

RITA MEDICAL SYSTEMS INC  
Form 10-K  
March 15, 2006  
Table of Contents

---

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-K**

(Mark One)

**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

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

(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

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

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  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.

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

Large accelerated filer

Accelerated filer

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  No

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.

---

**Table of Contents**

**RITA Medical Systems, Inc.**

**Annual Report on Form 10-K**

**For the Fiscal Year Ended December 31, 2005**

**TABLE OF CONTENTS**

**Filing Sections**

<b><u>Item No.</u></b>		<b><u>Page</u></b>
<b>PART I</b>		
Item 1.	<u>Business</u>	1
Item 1A.	<u>Risk Factors</u>	17
Item 1B.	<u>Unresolved Staff Comments</u>	26
Item 2.	<u>Properties</u>	26
Item 3.	<u>Legal Proceedings</u>	26
Item 4.	<u>Submission of Matters to a Vote of Security Holders</u>	26
<b>PART II</b>		
Item 5.	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Repurchases of Equity Securities</u>	27
Item 6.	<u>Selected Financial Data</u>	28
Item 7.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	29
Item 7A.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	43
Item 8.	<u>Financial Statements and Supplementary Data</u>	44
Item 9.	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	44
Item 9A.	<u>Controls and Procedures</u>	45
Item 9B.	<u>Other Information</u>	46
<b>PART III</b>		
Item 10.	<u>Directors and Executive Officers of the Registrant</u>	47
Item 11.	<u>Executive Compensation</u>	47
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	47
Item 13.	<u>Certain Relationships and Related Transactions</u>	47
Item 14.	<u>Principal Accounting Fees and Services</u>	47
<b>PART IV</b>		
Item 15.	<u>Exhibits and Financial Statement Schedules</u>	48
	<u>Signatures</u>	54

## **Table of Contents**

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," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue," "our future success depends," "seek to continue" or the negative or other comparable terminology. These statements are only predictions. Actual events or results may differ materially. In evaluating these statements, you should specifically consider various factors, including the risks outlined under "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](http://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](http://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



## **Table of Contents**

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

## **Table of Contents**

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

## **Table of Contents**

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.

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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.

## **Table of Contents**

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.

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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.

## **Table of Contents**

**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 hemostasis 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.

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

*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

## **Table of Contents**

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.

**Table of Contents***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:

	<u>Product Name</u>	<u>Description</u>	<u>Year of Introduction</u>	<u>U.S. List Price</u>
<b>Disposable Electrodes:</b>	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
<b>Resection Device:</b>	HABIB 4X	Surgical resection device.	2005	\$ 2,995
<b>Generators:</b>	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



## **Table of Contents**

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, Triumph™ VTX and Genesis™ VTX; (ii) LifePort; (iii) Triumph-1; (iv) Infuse-a-Port; (v) OmegaPort; (vi) TitanPort; and (vii) the Vortex MP Port system.

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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

## **Table of Contents**

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<sup>®</sup> 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.

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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

## **Table of Contents**

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<sup>®</sup> 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;

**Table of Contents**

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

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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

## **Table of Contents**

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.

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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.

## **Table of Contents**

### **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 Health 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



## **Table of Contents**

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.

**Table of Contents****Executive Officers**

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

<u>Name</u>	<u>Age</u>	<u>Position</u>
Joseph DeVivo	39	President, Chief Executive Officer and Director
		<p>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.</p>
Michael Angel	50	Chief Financial Officer
		<p>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.</p>
Mario Martinez	52	Vice President, Operations, General Manager
		<p>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.</p>

**Table of Contents**

<u>Name</u>	<u>Age</u>	<u>Position</u>
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.**

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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.

## **Table of Contents**

**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.



## Table of Contents

**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.

## **Table of Contents**

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.**

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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.

## **Table of Contents**

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

## **Table of Contents**

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

## **Table of Contents**

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;

**Table of Contents**

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.**

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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

## **Table of Contents**

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;

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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.

**Table of Contents**

**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.

**Table of Contents****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:

	<b>HIGH</b>	<b>LOW</b>
	<u>          </u>	<u>          </u>
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*.

**Table of Contents****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
<b>Statement of Operations Data:</b>					
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
<b>December 31,</b>					
	2005	2004	2003	2002	2001
<b>Balance Sheet Data:</b>					
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		

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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

## **Table of Contents**

### **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.*

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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

## Table of Contents

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.

---

## **Table of Contents**

### **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

---

**Table of Contents**

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.

## **Table of Contents**

### *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



**Table of Contents**

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.

**Table of Contents****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):

	<b>2005</b>	<b>2004</b>	<b>Dollar Growth</b>	<b>Percent Growth</b>	<b>2004</b>	<b>2003</b>	<b>Dollar Growth</b>	<b>Percent Growth</b>
<b>Domestic Sales</b>								
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	
<b>Total domestic sales.</b>	<b>\$ 39,343</b>	<b>\$ 23,612</b>	<b>\$ 15,731</b>	<b>67%</b>	<b>\$ 23,612</b>	<b>\$ 13,275</b>	<b>\$ 10,337</b>	<b>78%</b>
<b>International Sales</b>								
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	
<b>Total international sales.</b>	<b>\$ 7,098</b>	<b>\$ 4,603</b>	<b>\$ 2,495</b>	<b>54%</b>	<b>\$ 4,603</b>	<b>\$ 3,332</b>	<b>\$ 1,271</b>	<b>38%</b>
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	
<b>Total Sales.</b>	<b>\$ 46,441</b>	<b>\$ 28,215</b>	<b>\$ 18,226</b>	<b>65%</b>	<b>\$ 28,215</b>	<b>\$ 16,607</b>	<b>\$ 11,608</b>	<b>70%</b>

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:

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

	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.

**Table of Contents**

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
<i>Percentage change from comparable prior period</i>	4%	(12)%	
<i>As a percentage of net sales</i>	8%	13 %	26%
Selling, general and administrative expense	27,281	20,637	17,418
<i>Percentage change from comparable prior period</i>	32%	18 %	
<i>As a percentage of net sales</i>	59%	73 %	105%
Impairment of intangible assets	1,947		
Restructuring charges	60	1,309	
<b>Total operating expenses</b>	<b>\$ 33,219</b>	<b>\$ 25,733</b>	<b>\$ 21,712</b>
<i>As a percentage of net sales</i>	72%	91%	131%

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

Research and development expenses increased 4% to \$3.9 million in 2005 compared to \$3.8 million in 2004. The increase was mainly due to the expansion of our product line after the Horizon merger. Research and development expenses for the year ended December 31, 2004 were \$3.8 million as compared to \$4.3 million in

## Table of Contents

2003. This decrease was due to reduced new product development and clinical trial costs. We expect a modest increase in research expenditures for 2006 as a result of developmental charges associated with technical innovation of our products, application of our products to new markets and, to some extent, the implementation of SFAS 123R.

Selling, general and administrative expenses increased 32% to \$27.3 million in 2005 compared to \$20.6 million in 2004. Approximately \$1.7 million of the increase reflects higher marketing expenses associated with our increased size and sales volume after the Horizon merger. Our domestic sales expense decreased by \$0.5 million in 2005 compared to 2004, as this was a primary area of savings following the merger. International selling expense increased \$0.9 million in 2005 compared to 2004, reflecting additional investment supporting our transition to direct selling in Germany, France and the United Kingdom. This transition will likely result in increased international selling expenses in 2006, compared to 2005. General and administrative expense increased \$2.9 million in 2005 compared to 2004, including a \$0.9 million increase in amortization of merger-related intangibles, which were amortized for the entire year during 2005 versus seven months during 2004. Our bad debt expense increased \$0.5 million in 2005 compared to 2004 primarily because the 2004 period had a \$0.7 million recovery that did not recur in 2005. The balance of the increase in our general and administrative expense was related to personnel and professional costs related to our public company expenses, including audit and compliance with the Sarbanes-Oxley Act of 2002. Additionally, we recognized a \$1.9 million impairment of merger-related intangible assets in 2005, as a result of lower expectations regarding projected sales of our specialty access catheter products. In 2006, we expect selling, general and administrative expenses to increase as a result from implementation of SFAS 123R, partially offset by lower amortization of intangibles associated with the Horizon merger due to the impairment charge recorded during 2005.

