RITA MEDICAL SYSTEMS INC
Form 10-K
March 15, 2006
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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, 2005

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.)**

46421 Landing Parkway

Fremont, CA 94538

(Address of principal executive offices, including zip code)

Registrant s telephone number, including area code: 510-771-0400

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 is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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 that 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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ Nox

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $104.5 million as of June 30, 2005, based upon the closing sale price on the Nasdaq National Market reported for such date. Shares of Common Stock held by each officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

There were 43,024,680 shares of the registrant s Common Stock issued and outstanding as of February 28, 2006.

Documents Incorporated by Reference

Part III incorporates information by reference from the definitive proxy statement to be filed in connection with the registrant s 2006 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, 2005

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Filing Sections

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

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

PART I

Item 1. Business.

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 specialty access ports and 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 Medtronic, Inc. s Isomed Hepatic Artery Infusion Pump, used for delivering high dose regionally delivered chemotherapy, and EMcision Limited s HABIB 4X resection device, used to minimize blood loss during surgical resection.

We were incorporated in California on January 6, 1994 and reincorporated in Delaware on May 9, 2000. Our principal executive offices are located at 46421 Landing Parkway, Fremont, CA 94538. Our telephone number at that location is (510) 771-0400 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.

With our RFA and SAC product lines, our sales and marketing organization often targets the same practicing clinicians: surgical oncologists and interventional radiologists. We believe that our blend of complex RFA technology with core SAC product offerings 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, new 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

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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 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 worldwide market for the radiofrequency ablation of unresectable liver tumors, which is currently estimated to be $500 million annually. We intend to execute this strategy by doing the following:

- increase awareness among key physicians through sales, marketing and training programs, including programs directed specifically at medical oncologists who are a key referral source for this procedure;
- conduct additional clinical research to provide data supporting the expanded use of our products; and
- increase 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, uterus, prostate, and kidney. In 2002 we received FDA clearance for treating painful bone metastases. 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. An important example of our efforts to extend our technology to additional applications in the future is our clinical and development work in the breast cancer market, where we believe our technology may permit significant reductions in the existing rate of surgical re-operation. We estimate that the market for these additional applications exceeds $1 billion annually.

Increase our Market Share for our Specialty Access Catheter Product Line. By means of more cost effective delivery of products, 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 will bring to the market place.

Acquire Distribution Rights to Products that Complement our Existing Technology and / or Leverage our Existing Sales Force. We believe our focus on surgical oncologists and interventional radiologists makes us a potentially attractive distribution partner for other companies that may lack our selling infrastructure, but whose technology otherwise complements our own. Our 2005 acquisition of distribution rights for the HABIB 4X resection device from EMcision Limited is an example of a business arrangement that we believe leverages our technology and our existing sales group. We intend to pursue other such opportunities as they arise in the future.

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 focused primarily on the liver cancer market and the bone cancer market. We believe our RFA system offers an attractive option to patients who previously had few or no effective

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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. Additionally, we are marketing the HABIB 4X resection device, which we believe provides us additional opportunity to penetrate the market for liver cancer surgery.

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 worldwide 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 became the first company to receive specific FDA clearance, this time for the palliation of pain associated with metastatic lesions involving bone. Our RFA system is distributed in the United States through our direct sales force. Internationally, we distribute through our direct sales force in France, Germany and the United Kingdom, and through distribution partners elsewhere. Since our product launch, we have sold approximately 90,000 disposable radiofrequency electrodes.

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.

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

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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 those 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- 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%, 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.

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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

Lung Cancer: According to the American Cancer Society (ACS), lung cancer is the leading cause of death from cancer in the United States in both men and women, with more than 174,000 new cases of lung cancer expected to be diagnosed in the United States in 2006. The ACS estimates that lung cancer now claims more than 162,000 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.

Breast Cancer: According to the ACS, breast cancer is the most common cancer among women, excluding non-melanoma skin cancers. In 2004, the ACS estimated there are more than 200,000 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 early 2006, we announced that we intend to increase our investment in this potential market opportunity. 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 to pursue this at this time.

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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 38,000 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 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 wound 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

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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 the RITA 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, breast, uterus, 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 often be repeated. In rare cases, unintentional 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 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 and permits ablation of larger tumors.

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Radiofrequency Ablation Products

The RITA system consists of a radiofrequency generator and a family of disposable devices. We also market the HABIB 4X resection device under a distribution agreement with EMcision Limited. Sales of radiofrequency ablation products were $20.5 million, $17.6 million and $16.6 million in the years ended December 31, 2005, 2004 and 2003, respectively. The following chart summarizes our current product offerings:

	Product Name	Description	Year of Introduction	U.S. List Price
Disposable Electrodes:	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 centimeter ablation, via a side-deployed array.	2003	$ 1,995
	StarBurst Semi-Flex	Creates a scalable 3 to 5 centimeter ablation and has a partially flexible shaft.	2003	$ 2,195
	StarBurst XLie	Creates a scalable 4 to 7 centimeter ablation. Requires an accessory infusion pump for irrigation of saline. Attached tubing standard.	2003	$ 2,695
	StarBurst Talon: Straight	Creates a scalable 2 to 4 centimeter ablation. Requires an accessory infusion pump for irrigation of saline.	2005	$ 1,995
	StarBurst Talon: Semi-Flex	Creates a scalable 2 to 4 centimeter ablation. Requires an accessory infusion pump for irrigation of saline.	2005	$ 2,295
Resection Device:	HABIB 4X	Surgical resection device.	2005	$ 2,995
Generators:	Model 1500X	250 Watt Capable Generator with Field-Software Upgradeability.	2002	$ 37,500

RFA Disposable Electrodes

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

Our RFA disposable electrodes 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

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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.

