Its aggregate fair value of approximately $110,000 was charged to operations in 2001. Fair value was determined using the Black-Scholes valuation model.

On July 29, 2004, the Company completed its merger with Horizon. Under the terms of the merger agreement, the Company assumed 125,000 Horizon warrants, which were converted into warrants exercisable for 52,650 shares of the Company s common stock at an average price of $2.11 per share. In 2005, 21,060 of these warrants will expire. Another 21,060 will expire in 2006, and the remaining 10,530 will expire in 2011. Their aggregate fair value of approximately $201,000 was recorded as part of the purchase price described in Note 2, Business Combination. Fair value was determined using the Black-Scholes valuation model.

As part of the November 24, 2004 Stock and Warrant Purchase Agreements, the Company issued warrants to purchase an aggregate of 3,272,724 shares of its common stock. The warrants have an initial exercise price of $4.00 per share and expire on November 24, 2009. The warrants provide for adjustment of the number and kind of securities purchasable upon exercise of the warrants, as well as for adjustment of the per share exercise price, upon the occurrence of certain specified events. These specified events include, without limitation, the payment by the Company of a dividend or a distribution on its common stock in shares of common stock, the consolidation or merger of the Company with another entity in which the Company is not the surviving entity, and the recapitalization, reclassification or reorganization of the capital stock of the Company. The warrants also contain an anti-dilution adjustment provision which provides for an adjustment in the per share exercise price in the event that the Company issues and sells shares of its common stock for per share consideration that is less than the exercise price then in effect, subject to customary limitations and exclusions, but in no event will the per share exercise price for the warrant be adjusted to less than

$3.23.

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 7: STOCK OPTIONS

1994 Incentive Stock Plan, 1998 Incentive Stock Plan, 2000 Director s Stock Option Plan and 2000 Stock Plan

Under the 1994 Incentive Stock Plan, options were granted to employees and non-employees at prices determined by the board of directors to be not lower than 85% of the fair market value of the common stock for non-statutory stock options or 100% of the fair market value of the common stock for incentive stock options. For individuals who at the time of grant owned stock representing more than 10% of the voting power of all classes of outstanding stock, options were granted at prices not lower than 110% of the fair value of the common stock for both non-statutory and incentive stock options. Options granted under this plan become exercisable and vest on a cumulative basis at the discretion of the board of directors and generally expire ten years from the date of grant. The average vesting period of options granted under this plan has been approximately 4 years. The Company s board of directors has determined that no future grants will be made under this plan.

Under the 2000 Director s Stock Option Plan, shares of common stock have been reserved for issuance to non-employee directors. Option grants have been and will continue to be made at the fair market value of the common stock on the date of the grant. Options granted under this plan become exercisable, vest on a cumulative basis and generally expire ten years from the date of grant. The average vesting period of options granted under this plan has been approximately 2 years.

The 1998 Incentive Stock Plan was assumed by the Company effective with its merger with Horizon. Options granted under this plan became fully vested immediately prior to the merger, and will generally expire ten years from the original date of grant. The Company s board of directors has determined that no future grants will be made under this plan.

The 2000 Stock Plan provides for the grant of incentive stock options to employees and non-statutory stock options and stock purchase rights to employees, directors and consultants. A total of 2,000,000 common shares were originally available for issuance under this plan at its inception in 2000. A total of 810,292 common shares were available for issuance as of December 31, 2004. Future increases to the shares available for issuance will occur on the first day of each fiscal year through 2010 in the amount of the lesser of 1,000,000 shares, 7% of the Company s outstanding common stock on the last day of the preceding fiscal year or a lower number as determined by the board of directors. Incentive stock options granted under this plan must have an exercise price of at least 100% of the fair market value of the common stock on the date of the grant, and at least 110% of the fair market value of the common stock if the options are awarded to an employee who holds more than 10% of the total voting power of all classes of the Company s stock. Options granted under this plan become exercisable and vest on a cumulative basis at the discretion of the board of directors and generally expire ten years from the date of grant. The average vesting period of options granted under this plan has been approximately 4 years.

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Combined activity under these plans has been as follows (in thousands, except per share data):

		Options Outstanding		
	Shares Available	Shares	Aggregate Price	Weighted Average Exercise Price
Balances, December 31, 2001	1,466	2,657	$ 9,517	$ 3.58
Options granted	(868)	868	5,422	6.25
Options exercised		(435)	(1,053)	2.42
Options canceled	293	(365)	(1,857)	5.09
Balances, December 31, 2002	891	2,725	12,029	4.41
Shares reserved	1,000			
Options granted	(1,724)	1,724	5,118	2.97
Options exercised		(714)	(1,029)	1.44
Options canceled	1,001	(1,060)	(5,607)	5.29
Balances, December 31, 2003	1,168	2,675	10,511	3.93
Shares reserved	1,000			
Options assumed in merger		3,814	7,452	1.95
Options granted	(1,455)	1,455	4,909	3.37
Options exercised		(244)	(546)	2.24
Options canceled	391	(427)	(2,090)	4.89
Balances, December 31, 2004	1,104	7,273	$ 20,236	$ 2.78

Stock Options: Options outstanding and exercisable

Options outstanding, from all plans, and exercisable as of December 31, 2004 are as follows by exercise price ranges (in thousands, except per share data):