Selling, general and administrative expenses for the year ended December 31, 2004 were \$20.6 million as compared to \$17.4 million in 2003. Approximately \$2.6 million of the increase reflects higher sales, marketing and administrative expenses associated with our increased size after the Horizon merger, including \$0.7 million in amortization of related intangibles. However, about \$0.4 million of the increase was due to expenses associated with merger integration and sales training, and another \$0.6 million of the increase was due to legal, audit and consulting expenses associated with compliance with the Sarbanes-Oxley Act of 2002. Our bad debt expense was about \$0.4 million lower in 2004 than in 2003, primarily reflecting reduced allowances relating to our domestic distributors.

We incurred \$60,000 in restructuring expenses during the year ended December 31, 2005 versus \$1.3 million during the year ended December 31, 2004, consisting of severance related to the termination of employees to eliminate certain duplicative activities, primarily in the areas of sales, accounting and operations. All restructuring expenses recognized since the Horizon merger have been paid as of December 31, 2005.

### *Interest Income*

Interest income was \$147,000 in 2005, \$46,000 in 2004 and \$201,000 in 2003. Fluctuations in our interest income year to year result from changes in interest rates and average daily cash balances on hand.

### *Interest Expense*

Interest expense increased 47% to \$886,000 in 2005 from \$604,000 in 2004. Our debt totaled \$9.8 million and \$16.8 million at December 31, 2005 and 2004, respectively. Our fiscal 2004 only includes five months of interest expense as opposed to twelve months interest expense incurred 2005, because we assumed all of our debt in the Horizon merger on July 29, 2004. While the longer period increased our interest expense in 2005, the effects of this increase were partially offset by lower average outstanding balance during 2005 as we repaid \$7.0 million of the debt during 2005 and refinanced the balance of our debt at a lower interest rate. We incurred no interest expense during 2003. We expect our

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

interest expense to decline during 2006 compared to 2005 as a result of a lower interest rate on our existing debt, but borrowings under our line of credit agreement (see Significant Events, above) could alter this expectation.

---

**Table of Contents****Liquidity and Capital Resources**

Our liquidity and capital requirements depend on numerous factors including our research and development expenditures, expenses related to selling, general and administrative operations and working capital to support business growth. Our net cash used in operating activities was \$2.7 million, \$5.6 million and \$8.8 million for the years ended December 31, 2005, 2004 and 2003, respectively. In 2008, we will be required to make \$9.7 million in debt payments, presuming no conversion of our convertible debt into equity prior to the maturity date of the issue. Our balance of cash, cash equivalents and marketable securities on December 31, 2005 was \$5.5 million. On January 31, 2006 we entered into a Credit Agreement with CapitalSource, which provides for a revolving credit facility in the principal amount of up to \$7 million and an availability as of January 31, 2006 of approximately \$3.3 million. Although it is difficult for us to predict future liquidity requirements with certainty, we believe that our current balances of cash and cash equivalents will satisfy our cash requirements for at least the next 12 months. During or after this period, if cash generated by operations is insufficient to satisfy our liquidity requirements, we may need to sell additional equity or debt securities, borrow from our existing credit facility, obtain an additional credit facility or renegotiate debt repayment terms. There can be no assurance that additional financing will be available to us or, if available, that such financing will be available on terms favorable to us and our stockholders, or that we will be successful in renegotiating debt repayment terms. Failure to obtain sufficient funds on acceptable terms when needed, to make timely debt payments, or to achieve our growth or profitability objectives may require us to curtail operations, perhaps to a significant extent.

Prior to August 2000, we financed our operations principally through private placements of convertible preferred stock, raising approximately \$37.9 million net of expenses. On August 1, 2000, we completed our initial public offering of 3.6 million common shares at a price of \$12 per share, raising approximately \$39.0 million net of expenses. All outstanding convertible preferred shares were converted to common shares at that time. To a lesser extent, we also financed our operations through equipment financing and other loans that were fully repaid as of December 31, 2002. In January of 2003, we raised an additional \$8.3 million, net of expenses, through a private placement of our common shares. In November of 2004, we raised an additional \$11.1 million, net of expenses, through a second private placement of our common shares. As of December 31, 2005, we had \$5.5 million of cash and cash equivalents and \$13.6 million of working capital.

For the year ended December 31, 2005, net cash used in operating activities was \$2.7 million principally due to our net loss of \$11.0 million, offset by non-cash charges of \$10.8 million, including impairment of intangible assets, depreciation and amortization, stock-based compensation and provision and reserves for uncollectible accounts receivable and inventory. Approximately \$0.8 million in cash was provided in 2005 by reduced levels of inventory. Cash was used in 2005 by an increase in accounts and notes receivable of \$1.0 million primarily as a result of increased sales, an increase in prepaid and current and long-term operating assets of \$0.5 million, a decrease in accounts payable of \$0.5 million and a decrease in accrued liabilities of \$1.4 million. The accrued liability decrease was mainly as a result of lower payroll, audit and legal related accrued expenses at the end of 2005. For the year ended December 31, 2004, net cash used in operating activities was \$5.6 million principally due to our net loss of \$9.3 million, offset by non-cash charges of \$2.1 million, including depreciation and amortization, stock-based compensation and provisions to reserves for uncollectible accounts receivable and inventory. Approximately \$1.6 million in cash was provided in 2004 by changes in working capital accounts, including \$0.7 million in reduced inventory, \$0.4 million in reduced prepaid and other current assets, a \$0.2 million in reduced accounts receivable and \$0.2 million in higher accounts payable and current accrued liabilities.

For the year ended December 31, 2005, \$0.6 million was used in investing activities, with net sales of marketable securities providing \$0.9 million offset by \$1.3 million used in purchase of property and equipment and \$0.3 million used in the acquisition of a patent license from EMcision Limited Incorporated ( EMcision ). The acquisition of the EMcision license further required us to issue 150,000 of our common shares valued at \$0.4 million and committed us to a future payment in 2006 of an additional \$0.5 million. During 2004, \$3.2 million was provided by investing activities, with net sales of marketable securities providing \$4.9 million offset by \$0.7 million used in purchase of property and equipment. Further, the acquisition of Horizon used \$1.2 million in cash, the excess of professional service expenses incurred in the merger over Horizon's cash as of the merger date.

**Table of Contents**

Financing activities for the year ended December 31, 2005 used \$4.1 million in cash, reflecting \$16.7 million in debt payments made during the period offset by \$9.6 million net proceeds from issuance of convertible debt and \$3.0 million raised by the issuance of common stock in conjunction with the exercise of stock options. Financing activities for the year 2004 provided \$11.6 million in cash, including the \$11.1 million we raised in our November 2004 private placement of common stock and \$0.7 million related to the issuance of common stock in conjunction with the exercise of stock options. Further, in 2004 we used \$0.3 million to make payments on our debt.

We have, from time to time, financed equipment through capital and operating leases. In the course of the Horizon merger, we acquired debt of \$16.8 million. During 2005 we repaid \$16.7 million of this debt and completed a private placement of convertible notes with an aggregate principal amount of \$9.7 million. On January 31, 2006, we entered into a Credit Agreement with CapitalSource, which provides for a revolving credit facility in principal amount of up to \$7.0 million. Under the agreement we are required to pay CapitalSource monthly a collateral management fee equal to 0.05% per month of the average outstanding principal amount of the revolving facility during the month and an unused line fee in an amount equal to 0.04% per month of the difference derived by subtracting the daily average amount of the balances under the facility outstanding during the preceding month from the facility cap of \$7.0 million. As of December 31, 2005, we had no future minimum payments due under capital leases. Future minimum payments due under operating leases, debt agreements and revolving credit facility assuming no borrowings are made are as follows as of December 31, 2005 (in thousands):

<u>Year ending December 31,</u>	<u>Operating Leases</u>	<u>Debt</u>	<u>Unused line fee</u>	<u>Total</u>
2006	\$ 409	\$ 113	\$ 31	\$ 553
2007	386		34	420
2008	354	9,700	34	10,088
2009	355		3	358
2010 and thereafter	101			101
<b>Total of future minimum payments</b>	<b>\$ 1,605</b>	<b>\$ 9,813</b>	<b>\$ 102</b>	<b>\$ 11,520</b>

We have not yet borrowed any funds under our revolving line of credit. Our purchase orders for products are based on our current manufacturing needs and are fulfilled by our vendors within short time horizons. In addition, some of our purchase orders represent authorizations to purchase rather than binding agreements. We generally do not have significant agreements for the purchase of raw materials or other goods specifying minimum quantities and pre-determined prices that exceed our expected requirements. Therefore, agreements for the purchase of raw materials and other goods and services are not included in the table above. Agreements for outsourced services generally contain clauses allowing for cancellation without significant penalty, and are therefore not included in the table above.