RF Resection Device

In May 2005, we signed an exclusive worldwide license with EMcision Limited, thereby obtaining the right to sell the HABIB 4X bipolar radiofrequency resection device. This product is designed to coagulate a surgical resection plane to facilitate a fast dissection with limited blood loss. It is compatible with our Model 1500 and Model 1500X radiofrequency generators.

RFA Generators

All of our generators employ an internal computer to assist the physician in safely and effectively controlling the delivery of radiofrequency during ablation or surgical resection procedures. 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 are designed to have their software changed in the field through the insertion of a small card containing electronic memory circuits

Overview: Specialty Access Catheter Products

We manufacture and market specialty access catheter (SAC) products including implantable ports, hemodialysis catheters, central venous catheters, needle infusion sets, peripherally inserted central venous catheters and other accessories used in vascular procedures. Our sales of specialty access catheter products totaled $26.0 million and $10.7 million for the years ended December 31, 2005 and 2004, respectively. We acquired our SAC product line in connection with our merger with Horizon Medical Products on July 29, 2004 and therefore report sales of SAC products only subsequent to that date.

Specialty Access Ports

Specialty 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 specialty 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. This product line consists 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.

Our Vortex® line of ports is a clear-flow port technology that revolutionized 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

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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 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 innovative designs, allowing some of the highest flow rates available in the market. Also, in November 2005, we received FDA approval to market our OmniPICC PI power injectable peripherally inserted central catheter that is designed to permit power injection delivery of contrast media in radiological imaging and interventional procedures.

The LifeGuard Safety Infusion Set, launched in 2002 and The LifeGuard Vision launched in 2005, used to infuse our ports, complement our port and specialty access catheter products. The innovative design of these products 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 approximately 40 field representatives and managers. We also utilize three domestic distributors. Overseas, we market our products primarily through distribution partners, but during the fourth quarter of 2005 we expanded our team of full-time international field representatives to ten in order to support direct distribution in France, Germany and the United Kingdom.

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

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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 our plan to increase market share by having physicians switch from our competitors products to our OmniPICC power injectable PICC line and Vortex® port systems. We believe that a direct, targeted, and focused strategy supported by our clinically proven SAC technology will achieve this result. 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 intend to 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 markets for RFA and SAC 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. With respect to our RFA products, 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;

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patent protection;

product quality and reliability; and

cost effectiveness.

The market for our SAC product line is also highly competitive. We face substantial competition from a number of other manufacturers and suppliers of vascular access ports, dialysis and central venous 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. Boston Scientific and Sims Deltec, Inc. are also competitors of ours in the market for specialty access catheter products.

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

product quality and reliability;

regulatory approvals;

patent protection;

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 current procedural technology (CPT) codes approved by the American Medical Association (AMA). 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 AMA 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 s 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.

On January 1, 2006 the AMA s CPT code number 50592 for percutaneous radiofrequency ablation (RFA) of renal tumors became effective. Following the AMA s establishment of this CPT code, Medicare issued new

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National Unadjusted Payment Rate Relative Value Units(a) (RVU) calculations for both facility and non-facility based percutaneous radiofrequency ablation treatment of renal tumors.

Also, during 2005, the Centers for Medicare and Medicaid Services reconfigured the 2006 hospital outpatient payment for RFA of liver tumors, with the reconfiguration effective on January 1, 2006. This resulted in a 35% increase over 2005 levels in hospital outpatient payments for percutaneous liver RFA procedures and a 55% increase over 2005 levels in hospital outpatient payments for laparoscopic liver RFA procedures.

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 economically 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 lung, breast, and kidney, and initial results of our lung, breast and kidney clinical investigations have been published or presented. We also continue to develop new catheter and port products featuring improved performance and lower cost. Our research and development expenses totaled $3.9 million, $3.8 million and $4.3 million during 2005, 2004 and 2003, respectively.

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, 2005, we had, worldwide, 65 issued patents and 52 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.

We also have, worldwide, 26 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.

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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 (PMA) 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 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.

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 products may have caused or contributed to a death or serious injury, or in which

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our products 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 have also filed medical device reports with the FDA for field failures of our SAC products, typically involving either leaking or occlusion of tubing.

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 originally obtained MDD certification in December 1996 for the RFA line and in October 1997 for the specialty access catheter line of products. We believe we 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 to such products.

Manufacturing

Our Manchester, Georgia facility assembles most of our products including electrodes, ports, infusion sets, hemodialysis catheters, other miscellaneous catheters, and dialysis accessories. Some component parts are produced for us by other manufacturers. Our Habib 4X resection device, generators and infusion pumps are currently manufactured to our specifications by outside contractors.

We devote significant attention to quality control of our products. We have established quality systems in conformance with the Quality System Regulation as mandated by the FDA. Our Manchester, Georgia facility is registered with FDA and as a medical device manufacturer in conformance with the European Medical Device Directive. The Manchester, Georgia facility is audited to both ISO 13485 and the European MDD requirements by our Notified Body (British Standards Institution, Inc.) on a semi-annual basis. Good Manufacturing Practice regulations may also apply to third party manufacturers depending on the type of component they manufacture for us.

Backlog

Our backlog for products at any point in time is not believed to be significant since products are shipped upon receipt of order or, in the case of distributor orders, assembled to order. We do not believe that our backlog at any particular point in time is indicative of future sales levels. The timing and volume of customer orders are difficult to forecast because our customers typically require prompt delivery of products and a majority of our sales are booked and shipped in the same quarter. In addition, sales are generally made pursuant to standard purchase orders that can be rescheduled, reduced or canceled prior to shipment with little or no penalty.

Employees

As of February 28, 2006, we had 221 full-time employees, including 63 in sales and marketing, 100 in manufacturing, 19 in research and development and 39 in general and administrative functions. From time to time, we also employ independent contractors to support our organization.