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average	Weighted-Average	Number Outstanding	Weighted-Average

		Remaining Contractual Life	Exercise Price		Exercise Price
$ 0.50 to $ 1.07	1,847	7.02 years	$ 1.06	1,848	$ 1.06
$ 1.19 to $ 1.94	678	3.09 years	$ 1.75	678	$ 1.75
$ 2.02 to $ 2.52	1,434	7.40 years	$ 2.35	915	$ 2.25
$ 2.59 to $ 3.07	853	8.96 years	$ 2.86	240	$ 2.81
$ 3.10 to $ 3.87	1,164	8.92 years	$ 3.28	231	$ 3.3
$ 3.92 to $ 6.75	1,117	7.59 years	$ 4.56	805	$ 4.56
$ 8.02 to $34.73	180	4.92 years	$ 13.18	171	$ 13.36
	7,273	7.30 years	$ 2.78	4,888	$ 2.58

At December 31, 2003, the Company had 2,675,000 options outstanding at a weighted average exercise price of $3.93 and 740,000 options outstanding and exercisable at a weighted average exercise price of $5.36.

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2000 Employee Stock Purchase Plan

The Company s 2000 employee stock purchase plan was adopted in the second quarter of 2000. A total of 650,000 common shares were initially reserved for issuance under this plan. Automatic increases occurred on the first day of 2002, 2003 and 2004, and will occur on the first day of each year until 2010, in amounts equal to the lesser of 650,000 shares, 4% of the Company s outstanding common stock on the last day of the preceding year, or such lesser number that board of directors determines. This plan permits employees to purchase common shares at a price equal to the lower of 85% of the fair market value of the common stock at the beginning of each offering period or the end of each offering period. Employee purchases are nonetheless limited to 15% of eligible cash compensation, and other restrictions regarding the amount of annual purchases also apply. As of December 31, 2004, there have been 342,205 shares issued under this plan.

Stock-based compensation

During the years ended December 31, 2004, 2003 and 2002, the Company recorded approximately $26,000, $0 and $454,000, respectively, in employee stock compensation expense. The expense incurred in 2004 was due to modifications of employee stock options. This employee stock compensation expense was recognized over the vesting periods of the related options, generally four years. Option grants to a director in compensation for consulting services were made in 2004 and 2003. (See Note 9, Related Party Transactions). No option grants were made to non-employees in 2002.

NOTE 8: INCOME TAXES

No provisions for federal income taxes were recorded during the years ended December 31, 2004 and 2003, as the Company incurred net operating losses during these years.

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

	December 31,	
	2004	2003
Net operating loss carryforwards	$ 38,525	$ 23,771
Capitalized startup and research and development costs	1,371	909
Research and development credit	1,225	1,392

Other	2,466	2,546
Gross deferred tax assets	43,587	28,618
Deferred tax liability intangible assets	(10,478)	
Total deferred tax assets	33,109	28,618
Less: Valuation allowance	(33,109)	(28,618)
Net deferred tax assets	$	$

At December 31, 2004, the Company had federal and state net operating loss carryforwards of approximately $103.5 million and $56.6 million, respectively, available to offset future taxable income. The Company s federal and state operating loss carryforwards expire between 2008 and 2024 and between 2005 and 2014, respectively, if not utilized.

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. In the event the Company has a change in ownership, utilization of the carryforwards could be restricted.

Reconciliation of the statutory federal income tax to the Company s effective tax rate follows:

	2004	2003	2002
Tax at federal statutory rate	34.0 %	34.0 %	34.0 %
State, net of federal benefit	6.0 %	6.0 %	6.0 %
Other	0.0 %	0.0 %	1.0 %
Deferred tax assets not benefited	(39.0)%	(38.0)%	(39.0)%
Federal research and development credit	(1.0)%	(2.0)%	(2.0)%
Provision for taxes	0.0%	0.0%	0.0%

NOTE 9: RELATED PARTY TRANSACTIONS

In August 1994, the Company entered into a cross-license agreement (the Agreement) with VIDAMed (a company whose founder was also one of the founders of the Company) whereby the Company granted VIDAMed an exclusive royalty-free license to use the Company s technology for certain applications. In return, VIDAMed granted the Company an exclusive license to use VIDAMed s technology for certain applications. The Company was required to pay a royalty of 2.5% of net sales on products developed incorporating the VIDAMed technology. This obligation terminated in August 2004, with the Company having made no payments under this agreement. During 2002, VIDAMed was acquired by Medtronic, Inc.

During the years ended December 31, 2004, 2003 and 2002 the Company has received professional services relating to the administration of its clinical trials as well as regulatory advice from a firm in which one of the Company s directors serves as an officer. The Company has recognized expenses relating to the services received from this firm of approximately $14,000, $55,000 and $160,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

In April 2003, a member of the Company s Board of Directors began providing consulting services to the Company. In 2003, this board member was paid approximately $164,000 and was granted options to purchase 35,000 shares of the Company s common stock under his consulting agreement. In 2004, this board member was granted options to purchase an additional 10,000 shares of the Company s common stock in connection with his consulting services. The Company is recognizing the expense of all of the options granted to this board member for consulting services using the Black-Scholes valuation model; through December 31, 2004, this consulting expense totaled approximately $94,000.