**Off-Balance Sheet Arrangements**

We had no off-balance sheet arrangements as of December 31, 2005.

**Private Placement of Securities**

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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

## **Table of Contents**

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 like events. 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.

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

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

## **Income Taxes**

As of December 31, 2005, we had federal net operating loss carryforwards of approximately \$111.3 million and state net operating loss carryforwards of approximately \$55.2 million, available to offset future regular taxable income. We have fully reserved our deferred tax assets, however, because realization of favorable tax assets in future returns is very uncertain. The federal net operating loss carryforwards will expire between 2008 and 2025, and the state net operating loss carryforwards will expire between 2006 and 2015, if not utilized. The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of the Company, and our utilization of our carryforwards could be restricted. See also Note 9, Income Taxes, in the Notes to Consolidated Financial Statements appearing elsewhere in this Form 10-K.

## **Recent Accounting Pronouncements**

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

In December 2004, the Financial Accounting Standards Board ( FASB ) issued Statement of Accounting Standards (SFAS) No. 123R, Share-Based Payment , which replaces SFAS No. 123. SFAS No. 123R requires public companies to recognize an expense for share-based payment arrangements including stock options and

## **Table of Contents**

employee stock purchase plans. The statement eliminates a company's ability to account for share-based compensation transactions using APB 25, and generally requires instead that such transactions be accounted for using a fair-value based method. SFAS No. 123R requires an entity to measure the cost of employee services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant, and to recognize the cost over the period during which the employee is required to provide service in exchange for the award. SFAS No. 123R is effective for us in the quarter ending March 31, 2006. Upon adoption of SFAS 123R, companies are allowed to select one of three alternative transition methods, each of which has different financial reporting implications. Management is currently evaluating the transition methods, valuation methodologies and other assumptions for employee stock options in light of SFAS No. 123R. Current estimates of option values using the Black-Scholes method may not be indicative of results from the valuation methodologies we ultimately implement upon adoption of SFAS No. 123R. Although we have not yet fully quantified the impact this standard will have on our financial statements, it is likely that the adoption of SFAS No. 123R will have a material impact on our financial position and results of operations.

In March 2005, the SEC released Staff Accounting Bulletin No. 107 ( SAB 107 ), Share-Based Payment, which provides interpretive guidance related to the interaction between SFAS No. 123R and certain SEC rules and regulations. It also provides the SEC staff's views regarding valuation of share-based payment arrangements. Management is currently evaluating the impact SAB 107 will have on our consolidated financial statements.

In November 2005, the FASB issued FASB Staff Position, or FSP, FAS 115-1 and FAS 124-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments, or FSP 115-1, which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and on measuring such impairment loss. FSP 115-1 also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. We are currently evaluating the effect that the adoption of FSP 115-1 will have on our consolidated results of operations and financial condition but do not expect FSP 115-1 to have a material impact.

Effective April 1, 2004, the SEC adopted Staff Accounting Bulletin No. 105, Application of Accounting Principles to Loan Commitments ( SAB 105 ). SAB 105 clarifies the requirements for the valuation of loan commitments that are accounted for as derivatives in accordance with SFAS No. 133. The Company has no such loan commitments. We do not expect the implementation of this new bulletin to have any material impact on our financial position, results of operations and cash flows.

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

In December 2004, the FASB issued Statement SFAS No. 153, Exchanges of Nonmonetary Assets an amendment of APB Opinion No. 29, which amends Opinion 29 by eliminating the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for fiscal periods beginning after June 15, 2005, and implementation is done prospectively. We do not expect the implementation of this new standard to have a material impact on our financial position, results of operations or cash flows.

In December 2004, the FASB issued and made effective two Staff Positions (FSP) that provide accounting guidance on how companies should account for the effect of the American Jobs Creation Act of 2004 that was



---

**Table of Contents**

signed into law on October 22, 2004. In FSP FAS 109-1, Application of FASB Statement No. 109, Accounting for Income Taxes, to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004, the FASB concluded that the special tax deduction for domestic manufacturing, created by the new legislation, should be accounted for as a special deduction instead of a tax rate reduction. As such, the special tax deduction for domestic manufacturing is recognized no earlier than the year in which the deduction is taken on the tax return. FSP FAS 109-2, Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004, allows additional time to evaluate the effects of the new legislation on any plan for reinvestment or repatriation of foreign earnings for purposes of applying FASB Statement No. 109. We do not anticipate that this legislation will impact our results of operations or financial condition.

In March 2005, the FASB issued FASB Interpretation (FIN) No. 47, Accounting for Conditional Asset Retirement Obligations An Interpretation of FASB Statement No. 143. FIN No. 47 was issued to address diverse accounting practices regarding the timing of liability recognition for legal obligations associated with the retirement of tangible long-lived assets when the timing or method of settlement of the related obligations are conditional on future events. FIN No. 47 concludes that liability should be recognized when incurred if the liability can be reasonably estimated. FIN No. 47 is effective for reporting periods after December 31, 2005. We do not believe the adoption of FIN No. 47 will have a material impact on our consolidated financial position, results of operations or cash flows when effective.

In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections a replacement of APB Opinion No. 20 and FASB Statement No. 3. SFAS No. 154 replaces APB Opinion No. 20, Accounting Changes, and FASB Statement No. 3, Reporting Accounting Changes in Interim Financial Statements and changes the requirements for the accounting for and reporting of a change in accounting principle. This statement applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. When a pronouncement includes specific transition provisions, those provisions should be followed. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 31, 2005. We do not believe the adoption of SFAS No. 154 will have a material effect on our consolidated financial position, results of operations or cash flows.

In June 2005, the EITF issued a draft abstract for EITF Issue No. 05-6, Determining the Amortization Period for Leasehold Improvements Purchased after Lease Inception or Acquired in a Business Combination. This draft issue was subsequently finalized. The conclusion of the EITF was that leasehold improvements placed in service significantly after and not contemplated at or near the beginning of the lease term should be amortized over the shorter of the useful life of the assets or a term that includes both required lease periods and renewals that are reasonably assured (as defined in paragraph 5 of Statement 13) as of the date the leasehold improvements are purchased. We do not believe the adoption of EITF Issue No. 05-6 will have a material impact on our consolidated financial position, results of operations or cash flows when effective.

In February 2006, the FASB issued a final FSP FAS 123R-4, Classification of Options and Similar Instruments Issued as Employee Compensation That Allow for Cash Settlement upon the Occurrence of a Contingent Event. The guidance in this FSP FAS 123R-4 amends paragraphs 32 and A229 of FASB Statement No. 123R to incorporate the concept articulated in footnote 16 of FAS 123R. As a result, a cash settlement feature that can be exercised only upon the occurrence of a contingent event that is outside the employee's control does not meet the condition in paragraphs 32 and A229 until it becomes probable that the event will occur. Originally under FAS 123R, a provision in a share-based payment plan that required an entity to settle outstanding options in cash upon the occurrence of *any contingent event* required classification and accounting for the share based payment as a liability. This caused an issue under certain awards that require or permit, at the holder's election, cash settlement of the option or similar instrument upon (a) a change in control or other liquidity event of the entity or (b) death or disability of the holder. With this new FSP, these types of cash settlement features will not require liability accounting so long as the feature can be exercised only upon the occurrence of a contingent event that is outside the employee's control (such as an initial public

---

**Table of Contents**

offering) until it becomes probable that event will occur. The guidance in this FSP shall be applied upon initial adoption of Statement 123(R). An entity that adopted Statement 123(R) prior to the issuance of the FSP shall apply the guidance in the FSP in the first reporting period beginning after February 2006. Early application of FSP FAS 123R-4 is permitted in periods for which financial statements have not yet been issued. We do not anticipate that this new FSP will have any material impact on our financial condition or results of operations.