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Executive Officers

The following table shows the name, age and position of each of our executive officers as of February 28, 2006:

Name	Age	Position
Joseph DeVivo	39	President, Chief Executive Officer and Director

Mr. DeVivo has served as our Chief Executive Officer and as a member of our Board since August 2003. Prior to joining us, Mr DeVivo was President, Chief Operating Officer and Director at Computer Motion Inc. (CMI) from August 2002 to June 2003. Prior to CMI, Mr DeVivo held various positions at United States Surgical Corporation (USS), a division of TYCO Healthcare from May 1993 to August 2002, where in his last role, he was the Vice President and General Manager of U.S Surgical/Davis and Geck suture division from October 2001 through August 2002. Mr. DeVivo holds a B.S in Business Administration from the E. Claiborne Robins School of Business at the University of Richmond.

Michael Angel	50	Chief Financial Officer

Mr. Angel has served as our Chief Financial Officer since October 2005. From April 2004 to August 2005 he was employed as Executive Vice President and Chief Financial Officer of Proxim Corporation, a provider of wireless networking products, the assets of which were acquired by Terabeam Wireless in July 2005. From July 2005 to September 2005, Mr. Angel served as a consultant to Terabeam Wireless. From March 2003 to April 2004, he was an independent consultant providing financial consulting services for various technology companies. In May 2003, he acted as Vice President and Chief Financial Officer for Omnivision Technologies, Inc., a technology company. From September 1999 to December 2002, he served as Executive Vice President and Chief Financial Officer for Spectrian Corporation, a wireless infrastructure company. Prior to joining Spectrian Corporation, he held a number of senior finance positions with technology companies, including National Semiconductor and Hitachi Data Systems, and was a Senior Audit Manager with Price Waterhouse, now known as PricewaterhouseCoopers, L.L.P. He is a Certified Public Accountant and holds a B.S degree from California State University, Chico.

Mario Martinez	52	Vice President, Operations, General Manager

Mr. Martinez has served as our Vice President, Operations and General Manager since August 2005. Before joining us, he was a founder, President and Chief Executive Officer of Tecnix, LLC from January 2000 to July 2005. From October 1997 to December 2000, Mr. Martinez held corporate officer, senior management and engineering positions with 2C Optics. Prior to joining 2C Optics he served as Vice President of Operations for Biofield Corp., a publicly held company developing breast cancer diagnosis tools, and Vice President of Operations for EP Technologies, a publicly held company that pioneered RF Ablation for Cardiac Arrhythmias. Mr. Martinez is a graduate of the Emory University Mini Medical School, the Goldratt Institute, the Covey Leadership Center and Leadership Miami, and received his bachelor s degree in industrial systems from Florida International University. In June of 2005 Mr. Martinez was appointed by Georgia Governor Sonny Perdue as Chairman of the Latino Commission for a New Georgia.

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Name	Age	Position
Darrin Uecker	40	Chief Technology Officer

Mr. Uecker has served as our Chief Technology Officer since January 2004. Before joining us, he served as Vice President at Intuitive Surgical from June 2003 to December 2003. Prior to the merger of Intuitive Surgical with Computer Motion Inc., Mr. Uecker held the position of Chief Operating Officer at Computer Motion from May 1993 to June 2003. Mr. Uecker received both his B.S. and M.S. degrees in Electrical and Computer Engineering from the University of California at Santa Barbara.

Juan Soto	41	Vice President, International Sales

Mr. Soto has served as our Vice President, International Sales since September 2003. Prior to joining us, Mr. Soto served as Vice President and General Manager of Operations at Computer Motion Inc from 2002 to September 2003. From 1999 through 2002, Mr. Soto was employed at Tyco Healthcare first as Product Director in the Cardiac Division and then as Managing Director for the European Division. Mr. Soto, a former pilot in the British Royal Navy, holds a degree in Electronic Engineering from the Royal Naval College in the UK and a degree in Medical Marketing from the University of California at Los Angeles.

Item 1A. Risk Factors

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

We are heavily dependent on our RFA product line, our line of specialty access catheters and the development and introduction of new products in order to achieve our sales goals and our profitability and cash flow targets. Failure to achieve and grow market acceptance for either product line or for new products could harm our results of operations and financial condition, including recognition of additional asset impairment charges, and could limit our ability to fund our research and development projects.

The majority of our sales are expected to come from the sale of our RFA products and our line of specialty access catheters. To date, our original sales expectations at the time of the consummation of the Horizon merger have not been met because sales of our SAC products declined on a quarterly basis throughout 2005. As a result of not meeting sales expectations for our SAC products, in 2005 we recognized an impairment of some of the intangible assets originally established upon consummation of the Horizon merger. Our future financial performance will primarily depend upon physician adoption and patient awareness of our RFA and SAC products for existing indications or, presuming FDA approval, new indications as well as from sales of new products. Our profitability and cash flows as well as our ability to fund our research and development projects will suffer if physician adoption and patient awareness of our products do not meet our expectations. Furthermore, we may be required to recognize additional asset impairment charges in the future if sales expectations of our SAC product line are not met.

If we become unable to meet customer demand through disruption of manufacturing operations, our business could suffer.

We have transitioned our California-based manufacturing operations for our RFA products to our Manchester, Georgia location. Our initial production of RFA products in that location resulted in relatively low product yields and relatively high unit costs. If we become unable to meet customer demand for our products, or if the high initial costs associated with manufacture of our RFA products in Georgia do not abate, our business could suffer. Additionally, we expect to begin manufacture of the HABIB 4X bipolar resection device in Manchester in 2006. It is possible that initial production of this product could similarly result in low yields or high unit costs, and, if so, our business could suffer.

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We may need to obtain additional capital to improve our cash liquidity to continue present operations and such additional capital could result in dilution to our stockholders or additional debt repayment obligations.