NOTE 10: SEGMENT INFORMATION

As a result of the merger with Horizon, the Company expanded its customer base and portfolio of products, which resulted in two groups of medical oncology products: radiofrequency ablation (RFA) systems, which consist largely of products sold by the Company prior to the merger, and specialty access catheter products, which are the products sold by Horizon prior to the merger.

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the Company s chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company s chief operating decision maker reviews financial information on a consolidated basis, accompanied by disaggregated information about sales by groups of similar products for purposes of making operating decisions and assessing financial performance. However, significant expenses such as research and development and corporate administration are not allocated to product groups or geographical regions, but rather are employed by the entire enterprise. For this reason, the Company s chief operating decision maker evaluates resource allocation on an enterprise-wide basis, and not on a product or geographic basis. Accordingly, the Company has concluded that it operates in only one reportable segment, the medical oncology products business.

The following table presents sales information for the Company s two product groups for the years ended December 31, 2004, 2003 and 2002 (in thousands):

	Years Ended December 31,		
	2004	2003	2002
Sales:			
Radiofrequency ablation products	$ 17,553	$ 16,607	$ 17,393
Specialty access catheter products	10,662		
Total	$ 28,215	$ 16,607	$ 17,393

Sales for geographic regions reported below are based upon the customers locations. Following is a summary of the geographic information related to revenues and long-lived assets for the years ended December 31, 2004, 2003 and 2002 (in thousands):

	Years Ended December 31,		
	2004	2003	2002
Sales:			
United States	$ 23,612	$ 13,274	$ 12,898
Italy	883	726	789
Japan	437	535	2,331
Other	3,283	2,072	1,375
Total	$ 28,215	$ 16,607	$ 17,393

	Years Ended December 31,		
	2004	2003	2002
Long-lived assets:			
United States	$ 1,966	$ 1,089	$ 1,501
Europe			64
Total	$ 1,966	$ 1,089	$ 1,565

In the years ended December 31, 2004 and 2003, the Company had no customers accounting for 10% or more of its sales. In the year ended December 31, 2002, the Company had one customer that accounted for 14% of its sales. In the year ended December 31, 2004, the Company had no customers accounting for 10% or more of its outstanding accounts and notes receivable. In the year ended December 31, 2003, the Company had one customer that accounted for 12% of its outstanding accounts and notes receivable.

NOTE 11: EMPLOYEE BENEFIT PLAN

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

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RITA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 12: RESTRUCTURING

In the year ended December 31, 2004, in connection with the merger of RITA and Horizon, the Company recorded a restructuring charge of $1,309,000 related to the termination of employees to eliminate certain duplicative activities, primarily in the sales, accounting and operations areas. These charges were accounted for in accordance with SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. As of December 31, 2004, $707,000 of the severance amounts had been paid and $602,000 remained accrued. The Company expects to pay remaining accrued severance amounts by June 30, 2005.

NOTE 13: SUBSEQUENT EVENTS

Prepayment of debt

In February 2005, the Company paid $6,501,000 in principal, plus accrued interest, to some of our Senior Note holders. By agreement, ComVest Venture Partners, L.P. and Medtronic, Inc., the majority holders of our Senior Notes, did not receive any portion of this payment and the notes they hold remain outstanding. This $6,501,000 payment would otherwise have been due in July 2005.

Operating lease on office space in Fremont, California

In February 2005, the Company entered a non-cancelable operating lease on approximately 14,500 square feet of office space in Fremont, California. The lease term is from April 2005 through May 2010. Rent on the facility will be approximately $146,000 during the first year of the lease, with annual increases of approximately 3.4% in subsequent years; these amounts have been reflected in the Company s future minimum payments under operating leases as presented in Note 5, Commitments and Contingencies. The Company plans to use this facility as its corporate headquarters beginning in April 2005 and, as of that date, we expect that the Company s current headquarters location in Mountain View, California will be vacated. The lease on the Company s Mountain View, California facility expires in April 2005.

NOTE 14: QUARTERLY RESULTS OF OPERATIONS (UNAUDITED):

The following table sets forth selected items from the Company s consolidated statements of operations for each of the eight quarters ended December 31, 2004. This data has been derived from unaudited consolidated financial statements that, in the opinion of the Company s management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of such information when read in conjunction with our annual audited consolidated financial statements and notes thereto appearing elsewhere in this Form 10-K. The

operating results for any quarter are not necessarily indicative of results for any future period.

	Quarter Ended							
	Dec. 31, 2004	Sept. 30, 2004	June 30, 2004	Mar. 31, 2004	Dec. 31, 2003	Sept. 30, 2003	June 30, 2003	Mar. 31, 2003
Sales	$ 10,961	$ 7,951	$ 4,659	$ 4,644	$ 4,196	$ 3,865	$ 4,049	$ 4,497
Gross profit	5,867	5,130	2,989	3,029	2,559	2,612	2,347	2,923
Net loss	$ (1,872)(a)	$ (3,258)(a)	$ (2,003)	$ (2,170)	$ (2,241)	$ (2,514)	$ (3,400)	$ (2,924)
Net loss per common share, basic and diluted	$ (0.05)	$ (0.10)	$ (0.11)	$ (0.12)	$ (0.12)	$ (0.14)	$ (0.19)	$ (0.17)
Shares used in computing net loss per common share, basic and diluted	38,574	31,079	18,025	17,998	17,971	17,807	17,578	17,223

(a) Net loss during the quarters ended December 31, 2004 and September 30, 2004 include restructuring charges of $220 and $1,089, respectively. Restructuring charges are discussed in Note 12, Restructuring.