In February 2006, the FASB issued SFAS 155 Accounting for Certain Hybrid Financial Instruments, an amendment of FASB Statements No. 133 and 140. This Statement amends FASB Statements No. 133, Accounting for Derivative Instruments and Hedging Activities, and No. 140, Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities. This Statement resolves issues addressed in Statement 133 Implementation Issue No. D1, Application of Statement 133 to Beneficial Interests in Securitized Financial Assets. This Statement:

- a. Permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation
- b. Clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement 133
- c. Establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation
- d. Clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives
- e. Amends Statement 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument.

This Statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. The fair value election provided for in paragraph 4(c) of this Statement may also be applied upon adoption of this Statement for hybrid financial instruments that had been bifurcated under paragraph 12 of Statement 133 prior to the adoption of this Statement. Earlier adoption is permitted as of the beginning of an entity's fiscal year, provided the entity has not yet issued financial statements, including financial statements for any interim period for that fiscal year. Provisions of this Statement may be applied to instruments that an entity holds at the date of adoption on an instrument-by-instrument basis. We are in the process of evaluating the impact of SFAS 155.

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

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

We invest our excess cash in debt instruments of the United States government and its agencies and in high quality corporate issuers. The average contractual duration of our investments in 2005 and in 2004 was less than one year. Due to the short-term nature of these investments,

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

we believe that there is no material exposure to interest rate risk arising from our investments.

Our outstanding long-term debt is fixed rate and not subject to rate fluctuation. The fair value of our debt will increase or decrease as interest rates decrease or increase, respectively.

## **Table of Contents**

Nearly all of our sales and purchases have historically been denominated in United States dollars. In 2005, we began to make sales in other currencies, particularly the Euro and the GB pound. We currently have no significant direct foreign currency exchange rate risk and such risk in the future is expected to be only modest.

### **Item 8. Consolidated Financial Statements and Supplementary Data.**

The financial statements required by this item are presented in Item 15 and follow the signature page.

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

In May 2005, we received notice from PricewaterhouseCoopers LLP (PwC) that PwC was resigning as the Company's independent registered public accounting firm, effective May 23, 2005. We had engaged PwC as our independent registered public accounting firm in 1997. The Audit Committee of our Board of Directors immediately began the process of selecting a new independent registered public accounting firm to audit our financial statements for the fiscal year ended December 31, 2005. We authorized PwC to respond fully to successor auditor inquiries.

The reports of PwC on our financial statements for the fiscal years ending December 31, 2004 and 2003 contained no adverse opinion or disclaimer of opinion, and were not qualified or modified as to uncertainty, audit scope or accounting principles.

During our three most recent fiscal years ended December 31, 2005, 2004 and 2003 and 2002, none of the events described in Item 304(a)(1)(v) of Regulation S-K occurred except that as of December 31, 2004, the Company did not maintain effective internal control over financial reporting because the Company did not maintain effective controls over the reconciliation of accrued expenses and certain cash accounts and the completeness and accuracy of accounts payable. Specifically, the Company failed to reconcile the supporting documentation for certain material expense accruals, foreign cash accounts and the primary operating cash account to the general ledger, impacting the Company's ability to ensure all transactions flowing through the accounts are properly reflected in the recorded account balances. This control deficiency resulted in audit adjustments to accrued liabilities, general operating expenses and cash in the Company's 2004 annual consolidated financial statements. Additionally, this control deficiency could have resulted in a misstatement of accrued liabilities, general operating expenses and cash that would have resulted in a material misstatement to the annual or interim financial statements that would not have been prevented or detected. Accordingly, management determined that this control deficiency constituted a material weakness as of December 31, 2004. The Company had no material weaknesses as of December 31, 2005.

Additionally, as of December 31, 2004, the Company did not maintain effective controls over the completeness and accuracy of accounts payable. Specifically, the Company failed to identify and record, at year end, certain operating expenses including franchise taxes and general corporate expenses. This control deficiency resulted in audit adjustments to accounts payable and the related operating expenses in the Company's 2004 annual consolidated financial statements. Additionally, this control deficiency could have resulted in a misstatement of accounts payable and operating expenses that would have resulted in a material misstatement to the annual or interim financial statements that would not have been prevented or detected. Accordingly, management has determined that this control deficiency constituted a material weakness as of December 31, 2004.

Based on the material weaknesses at December 31, 2004, management concluded that we did not maintain effective internal control over financial reporting as of December 31, 2004, based on the criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company had no material weaknesses as of December 31, 2005.

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

On July 5, 2005, the Audit Committee of our Board of Directors appointed Stonefield Josephson, Inc. (Stonefield Josephson) as our independent registered public accounting firm. During the years ended

## **Table of Contents**

December 31, 2004 and 2003 and the period from December 31, 2004 to the date of appointment of Stonefield Josephson, neither the Company nor anyone acting on its behalf consulted with Stonefield Josephson with respect to either (i) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on our financial statements, or (ii) any other subject matter or reportable event set forth in Item 304(a)(2)(ii) of Regulation S-K.

### **Item 9A. Controls and Procedures.**

#### **Disclosure Controls and Procedures**

The Company's management, with the participation of the Company's chief executive officer (CEO) and chief financial officer (CFO), evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of December 31, 2005. Based on this evaluation, the Company's CEO and CFO concluded that as of December 31, 2005, the Company's disclosure controls and procedures were effective.

#### **Changes in Internal Control over Financial Reporting**

No change in the Company's internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fourth quarter ended December 31, 2005, that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

#### **Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that as of December 31, 2005, our internal controls over financial reporting were effective based on those criteria.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by Stonefield Josephson, Inc., an independent registered public accounting firm, as stated in their attestation report which is included herein.

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of

RITA Medical Systems, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that RITA Medical Systems, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control*

## Table of Contents

*Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). RITA Medical Systems, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that RITA Medical Systems, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, RITA Medical Systems, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheet and the related statements of income and comprehensive loss, stockholders' equity and cash flows of RITA Medical Systems, Inc. as of December 31, 2005 and our report dated February 9, 2006 expressed an unqualified opinion thereon.

/s/ Stonefield Josephson, Inc.

San Francisco, California

February 9, 2006

**Item 9B. Other Information.**

Not applicable

**Table of Contents**

**PART III**

**Item 10. Directors and Executive Officers of the Registrant.**

The information required by this item is included under Board of Directors, and Section 16(a) Beneficial Ownership Reporting Compliance in our Proxy Statement, to be filed in connection with our 2006 Annual Meeting of Stockholders, and is incorporated herein by reference. Certain information on Executive Officers is included in Item 1 of this report.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer or controller), and employees. This code of ethics is available on our website at [www.Ritamedical.com](http://www.Ritamedical.com) and any waivers from or amendments to the code of ethics, if any, will be posted on our website.

**Item 11. Executive Compensation.**

The information required by this item is included under the caption Executive Compensation in our Proxy Statement, to be filed in connection with our 2006 Annual Meeting of Stockholders, and is incorporated herein by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this item is included under the captions Security Ownership by Certain Beneficial Holders and Equity Compensation Plan Information in our Proxy Statement, to be filed in connection with our 2006 Annual Meeting of Stockholders, and is incorporated herein by reference.

**Item 13. Certain Relationships and Related Transactions.**

The information required by this item is included under the caption Certain Relationships and Related Transactions in our Proxy Statement, to be filed in connection with our 2006 Annual Meeting of Stockholders, and is incorporated herein by reference.

**Item 14. Principal Accountant Fees and Services.**

The information required by this item is included under the caption Ratification of Independent Public Accountants in our Proxy Statement, to be filed in connection with our 2006 Annual Meeting of Stockholders, and is incorporated herein by reference.

**Table of Contents****PART IV****Item 15.****Exhibits and Financial Statement Schedules**

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

**1. Financial Statements**

The following are included in Item 8 and are filed as part of this Annual Report on Form 10-K:

	<b>Page</b>
<u>Report of Stonefield Josephson, Inc., Independent Registered Public Accounting Firm, on Financial Statements</u>	56
<u>Report of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm, on Financial Statements</u>	57
<u>Consolidated Balance Sheets</u>	58
<u>Consolidated Statements of Operations and Comprehensive Loss</u>	59
<u>Consolidated Statements of Stockholders' Equity</u>	60
<u>Consolidated Statements of Cash Flows</u>	61
<u>Notes to Consolidated Financial Statements</u>	62

**2. Financial Statement Schedule**

All financial statement schedules have been omitted since they are either not required, not applicable, or because the information required is included in the consolidated financial statements or the notes thereto.