We may need to raise additional funds in the future for our business operations and to execute our business strategy. We may seek to sell additional equity or debt securities or utilize our existing credit facility if it is available or to obtain another 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, including the use of our existing credit facility or any new credit facility, may not be available in amounts or on terms acceptable to us, or 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.

We are dependent on two third-party suppliers 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 suppliers to produce our RFA generators. In practice, we rely primarily on only one 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, including the disposable electrodes and resection devices which require generators in order to operate.

We are dependent on one third-party contractor for the supply of our HABIB 4X bipolar resection device, and any failure to deliver this product to us could result in lower than expected sales.

We are dependent on one supplier to manufacture our HABIB 4X bipolar device. In the quarter ended September 30, 2005, we received reports that the sterile packaging of some of these devices delivered to customers in the United States had been compromised during shipping. We inspected the first manufacturing lots received in the U.S. from our supplier and determined that a problem existed. As a result, we rejected subsequent product shipments from the manufacturer and requested that all products previously shipped to U.S. customers be returned for replacement. As a result, we were not able to sell as many HABIB 4X bipolar resection devices in the third quarter of 2005 as we had expected. We resumed shipment of HABIB 4X bipolar resection devices in the United States in November 2005 after a packaging redesign was implemented and validated by the manufacturer, and approved by us. The third quarter failure in shipments and any other future delay or failure in shipments of HABIB 4X bipolar resection devices to us has resulted in, and in the future may result in, our failure to ship the products to customers, resulting in lower than expected sales.

Any material weaknesses identified in our internal control over financial reporting or disclosure controls and procedures could have an adverse effect on our business. Additionally, we have expended substantial resources to comply with the Sarbanes-Oxley Act and may be required to expend significant resources in the future.

For the year ended December 31, 2004, we identified material weaknesses in our procurement process which prior to adjustment, could have resulted in a material misstatement of our annual or interim financial statements. As a result of these material weaknesses, we determined that we did not maintain effective internal control over financial reporting as of December 31, 2004. These material weaknesses have been remediated and no material weaknesses in our internal control over financial reporting have been identified for the year ended December 31, 2005. However, because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. A material misstatement in our future annual or interim financial statements could result and our business could suffer. Additionally, we have expended substantial resources to comply with the Sarbanes-Oxley Act and may be required to expend significant resources in the future.

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We have limited experience manufacturing our RFA and SAC 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 have consolidated 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 will need to hire additional personnel and may need to purchase additional equipment. If we are unable to sufficiently staff and equip our manufacturing operations, or are otherwise unable to meet customer demand for our products, our business could suffer.

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

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

- coordinating geographically disparate organizations, systems and facilities;
- 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.

We believe that the integration of the two companies was essentially complete as of June 30, 2005. However, as of December 31, 2005, we have only seventeen months of combined operations, and we may, in the future, encounter again any or all of the difficulties in operational integration we have faced in the period since the merger. These difficulties could include an interruption of, or loss of momentum in, the activities of the combined company s business and the loss of key personnel. Further, the diversion of our management s attention and any delays or difficulties encountered in connection with the operation of our geographically disparate organization could harm our business, results of operations, financial condition or prospects.

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

We incurred net losses of $11.0 million in 2005, $9.3 million in 2004 and $11.1 million in 2003. At December 31, 2005, we had an accumulated deficit of $99.3 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. We expect that the implementation of SFAS 123R will negatively impact our profitability in 2006 and beyond.

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

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

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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. 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, Boston Scientific and Sims Deltec, Inc. All of these competitors are publicly traded companies with substantially greater resources than what 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 our radiofrequency ablation system or our implantable specialty access 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 products or to have less severe side effects than those resulting from our products, physician adoption of our products could be negatively affected and our sales could decline.

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 markets, 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.

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Under certain circumstances these patent applications 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, such as by filing a lawsuit, 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 sales, which account for a significant portion of our total sales, 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 risk of establishing, expanding and maintaining a direct sales force if any of our existing distributor agreements are terminated, as we have done in Germany, France and the United Kingdom;
- the challenge of managing international sales in other international markets 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;
- 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 our Italian distributor and if we lose this distributor, or if this distributor significantly reduces its product demand, our international and total sales could decline.

We are substantially dependent on M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, which accounted for 25% and 19% of our international sales for the year ended December 31, 2005 and 2004, respectively. International sales accounted for 15% and 16% of our total sales for the year ended December 31, 2005 and 2004, respectively. The loss of this distributor, or a significant decrease in demand from this distributor, could cause our sales to decline substantially.

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

We currently sell our products in selected international markets and domestic markets through third-party distributors over whom we have limited control, and, if they fail to adequately support our products, our sales

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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. During 2005, we terminated distributor agreements to initiate direct sales efforts in Germany, the United Kingdom and France and incurred approximately $180,000 in expense in the fourth quarter of fiscal 2005. We may in the future terminate distributor agreements with the intent to locate new distributors or with the intent to initiate direct sales efforts in specific markets. 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 or in establishing a direct sales force, and our sales could decrease during any related transition period.

We are aware that some of our distributors have, in the past, 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.

We have, in the past, experienced collection difficulties, particularly in our international markets. Although these difficulties have been resolved, 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 our distributors, making collection of accounts receivable with these customers difficult. Also, the change to direct selling in Germany, France and the United Kingdom may present us with new collections difficulties as we have only very limited collection experience with hospital customers in these countries. 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 or increase our losses.

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 the use of our products will continue at current levels, or that future reimbursement policies of third-party payors will not adversely affect our ability to sell our 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.

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

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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 sales.

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 as well as key staff in the areas of finance, operations and research and development. During our second quarter ended June 30, 2005, our then Chief Financial Officer announced his resignation effective as of October 2005. His replacement began service with the Company in October 2005. 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 our primary operating facilities are located, are competitive and expected to remain so. In addition, our Manchester, Georgia facility is located in a rural area and the number of skilled personnel is limited. Because the environment for qualified 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.