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

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in the Company s Securities Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the Securities Exchange Commission s rules and forms, and that such information is accumulated and communicated to the Company s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required financial disclosure.

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of Company management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to the Securities Exchange Act of 1934 (Exchange Act) Rules 13a-15(b) and 15d-15(b). Based upon, and as of the date of this evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were not effective, because of the material weaknesses discussed below. To address the material weaknesses described below, the Company performed additional analysis and other post-closing procedures to ensure that the consolidated financial statements were prepared in accordance with generally accepted accounting principles. Accordingly, management believes that the financial statements included in this report fairly present in all material respects our financial condition, results of operations and cash flows for the periods presented.

Status of Management s Report on Internal Control Over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with established policies or procedures may deteriorate.

The Company is in the process of conducting an evaluation of its internal control over financial reporting as of December 31, 2004. In making its assessment of internal control over financial reporting, management is using the criteria described in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Management has not yet completed its assessment of the effectiveness of the Company s internal control over financial reporting. However, to date, management has identified certain control deficiencies which represent material weaknesses. A material weakness is a control deficiency,

or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. As of December 31, 2004, we did not maintain effective controls over the reconciliation of accrued expenses. Specifically, we failed to reconcile the supporting documentation for certain material expense accruals to the general ledger. Furthermore, we failed to maintain effective controls over the completeness of accounts payable. Specifically, we failed to identify and record, at year end, certain of the Company s general operating obligations. These control deficiencies resulted in our inability to prevent and detect incomplete accounting and disclosure of accounts payable, accrued liabilities and the related general operating expenses. These control deficiencies also resulted in material audit adjustments to the financial statements for the fourth quarter of 2004. Additionally, these control deficiencies could result in

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material misstatements to the annual or interim financial statements that would not be prevented or detected. Accordingly, management has determined that each of these control deficiencies individually represent material weaknesses. The existence of one or more material weaknesses at December 31, 2004 precludes management from concluding that the Company s internal control over financial reporting was effective as of December 31, 2004, based on the criteria in the *Internal Control Integrated Framework*.

The Company s evaluation of its internal control over financial reporting as of December 31, 2004 is not complete. Further, there can be no assurance that as a result of the ongoing evaluation of internal control over financial reporting, additional deficiencies will not be identified or that any deficiencies identified, either alone or in combination with others, will not be considered a material weakness.

Securities and Exchange Commission Release No. 34-50754, subject to certain conditions, provides up to 45 additional days beyond the due date of this Annual Report on Form 10-K for the filing of management s annual report on internal control over financial reporting required by Item 308(a) of Regulation S-K and the related attestation report of the independent registered public accounting firm required by Item 308(b) of Regulation S-K. Pursuant to the Release, management s report on internal control over financial reporting and the associated report on the audit of management s assessment of the effectiveness of the Company s internal control over financial reporting as of December 31, 2004 are not filed herein and are expected to be filed no later than May 2, 2005 with an amendment to this Annual Report on Form 10-K.

The Company expects that the material weaknesses identified will result in an adverse opinion by the Company s independent registered public accounting firm on the effectiveness of the Company s internal control over financial reporting as of December 31, 2004.

Changes in Internal Control Over Financial Reporting

As discussed above, management has not completed its assessment of the Company s internal control over financial reporting. However, management is aware of material weaknesses, that have resulted in changes in the Company s internal control over financial reporting during the quarter ended December 31, 2004 that have materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

In connection with our July 2004 merger with Horizon Medical Products, we transferred most of our accounting function and processes from our headquarters in California to our Manchester, Georgia location during the fourth quarter of 2004. Accounting staff in our California location was reduced, but corresponding resources in Georgia had not been added as of December 31, 2004, resulting in lapses in review. Also, procedures governing transfer of invoices and other source documents from California to Georgia had not been finalized, which resulted in certain expenses related to 2004 not being properly accrued for during our internal accounting close at year-end. To address the material weaknesses identified, we have implemented the following remedial actions:

Hired additional personnel, permitting enhanced segregation of duties and additional review;

Completed additional training of staff;

Engaged outside consultants to perform additional testing and to identify procedural improvements in our accounting processes;

Changed procedures for timely submission of invoices, particularly those received in California, to our Georgia-based accounting department.

Other than the changes discussed above, there have been no changes to the Company s internal control over financial reporting that occurred since the beginning of the Company s fourth quarter of 2004 that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

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PART IV

Item 15. 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 Independent Registered Accounting Firm on Financial Statements

(2) Financial statement schedules
All schedules have been omitted since the required information is not present in amounts sufficient to require submission of the schedule or because the information required is included in the financial statements or notes thereto.

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

(b) Reports on Form 8-K:

A current report on Form 8-K reporting Item 5.02 was filed with the SEC on October 15, 2004.