**3. Exhibits**

- 2.1(1) Form of Agreement and Plan of Merger between the Company and RITA Medical Systems, Inc., a Delaware corporation.
- 2.2(9) Agreement and Plan of Merger by and among RITA Medical Systems, Inc., a Delaware corporation, Hornet Acquisition Corp., a Delaware corporation, and Horizon Medical Products, Inc., a Georgia corporation, dated as of May 12, 2004, including exhibits thereto.
- 3.2(1) Amended and Restated Certificate of Incorporation of RITA Medical Systems, Inc., a Delaware corporation.
- 3.3(10) Certificate of Amendment of Certificate of Incorporation of RITA Medical Systems, Inc.
- 3.4(1) Amended and Restated Bylaws of RITA Medical Systems, Inc.
- 4.1(1)

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

Preferred Shares Rights Agreement, dated as of July 31, 2001, between RITA Medical Systems, Inc. and U.S. Stock Transfer Corporation, including the Certificate of Designation, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B and C, respectively.

- 4.2(2) Sixth Amended and Restated Shareholder Rights Agreement dated June 20, 2000 by and among RITA Medical Systems, Inc. and certain security holders.
- 4.3(6) Stock Purchase Agreement with SF Capital Partners Ltd., dated January 24, 2003.
- 4.4(6) Stock Purchase Agreement with RIVERVIEW GROUP, LLC, dated January 24, 2003.
- 4.5(6) Stock Purchase Agreement with BAYSTAR CAPITAL GROUP II, dated January 24, 2003.

**Table of Contents**

4.6(6)	Stock Purchase Agreement with BAYSTAR INTERNATIONAL II, Ltd., dated January 24, 2003.
4.9(10)	Warrant dated June 17, 2003 between Horizon Medical Products, Inc. and Lippert/Heilshorn & Associates, Inc.
4.10(11)	Form of Stock and Warrant Purchase Agreement, dated as of November 24, 2004, by and between RITA Medical Systems, Inc. and each of SF Capital Partners Ltd., BayStar Capital II, L.P., Walker Smith Capital, L.P., Walker Smith Capital (QP), L.P., Walker Smith International Fund, Ltd. and Capital Ventures International.
4.11(11)	Form of Warrant dated as of November 24, 2004, issued to each of SF Capital Partners Ltd., BayStar Capital II, L.P., Walker Smith Capital, L.P., Walker Smith Capital (QP), L.P., Walker Smith International Fund, Ltd. and Capital Ventures International.
10.2(1)	1994 Incentive Stock Plan (as amended) and form of option agreement.
10.3(3)	2000 Stock Plan (as amended) and form of option agreement.
#10.4(16)	2000 Directors Stock Option Plan (as amended) and form of option agreement.
10.5(1)	2000 Employee Stock Purchase Plan and form of subscription agreement.
10.6(a)(1)	Master Lease Agreement with Brown Mountain View Joint Venture dated July 12, 1994 and extension of Master Lease Agreement dated May 12, 1999.
#10.7(1)	Form of Indemnification Agreement between the Company and its officers and directors.
#10.11(1)	Form of Change of Control Agreement entered into between the Company and its officers.
*10.13(1)	Distribution Agreement with Nissho Iwai Corporation (now named ITX Corporation) for South Korea dated March 12, 1999.
10.18(4)	Amendment of Distribution Agreement with Nissho Iwai Corporation (now named ITX Corporation) for Japan dated May 11, 2001.
*10.19(5)	Distribution Agreement with MDH s.r.l. Forniture Ospedaliene for Italy dated December 31, 2001.
10.22(5)	Amendment to Master Lease Agreement with Brown Mountain View Joint Venture dated June 4, 2001.
*10.32(7)	Litigation settlement agreement, dated April 4, 2003, between RITA Medical Systems, Inc., RadioTherapeutics Corporation, Boston Scientific Corporation, Scimed Life Systems, Inc., The Board of Regents of the University of Nebraska, Unemed Corporation, University of Kansas d/b/a University of Kansas Medical Center and University of Kansas Medical Center Research Institute.
#10.33(7)	Form of Indemnification Agreement between the Company and Randy Lindholm on April 25, 2003.
10.34(7)	Consulting Agreement with Randy Lindholm dated April 25, 2003.
#10.37(8)	Amended and Restated Consulting Agreement with Randy Lindholm dated August 5, 2003.
#10.38(8)	Form of Indemnification Agreement between the Company and Joseph DeVivo dated August 18, 2003, Wes Johnson dated August 5, 2003, Stephen Pedroff dated September 2, 2003 and Darrin Uecker dated January 12, 2004.
#10.39(8)	Form of Change of Control Agreement entered into between the Company and Joseph DeVivo dated August 18, 2003, Stephen Pedroff dated September 10, 2003 and Darrin Uecker dated January 12, 2004.

**Table of Contents**

#10.40(8)	Offer letter between the Company and Joseph DeVivo dated July 23, 2003.
#10.41(8)	Offer letter between the Company and Stephen Pedroff dated August 22, 2003.
#10.42(14)	Change of Control Agreement entered into between the Company and John J. Soto dated as of September 3, 2003.
#10.43(14)	Contract of Employment between RITA Medical Systems Netherlands BV of DeBoelelaan 7 and John J. Soto dated October 15, 2003.
#10.44(14)	Indemnification Agreement between the Company and John J. Soto dated November 1, 2003.
#10.45(14)	Offer letter between the Company and Darrin Uecker dated January 9, 2004.
^10.46	Lease Agreement dated as of July 1, 1996 between The Development Authority of the City of Manchester and Horizon Medical Products, Inc., filed as Exhibit 10.9 to the Form S-1 of Horizon Medical Products, Inc. dated February 13, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
^10.47	Amendment to Lease Agreement dated November 2, 1999 between The Development Authority of the City of Manchester and Horizon Medical Products, Inc., filed as Exhibit 10.10 to the Form 10-K of Horizon Medical Products, Inc. dated March 29, 2000 (SEC File No. 000-24025) and incorporated herein by reference.
^10.48	Lease Agreement dated as of August 29, 1997 between The Development Authority of the City of Manchester and Horizon Medical Products, Inc., filed as Exhibit 10.10 to the Form S-1 of Horizon Medical Products, Inc. dated February 13, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
^10.49	1998 Stock Incentive Plan, filed as Exhibit 10.11 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
^10.50	Equity Agreement, dated as of February 17, 1993, by and between CarboMedics, Inc. and Horizon Medical Products, Inc., as amended, filed as Exhibit 10.23 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
^10.51	Second Amended License Agreement dated January 1, 1995 between Dr. Sakharam D. Mahurkar and NeoStar Medical® Technologies, filed as Exhibit 10.26 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
^10.52	License Agreement dated July 1995 between Dr. Sakharam D. Mahurkar and Strato®/Infusaid™ Inc., filed as Exhibit 10.27 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
^10.53	Additional License Agreement dated January 1, 1997 between Dr. Sakharam D. Mahurkar and Horizon Medical Products, Inc., filed as Exhibit 10.28 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
^10.59	Non-Qualified Stock Option Agreement between Horizon Medical Products, Inc. and Marshall B. Hunt, dated March 15, 2002, for the purchase of 1,000,000 shares of the common stock of Horizon Medical Products, Inc. at an option price of \$0.45 per share, filed as Exhibit 10.66 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.