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 understand 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 increase our sales, lower our costs and expenses and manage our cash. 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;

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

We are dependent on two suppliers for a component used in our RFA disposable electrodes. 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 RFA 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 due to lower sales or higher costs.

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

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

Sales of our products outside the United States are subject to foreign regulatory requirements that vary from country to country. The time required to obtain approvals from foreign countries may be longer than that required for FDA approval or clearance, and requirements for foreign licensing may differ from FDA requirements. For

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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 or are exempt from the 510(k) clearance process. 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, breast, prostate, uterus and kidney, 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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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 4.3% of our outstanding common stock as of December 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 1B. Unresolved Staff Comments

None.

Item 2. Properties.

We are headquartered in Fremont, California, where we lease one building with approximately 14,500 square feet of office and research and development space. The lease is non-cancellable and expires in April 2010. Our principal 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 2006 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 2004 and 2005, and through February 28, 2006, as reported by the Nasdaq National Market:

	HIGH	LOW
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
Year ended December 31, 2005		
First quarter	$ 3.87	$ 2.95
Second quarter	$ 3.30	$ 2.57
Third quarter	$ 4.14	$ 3.06
Fourth quarter	$ 4.20	$ 3.14
First quarter of 2006, through February 28, 2006	$ 4.63	$ 3.52

On February 28, 2006, the last reported sales price of our common stock on the Nasdaq National Market was $3.74. 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 February 28, 2006, there were 162 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.

The disclosure required by Item 201(d) of Regulation S-K is incorporated by reference to the definitive proxy statement for our 2006 Annual Meeting of Stockholders to be filed with the SEC pursuant to Regulation 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*.

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Item 6. Selected Financial Data.

You should read the following selected financial data in conjunction with our financial statements and related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this Form 10-K. The annual data presented below is derived from our audited consolidated financial statements. Our audited consolidated statement of operations for the years ended December 31, 2005, 2004 and 2003 and our audited consolidated balance sheets at December 31, 2005 and 2004 are presented elsewhere in this Form 10-K. The information provided below is in thousands, except for per share data. Our selected financial data includes results for our specialty access catheter products only from the date of our merger with Horizon, July 29, 2004. Comparisons with prior periods may therefore be difficult.

	Years ended December 31,				
	2005	2004	2003	2002	2001
Statement of Operations Data:					
Sales	$ 46,441	$ 28,215	$ 16,607	$ 17,393	$ 14,791
Cost of goods sold	19,719	11,200	6,166	6,908	6,132
Impairment of product technology	3,595				
Gross profit	23,127	17,015	10,441	10,485	8,659
Operating expenses:					
Research and development	3,931	3,787	4,294	5,052	6,489
Selling, general and administrative	27,281	20,637	17,418	19,366	16,646
Impairment of intangible assets	1,947				
Restructuring charges	60	1,309			
Total operating expenses	33,219	25,733	21,712	24,418	23,135
Loss from operations	(10,092)	(8,718)	(11,271)	(13,933)	(14,476)
Interest income	147	46	201	473	1,610
Interest expense	(886)	(604)		(12)	(86)
Other expense, net	(144)	(27)	(9)	(27)	(8)
Net loss	$ (10,975)	$ (9,303)	$ (11,079)	$ (13,499)	$ (12,960)
Net loss per common share, basic and diluted	$ (0.26)	$ (0.35)	$ (0.63)	$ (0.91)	$ (0.90)
Shares used in computing net loss per common share, basic and diluted	41,778	26,465	17,647	14,890	14,353

	December 31,				
	2005	2004	2003	2002	2001
Balance Sheet Data:					
Cash, cash equivalents and marketable securities, current and long term	$ 5,522	$ 13,858	$ 9,535	$ 12,835	$ 23,537
Working capital	13,597	14,255	11,886	16,066	25,478
Total assets	136,467	152,309	22,033	24,166	35,834
Long-term obligations, net of current portion	9,762	9,722	23		

Common stock and additional paid-in capital	220,446	216,934	98,055	88,540	88,474
Total stockholders equity	121,195	128,656	19,084	20,603	32,145

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

The following discussion of our financial condition and results of operations should be read in conjunction with our Consolidated Financial Statements and related notes included in Item 8, Financial Statements and Supplementary Data in this Annual Report on Form 10-K. This discussion contains forward-looking statements, which involve risk and uncertainties. Our actual results could differ materially from those anticipated in the forward looking statements as a result of certain factors, including but not limited to those discussed in Risk Factors and elsewhere in this Annual Report on Form 10-K. See Forward Looking Statements at the beginning of this Annual Report on Form 10-K.

Business Overview

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. We also distribute a radiofrequency product, the HABIB 4X resection device, which is designed to limit blood loss in surgical resection procedures. 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 stem cell transplant procedures.

Our goal for the future is to remain a leading provider of minimally invasive medical devices for the treatment of solid cancerous or benign tumors and to achieve improved financial results for our stockholders. Our strategies to achieve these goals are as follows:

Increase Our Penetration of the Liver Cancer Market: This strategy encompasses our efforts to:

- increase awareness among key physicians;
- conduct additional clinical research to provide data supporting the expanded use of our products; and
- increase patient awareness with marketing efforts;

Expand the Application of Our Proprietary Radiofrequency Technology to Markets Beyond Liver Cancer;

Increase our Market Share for our Specialty Access Catheter Product Line;

Acquire Distribution Rights to Products that Complement our Existing Technology and Leverage our Sales Force; and

Continue to Advance Technology.