A current report on Form 8-K reporting Item 8.01 was filed with the SEC on October 29, 2004.

A current report on Form 8-K reporting Item 8.01 was filed with the SEC on November 3, 2004.

A current report on Form 8-K reporting Items 2.02 and 9.01 was filed with the SEC on November 4, 2004.

A current report on Form 8-K reporting Item 8.01 was filed with the SEC on November 10, 2004.

A current report on Form 8-K reporting Item 8.01 was filed with the SEC on November 12, 2004.

A current report on Form 8-K reporting Items 1.01, 3.02 and 8.01 was filed with the SEC on November 26, 2004.

A current report on Form 8-K reporting Item 8.01 was filed with the SEC on November 30, 2004.

A current report on Form 8-K reporting Item 8.01 was filed with the SEC on December 2, 2004.

A current report on Form 8-K reporting Items 8.01 and 9.01 was filed with the SEC on December 16, 2004.

(c) Exhibits:

Number	Description
2.1(1)	Form of Agreement and Plan of Merger between the Company and RITA Medical Systems, Inc., a Delaware corporation.
2.2(10)	Agreement and Plan of Merger by and among RITA Medical Systems, Inc., a Delaware corporation, Hornet Acquisition Corp., a Delaware corporation, and Horizon Medical Products, Inc., a Georgia corporation, dated as of May 12, 2004, including exhibits thereto.
3.2(1)	Amended and Restated Certificate of Incorporation of RITA Medical Systems, Inc., a Delaware corporation.
3.3(11)	Certificate of Amendment of Certificate of Incorporation of RITA Medical Systems, Inc.
3.4(1)	Amended and Restated Bylaws of RITA Medical Systems, Inc.
4.1(2)	Preferred Shares Rights Agreement, dated as of July 31, 2001, between RITA Medical Systems, Inc. and U.S. Stock Transfer Corporation, including the Certificate of Designation, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B and C, respectively.

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Number	Description
4.2(1)	Sixth Amended and Restated Shareholder Rights Agreement dated June 20, 2000 by and among RITA Medical Systems, Inc. and certain security holders.
4.3(7)	Stock Purchase Agreement with SF Capital Partners Ltd., dated January 24, 2003.
4.4(7)	Stock Purchase Agreement with RIVERVIEW GROUP, LLC, dated January 24, 2003.
4.5(7)	Stock Purchase Agreement with BAYSTAR CAPITAL GROUP II, dated January 24, 2003.
4.6(7)	Stock Purchase Agreement with BAYSTAR INTERNATIONAL II, Ltd., dated January 24, 2003.
4.7(11)	Warrant dated September 26, 2002 between Horizon Medical Products, Inc. and Epoch Financial Group.
4.8(11)	Warrant dated September 26, 2002 between Horizon Medical Products, Inc. and Lippert/Heilshorn & Associates, Inc.
4.9(11)	Warrant dated June 17, 2003 between Horizon Medical Products, Inc. and Lippert/Heilshorn & Associates, Inc.
4.10(12)	Form of Stock and Warrant Purchase Agreement, dated as of November 24, 2004, by and between RITA Medical Systems, Inc. and each of SF Capital Partners Ltd., BayStar Capital II, L.P., Walker Smith Capital, L.P., Walker Smith Capital (QP), L.P., Walker Smith International Fund, Ltd. and Capital Ventures International
4.11(12)	Form of Warrant dated as of November 24, 2004, issued to each of SF Capital Partners Ltd., BayStar Capital II, L.P., Walker Smith Capital, L.P., Walker Smith Capital (QP), L.P., Walker Smith International Fund, Ltd. and Capital Ventures International.
10.1(1)	Sixth Amended and Restated Shareholder Rights Agreement dated June 20, 2000 by and among the Company and certain security holders.
10.2(1)	1994 Incentive Stock Plan (as amended) and form of option agreement.
10.3(4)	2000 Stock Plan (as amended) and form of option agreement.
#10.4(4)	2000 Directors Stock Option Plan (as amended) and form of option agreement.
10.5(1)	2000 Employee Stock Purchase Plan and form of subscription agreement.
10.6(a)(1)	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(1)	Form of Indemnification Agreement between the Company and its officers and directors.
#10.11(1)	Form of Change of Control Agreement entered into between the Company and it officers.
*10.13(1)	Distribution Agreement with Nissho Iwai Corporation (now named ITX Corporation) for South Korea dated March 12, 1999.
10.18(3)	Amendment of Distribution Agreement with Nissho Iwai Corporation (now named ITX Corporation) for Japan dated May 11, 2001.
*10.19(5)	Distribution Agreement with MDH s.r.l. Forniture Ospedaliene for Italy dated December 31, 2001.
10.22(5)	Amendment to Master Lease Agreement with Brown Mountain View Joint Venture dated June 4, 2001.