**Table of Contents**

^10.60	Non-Qualified Stock Option Agreement between Horizon Medical Products, Inc. and Marshall B. Hunt, dated March 15, 2002, for the purchase of 2,500,000 shares of the common stock of Horizon Medical Products, Inc. at an option price of \$0.45 per share, filed as Exhibit 10.67 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.
^10.61	Non-Qualified Stock Option Agreement between Horizon Medical Products, Inc. and William E. Peterson, Jr., dated March 15, 2002, for the purchase of 1,000,000 shares of the common stock of Horizon Medical Products, Inc. at an option price of \$0.45 per share, filed as Exhibit 10.69 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.
^10.65	Common Stock Purchase Warrant, dated as of September 26, 2002, by and between Horizon Medical Products, Inc. and Epoch Financial Group, Inc. (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of Horizon Medical Products, Inc. dated November 14, 2002).
^10.67	Amendment to Option Agreement, dated November 15, 2002, between Horizon Medical Products, Inc. and Marshall B. Hunt (incorporated by reference to Exhibit 10.43 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. dated March 28, 2003).
^10.68	Lease Agreement, entered into as of December 15, 2000, by and between The Development Authority of the City of Manchester and Horizon Medical Products, Inc. (incorporated by reference to Exhibit 10.48 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. dated March 28, 2003).
^10.69	Exclusive Distribution Agreement, dated April 15, 2003, between Horizon Medical Products, Inc. and Medtronic, Inc. (incorporated by reference to Exhibit 10.2 of the Quarterly Report filed on Form 10-Q of Horizon Medical Products, Inc. dated August 14, 2003).
^10.70	Common Stock Purchase Warrant between Lippert/Heilshorn & Associates, Inc., dated June 30, 2003 (incorporated by reference to Exhibit 10.5 of the Quarterly Report filed on Form 10-Q of Horizon Medical Products, Inc. dated August 14, 2003).
^10.71	Amendment No. 1 to Note Purchase Agreement, dated October 21, 2003, by and among Horizon Medical Products, Inc., ComVest Venture Partners, L.P., Medtronic, Inc., and certain Additional Note Purchasers (incorporated by reference to Exhibit 10.1 of the Current Report filed on Form 8-K of Horizon Medical Products, Inc. dated November 12, 2003).
^10.73	Stock Option Agreement, dated October 21, 2003, between Horizon Medical Products, Inc. and Marshall Hunt (incorporated by reference to Exhibit 10.5 of the Current Report filed on Form 8-K of Horizon Medical Products, Inc. dated November 12, 2003).
^10.74	Stock Option Agreement, dated October 21, 2003, between Horizon Medical Products, Inc. and Robert Wenzel (incorporated by reference to Exhibit 10.6 of the Current Report filed on Form 8-K of Horizon Medical Products, Inc. dated November 12, 2003).
10.76(12)	Separation Agreement and Release of Claims, executed on or about August 20, 2004, between the Company, Horizon Medical Products, Inc. and Robert J. Wenzel.
^10.78	Equity Agreement, dated as of February 17, 1993, by and between CarboMedics, Inc. and Horizon Medical Products, Inc., as amended, filed as Exhibit 10.23 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.

**Table of Contents**

10.79(13)	Waiver and Amendment Agreement dated as of December 23, 2004 by and among RITA Medical Systems, Inc., SF Capital Partners Ltd. and BayStar Capital II, L.P.
10.87(14)	Standard Industrial/Commercial Multi-Tenant Lease Modified Net, dated as of January 25, 2005, by and between Fremont Ventures LLC and RITA Medical Systems, Inc.
#10.88(15)	Separation Agreement and Mutual Release, dated May 19, 2005, between RITA Medical Systems, Inc. and Donald Stewart.
#10.90(16)	RITA Medical Systems, Inc. 2005 Stock and Incentive Plan.
10.91(17)	Securities Purchase Agreement dated August 5, 2005, among the Company and the Purchasers, including form of Note.
#10.92(18)	Offer Letter to Mario Martinez dated July 25, 2005.
10.93(19)	Approval and Consent dated as of September 23, 2005 by and among RITA Medical Systems, Inc., SF Capital Partners Ltd., BayStar Capital II, L.P., Walker Smith Capital (and its affiliates) and Capital Ventures International.
#10.94(20)	Offer Letter to Michael D. Angel dated October 11, 2005.
10.95(21)	Revolving Credit and Security Agreement by and among RITA Medical Systems, Inc., Horizon Medical Products, Inc., RITA Medical Systems Netherlands, BV, RITA Medical Systems France, S.A.R.L. and CapitalSource Finance LLC dated as of January 31, 2006.
10.96(21)	Senior Subordination Agreement, dated as of January 31, 2006, by and among Atlas Master Fund, LLC, CapitalSource Finance LLC and RITA Medical Systems, Inc.
10.97	Form of Stock Option Agreement for 2005 Stock and Incentive Plan.
23.1	Consent of Stonefield Josephson Inc., Independent Registered Public Accounting Firm.
23.2	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1	Certification of Chief Executive Officer Filed Pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer Filed Pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer Filed Pursuant to Section 906 of Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer Filed Pursuant to Section 906 of Sarbanes-Oxley Act of 2002.

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

# Management contract or compensatory plan or arrangement.

^ Incorporated by reference to reports previously filed by Horizon Medical Products, Inc., which merged with the Company on July 29, 2004. The specific report filed by Horizon Medical Products, Inc. to which reference is made is set forth above.

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

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

(3) Incorporated by reference to our report on Form 10-Q filed with the SEC on November 14, 2001.

(4) Incorporated by reference to our report on Form 10-Q filed with the SEC on August 8, 2001.

(5) Incorporated by reference to our report on Form 10-K filed with the SEC on March 28, 2002.

**Table of Contents**

- (6) Incorporated by reference to our report on Form S-3 (File No. 333-102896) filed with the SEC on January 31, 2003.
- (7) Incorporated by reference to our report on Form 10-Q filed with the SEC on August 13, 2003.
- (8) Incorporated by reference to our report on Form 10-Q filed with the SEC on November 13, 2003.
- (9) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on May 14, 2004.
- (10) Incorporated by reference to our Post-Effective Amendment on Form S-3 to Registration Statement on Form S-4 (File No. 333-116378) filed with the SEC on August 9, 2004.
- (11) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on November 26, 2004.
- (12) Incorporated by reference to our report on Form 10-Q filed with the SEC on November 9, 2004.
- (13) Incorporated by reference to our Current Report on Form 8-K/A filed with the SEC on January 31, 2005.
- (14) Incorporated by reference to our report on Form 10-K filed with the SEC on March 15, 2004.
- (15) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on May 24, 2005.
- (16) Incorporated by reference to our Registration Statement on Form S-8 filed with the SEC on July 8, 2005.
- (17) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on August 9, 2005.
- (18) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on August 22, 2005.
- (19) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on September 29, 2005.
- (20) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on October 19, 2005.
- (21) Incorporated by reference to our Current Report on Form 8-K filed with the SEC on February 6, 2006.

**Table of Contents****SIGNATURES**

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

Date: March 15, 2006

RITA MEDICAL SYSTEMS, INC.

By: */s/* JOSEPH DeVIVO  
**Joseph DeVivo**

**President, Chief Executive Officer and Director**

***POWER OF ATTORNEY***

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

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

<u>Name</u>	<u>Title</u>	<u>Date</u>
<i>/s/</i> JOSEPH DeVIVO _____ <b>Joseph DeVivo</b>	President and Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2006
<i>/s/</i> MICHAEL ANGEL _____ <b>Michael Angel</b>	Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2006
<i>/s/</i> VINCENT BUCCI _____ <b>Vincent Bucci</b>	Director	March 15, 2006
<i>/s/</i> JAMES E. BRANDS _____ <b>James E. Brands</b>	Director	March 15, 2006
<i>/s/</i> THOMAS J. DUGAN _____ <b>Thomas J. Dugan</b>	Director	March 15, 2006

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

**Thomas J. Dugan**

/s/ STEVE LAPORTE

---

Director

March 15, 2006

**Steve LaPorte**

/s/ SCOTT HALSTED

---

Director

March 15, 2006

**Scott Halsted**

/s/ WESLEY JOHNSON

---

Director

March 15, 2006

**Wesley Johnson**

/s/ RANDY LINDHOLM

---

Director

March 15, 2006

**Randy Lindholm**

**Table of Contents**

**RITA Medical Systems, Inc.**

**Index to Consolidated Financial Statements**

	<b>Page</b>
<u>Report of Stonefield Josephson, Inc. Independent Registered Public Accounting Firm</u>	56
<u>Report of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm</u>	57
<u>Consolidated Balance Sheets</u>	58
<u>Consolidated Statements of Operations and Comprehensive Loss</u>	59
<u>Consolidated Statements of Stockholders' Equity</u>	60
<u>Consolidated Statements of Cash Flows</u>	61
<u>Notes to Consolidated Financial Statements</u>	62

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders

of RITA Medical Systems, Inc.:

We have audited the accompanying balance sheet of RITA Medical Systems, Inc. as of December 31, 2005, and the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year then ended. These financial statements are the responsibility of the company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of RITA Medical Systems, Inc. as of December 31, 2005, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of RITA Medical Systems, Inc.'s internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 9, 2006 expressed an unqualified opinion on management's assessment of internal control over financial reporting and an unqualified opinion on the effectiveness of internal control over financial reporting.