Our efforts to increase our penetration of the liver cancer market have historically centered on investment in our domestic sales group. Our sales in the United States have historically been 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. Additionally, we introduced our premium-priced Starburst Xli and Xlie families of disposable needles in the domestic markets earlier than in international markets. These actions have for some time resulted in a growing percentage of radiofrequency ablation product sales derived from the domestic market. The specialty access catheter products acquired in the merger with Horizon are also heavily concentrated in the domestic market and we believe the merger permits wider and more efficient sales force coverage of the domestic market. However, with the intent to improve our margins and to increase our sales internationally, we began to sell directly in Germany, France and the United Kingdom during the fourth quarter

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of 2005. We believe this change may result in higher international sales growth in 2006 compared to 2005, although selling expenses will increase as a result of this change.

Our merger with Horizon in 2004 was intended to leverage our existing sales force and provide an opportunity for increased operating efficiencies. We believe that improved costs will help us to pursue our strategic objective of increased market share in our specialty access catheter product lines. The Horizon merger, after our consolidation of manufacturing operations, resulted in higher production volumes which should result in lower costs because our costs are volume dependent. We acknowledge, however, that achievement of lower costs is dependent on more than just production volume. Technology in our marketplace has evolved rapidly and we have, from time to time, recognized relatively high expenses related to excess, obsolete and expiring inventory as our product lines have changed. We may experience similar product changes and related obsolete inventory provisions in the future. Additionally, our costs are burdened by the amortization of intangible assets related to our product technology. We expect these amortization charges to continue through 2016, although in 2005 we recognized partial impairment of our Horizon product technology asset as a result of not achieving the volume of sales anticipated at the date of merger. As a result of the impairment, total amortization charges affecting our costs are expected to be lower in future years.

In addition to the product technology asset described above, we also impaired merger-related assets for the value of trademarks and our Isomed distribution contract because our specialty access catheter sales have not achieved the levels anticipated at the date of the merger.

We believe that continual enhancement of our product technology is important to maintaining our market leadership position in radiofrequency ablation technology, developing our technology to penetrate markets beyond liver cancer and improving our market share positions in both the RFA and SAC markets. 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 than it was with previous generations of our devices. In the third quarter of 2004, we merged with Horizon and acquired our SAC product line. In the second quarter of 2005, we introduced our HABIB 4X resection device, which is part of our RFA product line, in our European markets, and in the third quarter of 2005 we received FDA approval for sale of the device in the United States. In November 2005, we received FDA approval to market our OmniPICC PI power injectable peripherally inserted central catheter that permits power injection delivery of contrast media in radiological imaging and interventional procedures. In the future, we will continue to make investments aimed at adapting our radiofrequency technology for use in applications other than liver and bone cancer, with a particular emphasis on research in the areas of lung and breast cancer which we believe offer large market opportunities. We will also continue to develop our specialty access catheter product line to add greater value to our customers while reducing cost, which we believe will result in a higher market share for these products.

We must also remain focused on activities that improve our financial results and provide a greater return to our stockholders. We note that consolidation of operations following the Horizon merger, completed in mid-2005, should reduce our costs and selling expenses. As a result, we expect our gross margin rate in 2006 to improve, compared to the 2005 gross margin rate. Also, in August 2005, we issued $9.7 million in convertible notes at a coupon rate of 6.5%. We used these funds to repay other debt that bore a higher interest rate, so we expect to have lower interest expense in 2006 than in 2005. We enhanced our liquidity in January 2006 with the signing of a revolving credit agreement that provides for as much as $7 million in borrowing capacity, although line availability given our current collateral is a lesser figure, approximately $3.3 million. Our 2006 results will also be affected by factors that we believe will increase costs and reduce earnings. We intend to increase our investments in marketing and research and development for new RFA products intended for application in the treatment of breast cancer and also invest in a minimally invasive resection device. In addition, adoption of SFAS 123R will result in increased expense in 2006 and future years, compared to 2005.

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Significant Events

Subsequent Event

On January 31, 2006, we entered into a Credit Agreement with CAPITALSource Finance LLC (CapitalSource). The Credit Agreement provides for a revolving credit facility in the principal amount of up to $7 million. The amount of principal available for us to borrow at any time is limited to the aggregate of (i) varying percentages of the amount of our eligible receivables and (ii) varying percentages of the amount of our eligible finished goods inventory. The applicable percentages are determined based on the level of our EBITDA, as defined in the Credit Agreement, for the prior three month period and our inventory turns ratio. In addition, the amount otherwise available to borrow based on the aforementioned criteria is reduced by a required liquidity reserve of $1,000,000 to $1,500,000 depending on the level of our EBITDA for the prior three month period. The principal available for us to borrow at January 31, 2006 was approximately $3.3 million.

The obligations under the Credit Agreement are secured by a security interest in substantially all of our and our subsidiaries tangible and intangible assets. The Credit Agreement provides for the use of a lockbox for the collection of our receivables if advances under the Credit Agreement are outstanding. Borrowings under the revolving credit facility bear interest at a floating rate equal to Citibank, N.A .s prime rate (the Prime Rate) plus 1.25%, provided, however, that the Prime Rate shall not be less than 7.25%. Interest on advances is payable on the first day of each calendar month. The full amount borrowed under the revolving credit facility will mature on the earlier of (i) January 31, 2009 or (ii) 30 days before the maturity date of the debt in the Senior Subordination Agreement, dated as of January 31, 2006, by and among Atlas Master Fund, Ltd. (Atlas), Capital Source and us (the Subordination Agreement). Pursuant to the terms of the Subordination Agreement, the claims, demands, rights and remedies of Atlas were subordinated to the claims, rights and remedies of Capital Source.

The Credit Agreement also includes requirements to maintain financial covenants in order to be eligible to borrow including (i) a minimum level quarterly EBITDA, as defined in the Credit Agreement, of $325,000 during 2006, $150,000 during 2007, and $62,500 during 2008, and (ii) cash balances of no less than $1,000,000 to $2,500,000 depending on the level of EBITDA, as defined in the Credit Agreement, for the prior three month period.