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Number	Description
#10.23(6)	Form of Change of Control Agreement entered into between the Company and Trent Reutiman on November 16, 2001 and between the Company and Donald Stewart on April 16, 2001.
#10.25(6)	Form of Indemnification Agreement between the Company and Trent Reutiman on November 16, 2001, between the Company and Donald Stewart on April 16, 2001.
**10.32(8)	Litigation settlement agreement, dated April 4, 2003, between RITA Medical Systems, Inc., RadioTherapeutics Corporation, Boston Scientific Corporation, Scimed Life Systems, Inc., The Board of Regents of the University of Nebraska, Unemed Corporation, University of Kansas d/b/a/ University of Kansas Medical Center and University of Kansas Medical Center Research Institute.
#10.33(8)	Form of Indemnification Agreement between the Company and Randy Lindholm on April 25, 2003 and between the Company and Lynn Saccoliti on May 1, 2003.
10.34(8)	Consulting Agreement with Randy Lindholm dated April 25, 2003.
#10.35(8)	Amendment to Offer Letter to Donald Stewart dated as of May 1, 2003.
#10.36(8)	Offer Letter to Lynn Saccoliti dated as of May 1, 2003.
#10.37(9)	Amended and Restated Consulting Agreement with Randy Lindholm dated August 5, 2003.
#10.38(9)	Form of Indemnification Agreement between the Company and Joseph DeVivo dated August 18, 2003, Wes Johnson dated August 5, 2003, Stephen Pedroff dated September 2, 2003 and Darrin Uecker dated January 12, 2004.
#10.39(9)	Form of Change of Control Agreement entered into between the Company and Joseph DeVivo dated August 18, 2003, Stephen Pedroff dated September 10, 2003 and Darrin Uecker dated January 12, 2004.
#10.40(9)	Offer letter between the Company and Joseph DeVivo dated July 23, 2003.
#10.41(9)	Offer letter between the Company and Stephen Pedroff dated August 22, 2003.
#10.42(17)	Change of Control Agreement entered into between the Company and Juan J. Soto dated as of September 3, 2003.
#10.43(17)	Contract of Employment between RITA Medical Systems Netherlands BV of DeBoelelaan 7 and Juan J. Soto dated October 15, 2003.
#10.44(17)	Indemnification Agreement between the Company and Juan J. Soto dated November 1, 2003
#10.45(17)	Offer letter between the Company and Darrin Uecker dated January 9, 2004.
^10.46	Lease Agreement dated as of July 1, 1996 between The Development Authority of the City of Manchester and Horizon Medical Products, Inc., filed as Exhibit 10.9 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
^10.47	Amendment to Lease Agreement dated November 2, 1999 between The Development Authority of the City of Manchester and Horizon Medical Products, Inc., filed as Exhibit 10.10 to the Form 10-K of Horizon Medical Products, Inc. dated March 29, 2000 (SEC File No. 000-24025) and incorporated herein by reference.
^10.48	Lease Agreement dated as of August 29, 1997 between The Development Authority of the City of Manchester and Horizon Medical Products, Inc., filed as Exhibit 10.10 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.

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Number	Description
^10.49	1998 Stock Incentive Plan, filed as Exhibit 10.11 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
^10.50	Equity Agreement, dated as of February 17, 1993, by and between CarboMedics, Inc. and Horizon Medical Products, Inc., as amended, filed as Exhibit 10.23 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
^10.51	Second Amended License Agreement dated January 1, 1995 between Dr. Sakharam D. Mahurkar and NeoStar Medical® Technologies, filed as Exhibit 10.26 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
^10.52	License Agreement dated July 1995 between Dr. Sakharam D. Mahurkar and Strato®/Infusaid TM Inc., filed as Exhibit 10.27 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
^10.53	Additional License Agreement dated January 1, 1997 between Dr. Sakharam D. Mahurkar and Horizon Medical Products, Inc., filed as Exhibit 10.28 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
^10.54	Note Purchase Agreement among Horizon Medical Products, Inc., ComVest Venture Partners, L.P. and certain Additional Note Purchasers dated March 1, 2002, filed as Exhibit 10.1 to the Form 8-K/A of Horizon Medical Products, Inc., filed on July 3, 2002 (SEC File Number 001-15459) and incorporated herein by reference.
^10.55	Senior Subordinated Convertible Note payable by Horizon Medical Products, Inc. to ComVest Venture Partners, L.P., dated March 16, 2002, filed as Exhibit 10.57 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.
^10.56	Senior Subordinated Convertible Note payable by Horizon Medical Products, Inc. to Medtronic, Inc., dated March 16, 2002, filed as Exhibit 10.58 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.
^10.57	Form of Senior Subordinated Convertible Note payable by Horizon Medical Products, Inc. to certain additional parties, dated March 16, 2002, filed as Exhibit 10.59 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.
^10.58	Junior Subordinated Promissory Note payable by ComVest Venture Partners, L.P. to Bank of America, dated March 15, 2002 and assumed by Horizon Medical Products, Inc. on March 15, 2002, filed as Exhibit 10.60 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.
^10.59	Non-Qualified Stock Option Agreement between Horizon Medical Products, Inc. and Marshall B. Hunt, dated March 15, 2002, for the purchase of 1,000,000 shares of the common stock of Horizon Medical Products, Inc. at an option price of $0.45 per share, filed as Exhibit 10.66 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.
^10.60	Non-Qualified Stock Option Agreement between Horizon Medical Products, Inc. and Marshall B. Hunt, dated March 15, 2002, for the purchase of 2,500,000 shares of the common stock of Horizon Medical Products, Inc. at an option price of $0.45 per share, filed as Exhibit 10.67 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.