/s/ Stonefield Josephson, Inc.

San Francisco, California

February 9, 2006

**Table of Contents**

**Report of Independent Registered Public Accounting Firm on Financial Statements**

To the Stockholders and Board of Directors

of RITA Medical Systems, Inc.:

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)(1) presents fairly, in all material respects, the financial position of RITA Medical Systems, Inc. and its subsidiaries at December 31, 2004, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 28, 2005

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****CONSOLIDATED BALANCE SHEETS****(in thousands, except per share data)**

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,522	\$ 12,978
Marketable securities		880
Accounts and note receivable, net of allowance for doubtful accounts of \$1,077 at December 31, 2005 and \$1,237 at December 31, 2004	7,264	6,410
Inventories	5,380	7,126
Prepaid and other current assets	941	792
	<u>19,107</u>	<u>28,186</u>
Total current assets	19,107	28,186
Long term note receivable, net of collection allowance of \$31 at December 31, 2005 and \$61 at December 31, 2004	58	177
Property and equipment, net	1,959	1,966
Goodwill	91,339	91,339
Intangible assets, net	23,502	30,600
Other assets	502	41
	<u>136,467</u>	<u>152,309</u>
Total assets	\$ 136,467	\$ 152,309
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,091	\$ 2,572
Accrued liabilities	3,306	4,159
Current portion of long term debt	113	7,200
	<u>5,510</u>	<u>13,931</u>
Total current liabilities	5,510	13,931
Long term debt, net of current portion	9,700	9,632
Other long term liabilities	62	90
	<u>15,272</u>	<u>23,653</u>
Total liabilities	15,272	23,653
Commitments and contingencies (Note 6)		
Stockholders equity :		
Preferred stock, \$0.001 par value:		
Authorized: 2,000 shares at December 31, 2005		
Issued and outstanding: No shares at December 31, 2005 and 2004		
Common stock, \$0.001 par value:		
Authorized: 150,000 shares at December 31, 2005		
Issued and outstanding: 42,676 shares at December 31, 2005 and 41,350 shares at December 31, 2004	43	41

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

Additional paid-in capital	220,403	216,893
Accumulated other comprehensive loss		(2)
Accumulated deficit	(99,251)	(88,276)
	<u>          </u>	<u>          </u>
Total stockholders' equity	121,195	128,656
	<u>          </u>	<u>          </u>
Total liabilities and stockholders' equity	\$ 136,467	\$ 152,309
	<u>          </u>	<u>          </u>

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

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****(in thousands, except per share data)**

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Sales	\$ 46,441	\$ 28,215	\$ 16,607
Cost of goods sold	19,719	11,200	6,166
Impairment of product technology	3,595		
Gross profit	23,127	17,015	10,441
Operating expenses:			
Research and development	3,931	3,787	4,294
Selling, general and administrative	27,281	20,637	17,418
Impairment of intangible assets	1,947		
Restructuring charges	60	1,309	
Total operating expenses	33,219	25,733	21,712
Loss from operations	(10,092)	(8,718)	(11,271)
Interest income	147	46	201
Interest expense	(886)	(604)	
Other expense, net	(144)	(27)	(9)
Net loss	(10,975)	(9,303)	(11,079)
Other comprehensive loss:			
Change in unrealized gain (loss) on marketable securities	2	(4)	(5)
Comprehensive loss	\$ (10,973)	\$ (9,307)	\$ (11,084)
Net loss per common share, basic and diluted	\$ (0.26)	\$ (0.35)	\$ (0.63)
Shares used in computing net loss per common share, basic and diluted	41,778	26,465	17,647

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



Table of Contents

## RITA MEDICAL SYSTEMS, INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(In thousands)

	Common Stock		Additional Paid-in Capital	Stockholder Notes Receivable	Accumulated Other Compre- hensive Income (loss)	Accumulated Deficit	Total Stockholders Equity
	Shares Issued	Amount					
Balances, December 31, 2002	15,155	15	88,525	(50)	7	(67,894)	20,603
Issuance of common stock	2,126	2	8,605				8,607
Stock options exercised	714	1	1,028				1,029
Cancellation of common stock	(20)		(20)	20			
Revaluation of common stock warrant			(101)				(101)
Forgiveness of stockholder note receivable				30			30
Change in unrealized gain (loss) on marketable securities					(5)		(5)
Net loss						(11,079)	(11,079)
Balances, December 31, 2003	17,975	18	98,037		2	(78,973)	19,084
Issuance of common stock	4,427	5	11,285				11,290
Issuance of common stock in conjunction with acquisition	18,704	18	91,560				91,578
Issuance of stock options and warrants in conjunction with acquisition			15,322				15,322
Stock options exercised	244		546				546
Stock-based compensation expense			143				143
Change in unrealized gain (loss) on marketable securities					(4)		(4)
Net loss						(9,303)	(9,303)
Balances, December 31, 2004	41,350	41	216,893		(2)	(88,276)	128,656
Issuance of common stock	229	1	605				606
Stock options exercised	1,097	1	2,807				2,808
Stock-based compensation expense			98				98
Change in unrealized gain (loss) on marketable securities					2		2
Net loss						(10,975)	(10,975)
Balances, December 31, 2005	42,676	\$ 43	\$ 220,403	\$	\$	\$ (99,251)	\$ 121,195

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



**Table of Contents****RITA MEDICAL SYSTEMS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(in thousands)**

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (10,975)	\$ (9,303)	\$ (11,079)
<b>Adjustments to reconcile net loss to cash used in operating activities:</b>			
Depreciation and amortization	4,061	2,597	1,713
Loss on disposal of property and equipment	64	23	275
Impairment of intangible assets	5,542		
Issuance and revaluation of common stock warrants for services received			(101)
Stock-based compensation expense	98	143	
Allowance for doubtful accounts	114	(694)	(99)
Provision for excess, obsolete and expiring inventories	910	40	551
<b>Changes in operating assets and liabilities:</b>			
Accounts and note receivable	(998)	221	(190)
Inventories	836	742	778
Prepaid and other current assets	(148)	441	(33)
Other long term operating assets	(383)		
Accounts payable	(481)	1,118	(295)
Accrued liabilities	(1,354)	(882)	(342)
Deferred maintenance revenue	(13)	(9)	23
<b>Net cash used in operating activities</b>	<b>(2,727)</b>	<b>(5,563)</b>	<b>(8,799)</b>
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	(1,283)	(662)	(1,003)
Purchases of marketable securities	(81)	(698)	(12,787)
Sales and maturities of marketable securities	963	5,568	15,424
Net cash used in acquisition of Horizon Medical Products, Inc		(1,150)	
Capitalization of patent litigation costs			(621)
Acquisition of intangibles	(250)		(2,650)
Note receivable and other assets	72	156	
Other long term liabilities	(14)	(6)	142
<b>Net cash provided by (used in) investing activities</b>	<b>(593)</b>	<b>3,208</b>	<b>(1,495)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of convertible debt, net	9,573		
Principal payments on debt	(16,719)	(283)	
Proceeds from issuance of common stock, net of issuance costs	3,010	11,836	9,636
<b>Net cash provided by (used in) financing activities</b>	<b>(4,136)</b>	<b>11,553</b>	<b>9,636</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(7,456)</b>	<b>9,198</b>	<b>(658)</b>

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

Cash and cash equivalents at beginning of year	12,978	3,780	4,438
	<u>          </u>	<u>          </u>	<u>          </u>
Cash and cash equivalents at end of year	\$ 5,522	\$ 12,978	\$ 3,780
	<u>          </u>	<u>          </u>	<u>          </u>
Supplemental disclosures of cash flow information:			
Cash paid for taxes	\$ 94	\$ 39	\$ 9
Cash paid for interest	\$ 797	\$ 572	\$
Supplemental disclosure of non-cash investing and financing activities:			
Non-cash net assets acquired in acquisition	\$	\$ 16,712	\$
Accrued liability in conjunction with acquisition of product license	\$ 500	\$	\$
Equity issued in conjunction with acquisition of product licenses	\$ 404	\$	\$

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

**Table of Contents**

**RITA MEDICAL SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1: THE COMPANY**

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

**NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

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

**Liquidity**

As of December 31, 2005, the Company's total assets were \$136.5 million, total liabilities were \$15.3 million, working capital was \$13.6 million and cash and cash equivalents \$5.5 million. Current and anticipated demand for the Company's products as well as procurement and production affect the need for capital. Changes in these or other factors could have a material impact on capital requirements and may require the Company to raise additional capital. While the Company believes that its existing cash resources will be sufficient to fund its operating needs for the next twelve months, additional financing may be required for the Company's currently envisioned long term needs. If the Company needs to raise additional financing, it will seek to sell additional equity or debt securities, utilize its existing credit facility or obtain an additional credit facility or renegotiate debt repayment terms. There can be no assurance that any additional financing will be available on terms acceptable to the Company, or at all. In addition, future equity financings could result in dilution to shareholders, and future debt financings could result in certain financial and operational restrictions. Failure to obtain sufficient funds on acceptable terms when needed, to make timely debt payments, or to achieve our growth or profitability objectives may require us to curtail operations, perhaps to a significant extent.