The Credit Agreement contains affirmative covenants that require us to promise, among other things, to deliver financial statements and other financial information to CapitalSource, to maintain its insurance policies, to allow inspection of our operations, to provide a customary right of first refusal to CapitalSource in the event that a third party proposes a debt financing, to pay its taxes and to maintain our inventory. The Credit Agreement also contains negative covenants that will limit the ability of us to, among other things, incur additional indebtedness, create any liens on any of its collateral, make certain investments, pay dividends, enter into certain transactions with affiliates, amend our charter documents, transfer our assets or make payments on permitted subordinated debt. The Credit Agreement contains customary events of default, including, but not limited to: (a) non-payment of amounts due; (b) material breach of representations, warranties or covenants under the Credit Agreement or the documents pertaining thereto; (c) insolvency; (d) receivership or bankruptcy; (e) certain changes in control; (f) loss of collateral; (g) withdrawal of United States Food and Drug Administration approval of products; (h) recall of products; or (i) other material adverse changes. Upon the occurrence of an event of default, the amounts due outstanding under the revolving credit facility may be accelerated and may become immediately due and payable. In addition, upon the occurrence of an event of default, CapitalSource shall, among other things, have the right to (a) apply any of our and our subsidiaries property held by CapitalSource to reduce the obligations; (b) foreclose on liens; (c) take possession of or sell any collateral or pledged securities; and (d) reduce the amount of capital available under the revolving credit facility.

At signing, we paid a commitment fee of $140,000, plus legal out-of-pocket costs incurred by CapitalSource of approximately $83,000, in connection with the Credit Agreement. We must also pay a collateral management fee equal to 0.05% of the average outstanding principal amount of the revolving credit facility each month and must pay a monthly unused line fee equal to 0.04% per month of the difference derived

by subtracting (i) the

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daily average amount of the balances under the revolving credit facility outstanding during the preceding month, from (ii) $7,000,000. Additionally, we are obligated to pay a termination fee of up to $210,000 we it decide to terminate the Credit Agreement prior to its expiration. We have not yet requested any advances under the revolving credit facility.

Private Placement of Convertible Debt

On August 5, 2005, we completed a private placement of subordinated Senior Convertible Notes (the New Notes) with an aggregate principal amount of $9.7 million. The New Notes were issued pursuant to a Securities Purchase Agreement (the Purchase Agreement) among the Company and Atlas Master Fund, Ltd., which is not related to us. No warrants or other securities were issued in conjunction with the Purchase Agreement and we incurred no financing costs other than normal and customary legal and other professional expenses. The New Notes are convertible into shares of our common stock at an initial conversion price of $4.03 per share of common stock which was greater than the per share fair market value of our common stock on the date of issuance of the New Notes. The conversion price is subject to adjustment in certain circumstances including common stock splits or other standard anti-dilution provisions. Until conversion or maturity, the New Notes bear interest at the rate of 6.5% per annum, payable semiannually in cash. Absent conversion, the New Notes mature on August 5, 2008 (the Maturity Date). If on the Maturity Date the closing price of the common stock has been at or above 102% of the then current conversion price for at least 10 consecutive business days immediately preceding the Maturity Date, then any remaining principal outstanding under the New Notes shall automatically be converted into common stock, subject to certain conditions. The issuance of the New Notes 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.

As of the issuance date of the New Notes, we also owed $8.3 million plus accrued interest to holders of our Senior Subordinated Convertible Notes (the Senior Notes) and $1.4 million plus accrued interest to the holder of our Junior Promissory Note (the Junior Note). Pursuant to the terms of the New Notes, the Company was required to repay the Senior Notes and the Junior Note within 21 days of the issuance of the New Notes, or August 26, 2005. The Senior Notes were repaid on August 9, 2005 and the Junior Note was repaid on August 11, 2005.

Business Combinations

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 a specialty access catheter product line, particularly oncology products 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 issued approximately 18.7 million shares of our 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.

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Impairment of Intangible Assets

Due to revised revenue projections of certain of our specialty access catheter products, we performed an analysis of our intangible assets acquired in connection with our merger with Horizon in accordance with the provisions of Statement of Financial Accounting Standards No. 144 (SFAS 144), Accounting for the Impairment or Disposal of Long-Lived Assets, which requires an impairment analysis performed whenever events or changes in circumstances indicate that the carrying value of the long-lived assets may not be recoverable. We measured the impairment related to our product technology, customer relationships, trademarks and Isomed distribution contract by comparing their net book values to their fair values which were calculated using the projected discounted cash flow method. Based on this analysis, confirmed by independent appraisal, we recorded an impairment charge of $3.6 million related to product technology, $1.5 million related to trademarks and $0.5 million for the Isomed distribution contract. Based on our analysis our customer relationship intangible asset was not impaired. Since this analysis relied on financial assumptions which are subject to variability, if events and circumstances change in the future, we may be required to perform a similar analysis, which could result in an impairment charge to earnings in a future period.

Critical Accounting Policies and Estimates

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States requires us to make judgments, assumptions, and estimates that affect the amounts reported in the Consolidated Financial Statements and accompanying notes. We base our assumptions, judgments and estimates on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates under different assumptions or conditions. On a regular basis we evaluate our assumptions, judgments and estimates and make changes accordingly. Historically, our assumptions, judgments and estimates relative to our critical accounting policies have not differed materially from actual results. Note 2 to our Consolidated Financial Statements describes the significant accounting policies and methods used in the preparation of our Consolidated Financial Statements. The accounting policies described below are significantly affected by critical accounting estimates.

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. Additionally, during the fourth quarter of 2005, we initiated direct distribution of our products to hospital customers in Germany, France and the United Kingdom, and our allowance for doubtful accounts may increase if our collection experience in these countries differs from our historical experience with foreign distributors.