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Number	Description
^10.61	Non-Qualified Stock Option Agreement between Horizon Medical Products, Inc. and William E. Peterson, Jr., dated March 15, 2002, for the purchase of 1,000,000 shares of the common stock of Horizon Medical Products, Inc. at an option price of $0.45 per share, filed as Exhibit 10.69 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.
^10.62	Agreement between Horizon Medical Products, Inc., Steven Picheny and Howard Fuchs, dated March 14, 2002, filed as Exhibit 10.71 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.
^10.63	Amendment No. 1 to Note Purchase Agreement, dated as of June 10, 2002, by and among Horizon Medical Products, Inc., ComVest Venture Partners, L.P. and the Additional Note Purchasers (incorporated by reference to Exhibit 10.2 to the Form 10-Q of Horizon Medical Products, Inc. for the three months ended June 30, 2002).
^10.64	Amendment No. 2 to Note Purchase Agreement, dated as of July 29, 2002, by and among Horizon Medical Products, Inc., ComVest Venture Partners, L.P. and the Additional Note Purchasers (incorporated by reference to Exhibit 10.3 to the Form 10-Q of Horizon Medical Products, Inc. for the three months ended June 30, 2002).
^10.65	Common Stock Purchase Warrant, dated as of September 26, 2002, by and between Horizon Medical Products, Inc. and Epoch Financial Group, Inc. (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of Horizon Medical Products, Inc. dated November 14, 2002).
^10.66	Common Stock Purchase Warrant, dated as of September 26, 2002, by and between Horizon Medical Products, Inc. and Lippert/Heilshorn & Associates, Inc. (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of Horizon Medical Products, Inc. dated November 14, 2002).
^10.67	Amendment to Option Agreement, dated November 15, 2002, between Horizon Medical Products, Inc. and Marshall B. Hunt (incorporated by reference to Exhibit 10.43 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. dated March 28, 2003).
^10.68	Lease Agreement, entered into as of December 15, 2000, by and between The Development Authority of the City of Manchester and Horizon Medical Products, Inc. (incorporated by reference to Exhibit 10.48 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. dated March 28, 2003).
^10.69	Exclusive Distribution Agreement, dated April 15, 2003, between Horizon Medical Products, Inc. and Medtronic, Inc. (incorporated by reference to Exhibit 10.2 of the Quarterly Report filed on Form 10-Q of Horizon Medical Products, Inc. dated August 14, 2003).
^10.70	Common Stock Purchase Warrant between Lippert/Heilshorn & Associates, Inc., dated June 30, 2003 (incorporated by reference to Exhibit 10.5 of the Quarterly Report filed on Form 10-Q of Horizon Medical Products, Inc. dated August 14, 2003).
^10.71	Amendment No. 1 to Note Purchase Agreement, dated October 21, 2003, by and among Horizon Medical Products, Inc., ComVest Venture Partners, L.P., Medtronic, Inc., and certain Additional Note Purchasers (incorporated by reference to Exhibit 10.1 of the Current Report filed on Form 8-K of Horizon Medical Products, Inc. dated November 12, 2003).
^10.72	Amended and Restated Securityholders Agreement, dated October 21, 2003, by and among Horizon Medical Products, Inc., ComVest Venture Partners, L.P., Medtronic, Inc., Standard Federal Bank National Association and Marshall B. Hunt (incorporated by reference to Exhibit 10.2 of the Current Report filed on Form 8-K of Horizon Medical Products, Inc. dated November 12, 2003).

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Number	Description
^10.73	Stock Option Agreement, dated October 21, 2003, between Horizon Medical Products, Inc. and Marshall Hunt (incorporated by reference to Exhibit 10.5 of the Current Report filed on Form 8-K of Horizon Medical Products, Inc. dated November 12, 2003).
^10.74	Stock Option Agreement, dated October 21, 2003, between Horizon Medical Products, Inc. and Robert Wenzel (incorporated by reference to Exhibit 10.6 of the Current Report filed on Form 8-K of Horizon Medical Products, Inc. dated November 12, 2003).
^10.75	Form of Bonus Agreement dated November 1, 2003, between Horizon Medical Products, Inc. and Robert Singer, L. Bruce Maloy and Elaine Swygert (incorporated by reference to Exhibit 10.61 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2003).
10.76(13)	Separation Agreement and Release of Claims, executed on or about August 20, 2004, between the Company, Horizon Medical Products, Inc. and Robert J. Wenzel.
10.77(13)	Amendment to Agreement, dated August 6, 2004, among the Company, Horizon Medical Products, Inc., Steven Picheny and Howard Fuchs.
^10.78	Equity Agreement, dated as of February 17, 1993, by and between CarboMedics, Inc. and Horizon Medical Products, Inc., as amended, filed as Exhibit 10.23 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
10.79(14)	Waiver and Amendment Agreement dated as of December 23, 2004 by and among RITA Medical Systems, Inc., SF Capital Partners Ltd. and BayStar Capital II, L.P.
10.80(15)	Consent and Waiver Agreement dated as of January 6, 2005, by and among Horizon Medical Products, Inc., ComVest Venture Partners, L.P., and Medtronic, Inc.
10.81(10)	Form of Voting Agreement entered into by RITA Medical Systems, Inc., a Delaware corporation, with each of Vincent Bucci, Joseph DeVivo, John Gilbert, Scott Halsted, Wesley E. Johnson, Jr., Randy Lindholm, Donald Stewart, Darrin Uecker, Lynn Saccoliti, Stephen Pedroff, Juan Soto and Morgan Stanley Venture Partners.
10.82(10)	Form of Lock-Up Agreement entered into by into by RITA Medical Systems, Inc., a Delaware corporation, and Horizon Medical Products, Inc., a Georgia corporation, with Morgan Stanley Venture Partners.
10.83(10)	Form of Lock-Up Agreement entered into by into by RITA Medical Systems, Inc., a Delaware corporation, and Horizon Medical Products, Inc., a Georgia corporation, with each of ComVest Venture Partners, L.P., Marshall B. Hunt and Medtronic, Inc.
10.84(16)	Form of Voting Agreement, dated as of May 12, 2004, between RITA Medical Systems, Inc., Horizon Medical Products, Inc. and certain shareholders of Horizon Medical Products, Inc.
10.85(16)	Amendment No. 4 to Note Purchase Agreement, dated as of May 12, 2004, by and among Horizon Medical Products, Inc., ComVest Venture Partners, L.P, and the Additional Note Purchasers (as defined therein).
10.86(16)	Amendment No. 1 to Amended and Restated Securityholders Agreement, dated as of May 12, 2004, by and among Horizon Medical Products, Inc., ComVest Venture Partners, L.P., Medtronic, Inc. and Marshall Hunt.
10.87	Standard Industrial/Commercial Multi-Tenant Lease Modified Net, dated as of January 25, 2005, by and between Fremont Ventures LLC and RITA Medical Systems, Inc.
23.1	Consent of PricewaterhouseCoopers LLP.