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, expiring 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: Product-related revenue is recognized upon shipment of products provided that there are no uncertainties regarding customer acceptance, persuasive evidence of an arrangement exists, the sales price is fixed and determinable and collectibility is deemed probable. This policy is applied to all of our customers. Except for our two distributors in the United States, our customers may only return undamaged product within thirty days of purchase. Our two distributors in the United States have no price protection, but they are given privileges to return undamaged product within 90 days of purchase with a placement of new orders for an equivalent amount of

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new product, 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 based on contractual obligations and historical experience 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. Through December 31, 2005, most of our billings have been denominated in U.S. dollars, although our initiation of direct distribution in Germany, France and the United Kingdom has resulted in billings in the Euro and GB pound.

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 measured 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 fourth 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.

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Results of operations

The following results of operations include the results of operations of Horizon from July 29, 2004. Therefore, the percentages shown for 2004 and 2003 are not indicative of future results.

Sales, Cost of Sales, and Gross Margin

The following tables set forth comparisons of key components of our net sales for the years ended December 31, 2005, 2004 and 2003 (in thousands):

	2005	2004	Dollar Growth	Percent Growth	2004	2003	Dollar Growth	Percent Growth
Domestic Sales								
Radiofrequency products.	$ 16,075	$ 13,865	$ 2,210	16%	$ 13,865	$ 13,275	$ 590	4%
Specialty access catheter products.	23,268	9,747	13,521	139%	9,747		9,747	
Total domestic sales.	$ 39,343	$ 23,612	$ 15,731	67%	$ 23,612	$ 13,275	$ 10,337	78%
International Sales								
Radiofrequency products	$ 4,407	$ 3,688	$ 719	19%	$ 3,688	$ 3,332	$ 356	11%
Specialty access catheter products.	2,691	915	1,776	194%	915		915	
Total international sales.	$ 7,098	$ 4,603	$ 2,495	54%	$ 4,603	$ 3,332	$ 1,271	38%
Total radiofrequency sales	$ 20,482	$ 17,553	$ 2,929	17%	$ 17,553	$ 16,607	$ 946	6%
Total specialty access catheter sales.	25,959	10,662	15,297	143%	10,662		10,662	
Total Sales.	$ 46,441	$ 28,215	$ 18,226	65%	$ 28,215	$ 16,607	$ 11,608	70%

During the year ended December 31, 2005, our sales increased 65% to $46.4 million from $28.2 million in 2004 primarily due to a $15.3 million increase in sales of our specialty access catheter products, which resulted from our merger with Horizon in 2004. While we included Horizon s results of operations only for approximately five months during 2004, our fiscal 2005 results include results of Horizon for the entire year. However, sales of our specialty access catheter products have not achieved the levels anticipated at the date of the merger, with sales of these products declining on a quarterly basis throughout 2005. In addition, our 2005 revenue increased by $2.9 million due to higher sales of our radiofrequency ablation products, which include the the HABIB 4X resection device we introduced during 2005.

For the year ended December 31, 2004, sales increased 70% to $28.2 million from $16.6 million in 2003 primarily due to our merger with Horizon, which added $10.7 million to our sales. Domestic sales of radiofrequency ablation products were 4% higher in 2004 than in 2003 while international sales of radiofrequency ablation products grew 11% over 2003.

The following tables set forth comparisons of domestic and international sales, relative percentages of our radiofrequency ablation versus specialty access catheter product sales and gross margin rates for the years ended December 31, 2005, 2004 and 2003:

	Years ended December 31,		
	2005	2004	2003
Total Sales (in thousands)	$ 46,441	$ 28,215	$ 16,607
Percentage of sales: Domestic	85%	84%	80%
Percentage of sales: International	15%	16%	20%
Percentage of sales: RFA products	44%	62%	100%
Percentage of sales: SAC products	56%	38%	0%
Gross margin	50%	60%	63%

The percentages shown above were calculated using specialty access catheter sales only for the period from the date of the Horizon merger, July 29, 2004. In future years, we expect our RFA products to grow faster than our SAC products and to account for a larger percentage of our sales than in the year ended December 31, 2005.

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Cost of goods sold for the year ended December 31, 2005 was $23.3 million compared to $11.2 million in 2004, resulting in a 50% gross margin for 2005 compared to 60% gross margin rate in 2004. Higher sales, including the effect of a full year of specialty access catheter product sales compared to a partial year in 2004, accounted for $7.1 million of the increase in cost. The balance of the increase is mainly attributable to a $3.6 million (8% of sales) impairment charge of our product technology acquired in the Horizon merger, $0.5 million in higher charges in 2005 for certain excess, obsolete and expiring inventories and $0.4 million in higher amortization of intangible assets in 2005 when compared to 2004. Also, during 2005 we incurred costs related to integration of our manufacturing operations in our Manchester, Georgia location. This transfer of operations was completed in the second quarter of 2005. During 2006 we expect our amortization of intangibles to be lower than in 2005 due to the impairment charge of our product technology recorded in 2005. We believe we have the opportunity to improve margins through higher volumes and improved manufacturing efficiency.

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. 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.

Operating Expenses

Our operating expenses consists 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. The following table sets forth period-over-period changes in our operating expenses and operating expenses as percentage of sales (dollars in thousands):

	Years ended December 31,		
	2005	**2004**	**2003**
Research and development expense	$ 3,931	$ 3,787	$ 4,294
Percentage change from comparable prior period	*4%*	*(12)%*	
As a percentage of net sales	*8%*	*13 %*	*26%*
Selling, general and administrative expense	27,281	20,637	17,418
Percentage change from comparable prior period	*32%*	*18 %*	
As a percentage of net sales	*59%*	*73 %*	*105%*
Impairment of intangible assets	1,947		
Restructuring charges	60	1,309	–