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Number	Description
24.1	Power of Attorney (See Signature Page).
31.1	Certification of Chief Executive Officer.
31.2	Certification of Chief Financial Officer.
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of Chief Executive Officer.
32.2	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of Chief Financial Officer.

* 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.
# Management contract or compensatory plan or arrangement.
^ Incorporated by reference to reports previously filed by Horizon Medical Products, Inc., which merged with the Company on July 29, 2004. The specific report filed by Horizon Medical Products, Inc. to which reference is made is set forth above.
(1) Incorporated by reference to our registration statement on Form S-1 (File No. 333-36160) initially filed with the SEC on May 3, 2000.
(2) Incorporated by reference to our registration statement on Form 8-A (File No. 000-30959) filed with the SEC on August 7, 2001.
(3) Incorporated by reference to our report on Form 10-Q (File No. 000-30959) filed with the SEC on August 8, 2001.
(4) Incorporated by reference to our report on Form 10-Q (File No. 000-30959) filed with the SEC on November 14, 2001.
(5) Incorporated by reference to our report on Form 10-K (File No. 000-30959) filed with the SEC on March 28, 2002.
(6) Incorporated by reference to our report on Form 10-Q (File No. 000-30959) filed with the SEC on May 15, 2002.
(7) Incorporated by reference to our report on Form S-3 (File No. 333-102896) filed with the SEC on January 31, 2003.
(8) Incorporated by reference to our report on Form 10-Q (File No. 000-30959) filed with the SEC on August 13, 2003.
(9) Incorporated by reference to our report on Form 10-Q (File No. 000-30959) filed with the SEC on November 13, 2003.
(10) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on May 14, 2004.
(11) Incorporated by reference to our Post-Effective Amendment on Form S-3 to Registration Statement on Form S-4 (File No. 333-116378) filed with the SEC on August 9, 2004.
(12) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on November 26, 2004.
(13) Incorporated by reference to our report on Form 10-Q (File No. 000-30959) filed with the SEC on November 9, 2004.
(14) Incorporated by reference to our Current Report on Form 8-K/A filed with the SEC on January 31, 2005
(15) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on January 7, 2005
(16) Incorporated by reference to our Registration Statement on Form S-4 (File No. 333-116378) filed with the SEC on June 10, 2004.
(17) Incorporated by reference to our report on Form 10-K (File No. 000-30959) filed with the SEC on March 15, 2004.

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SIGNATURES

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

Date: March 31, 2005

RITA MEDICAL SYSTEMS, INC.

By: /s/ JOSEPH DEVIVO

Joseph DeVivo

President, Chief Executive Officer and Director

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ JOSEPH DEVIVO **Joseph Devivo**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2005
/s/ DONALD STEWART **Donald Stewart**	Chief Financial Officer and Vice President, Finance and Administration (Principal Financial and Accounting Officer)	March 31, 2005
/s/ VINCENT BUCCI **Vincent Bucci**	Director	March 31, 2005
/s/ RANDY LINDHOLM **Randy Lindholm**	Director	March 31, 2005
/s/ JAMES E. BRANDS	Director	March 31, 2005

James E. Brands		
/s/ THOMAS J. DUGAN	Director	March 31, 2005
Thomas J. Dugan		
/s/ ROBERT TUCKER	Director	March 31, 2005
Robert Tucker		
/s/ SCOTT HALSTED	Director	March 31, 2005
Scott Halsted		
/s/ WESLEY JOHNSON	Director	March 31, 2005
Wesley Johnson		