**Use of estimates**

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

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

### **Cash and cash equivalents**

All highly liquid investments with original maturities of ninety days or less from the date of purchase, if not restricted, are considered to be cash equivalents. The Company has classified approximately \$103,000 and \$87,000 in restricted cash accounts as other current assets as of December 31, 2005 and 2004, respectively. An additional \$9,000 in restricted cash has been classified as a long term other asset as of December 31, 2005.

**Table of Contents**

**RITA MEDICAL SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Marketable securities**

The Company's marketable securities are categorized as available-for-sale. Marketable securities with original maturities greater than three months and remaining maturities of no more than one year are classified as short-term investments. Also, the Company's holdings of investment grade variable debt obligations, which are asset-backed and categorized as available-for sale, are classified as short-term investments. The Company's investments in these variable rate securities are recorded at cost, which approximates fair value because the periodic reset of their interest rates eliminates or greatly reduces realized or unrealized holding gains or losses on such securities. Further, variable rate securities are highly liquid despite the long term nature of the stated contractual maturities. Marketable securities with remaining maturities greater than one year are classified as long-term investments. Unrealized holding gains and losses are reflected as a net amount in a separate component of stockholders' equity until realized. For the purpose of computing realized gains and losses, cost is identified on a specific identification basis.

**Fair Value of Financial Instruments**

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

**Concentration of credit risk and other risks and uncertainties**

The Company's products include components subject to rapid technological change. Certain components used in the manufacture of some of our products have relatively few alternative sources of supply and establishing additional or replacement suppliers for such components cannot be accomplished quickly. The Company has been constrained by supply issues in the past, but was not affected by supply constraints as of December 31, 2005. While the Company has ongoing programs to minimize the adverse effect of such changes and considers technological change in estimating its reserves, such estimates could change in the future.

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

The Company extends credit to its customers, which are primarily comprised of accounts of private companies in the United States, Europe and Asia. The Company performs ongoing credit evaluations of its customers' financial conditions and generally requires no collateral.

**Accounts Receivable and Allowance for Doubtful Accounts**

Accounts receivable are recorded at the invoiced amount. The Company maintains an allowance for doubtful accounts receivable and/or notes receivable based on the expected collectibility of individual accounts. The Company regularly reviews the allowance by considering factors such as historical experience, credit quality, age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. Account balances are charged off against the allowance when the Company considers it is probable that receivable will not be recovered. The Company does not have any off-balance-sheet credit exposure related to its customers.

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Inventories**

Inventories are stated at lower of cost or market value. Cost is determined using standard cost, which approximates actual costs on a first-in, first-out basis. Market value is determined as the lower of replacement cost or net realizable value. The Company records provisions to write down its inventory for estimated obsolescence or unmarketable inventory equal to the difference between the cost of the inventory and its estimated market value based upon assumptions about future market demand and market conditions. If future demand or market conditions are less favorable than currently expected, additional inventory provisions may be required.

**Property and Equipment**

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

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

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

**Long-lived assets**

The Company periodically assesses the impairment of its long-lived assets, including its intangible assets, in accordance with the provisions of Statement of Financial Accounting Standards ( SFAS ) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. An impairment review is performed whenever events or changes in circumstances indicate that the carrying value of the Company's long-lived assets may not be recoverable. Indicators which could trigger an impairment review include, but are not limited to, significant underperformance relative to past or planned operating results, significant changes in the strategy for the overall business, significant negative industry trends and/or a significant decline in the stock price of the Company for a sustained period of time. When it is determined, based on one or more of these indicators, that the carrying value of the Company's long-lived assets may not be recoverable, the impairment is measured using the projected discounted cash flow method and charged to operations. In the year ended December 31, 2005, the Company's review of certain of its intangible assets resulted in an impairment charge of \$5.5 million (See note 4. Balance Sheet Components ).

**Intangible assets**

All of the Company's intangible assets are amortized using the straight-line method. The remaining amortization periods of our intangible assets as of December 31, 2005 are as follows:

	<b>Amortization periods of intangible assets</b>
Capitalized patent defense litigation costs	8 years
Capitalized patent license agreements	4-12 years
Customer relationships	14 years
Product technology	11 years
Trademarks	9 years
Loan closing costs	3 years

**Table of Contents**

**RITA MEDICAL SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The weighted average remaining life of the intangible assets as of December 31, 2005 was approximately 12 years.

**Goodwill**

The Company accounts for goodwill under SFAS No. 142, Goodwill and Other Intangible Assets. The SFAS No. 142 goodwill impairment model is a two-step process. First, it requires a comparison of the book value of net assets to the fair value of the reporting units that have goodwill assigned to them. Since the Company is operating in one business segment, the fair value of the reporting unit is equal to market capitalization. If the fair value drops below the net 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. The Company tests goodwill for impairment during the third quarter of every fiscal year, and when an event occurs or circumstances change such that it is reasonably possible that impairment exists. Events that could, in the future, result in impairment include, but are not limited to, sharply declining sales for a significant product or in a significant geographic region.

**Convertible debt**

The Company accounts for convertible debt under EITF Issue No. 04-08, The Effect of Contingently Convertible Debt on Diluted Earnings per Share (EITF 04-08). EITF 04-08 reflects the Task Force's conclusion that contingently convertible debt should be included in diluted earnings per share computations regardless of whether the market price trigger has been met.

**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 the Company's customers. Except for the Company's two distributors in the United States, the Company's customers may only return undamaged product within thirty days of purchase. The Company's 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 new product, subject to a limit of 5% of their purchases in the 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.

**Research and Development**

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

**Shipping**

Costs of shipping product to customers are charged to cost of revenues as incurred.

**Table of Contents**

**RITA MEDICAL SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Advertising**

Advertising production costs are expensed as incurred. Media for print placement costs are expensed in the period the advertising appears. Total advertising and promotional expenses were approximately \$198,000, \$85,000 and \$71,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

**Income Taxes**

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

**Accounting for stock-based compensation**

During the year ended December 31, 2002, the Company adopted SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. The Company accounts for stock-based employee compensation arrangements in accordance with provisions of Accounting Principles Board Opinion No. 25 ( *APB 25* ), *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board Interpretations No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans* and complies with the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*. *APB 25* does not require the recording of compensation costs when the exercise price of the options granted to employees is equal to or greater than the fair market value of the Company's stock on the date of grant or the measurement date, if later.

SFAS No. 123 requires the reporting of pro forma earnings as if the Company had accounted for its stock-based awards to employees under the fair value method. For purposes of pro forma reporting, the fair value of stock-based awards to employees is calculated using the Black-Scholes options pricing model, even though this model was developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which differ significantly from the terms and characteristics of the Company's stock option awards. The Black-Scholes model also requires subjective assumptions, including future stock price volatility and expected time to exercise, which greatly affect the calculated values.

The weighted-average fair value of stock-based compensation to employees is based on the single option valuation approach. Forfeitures are recognized as they occur and it is assumed no dividends will be declared. The value of each option grant was estimated on the date of grant using the Black-Scholes valuation model with the following weighted average assumptions:

	<b>Years ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Volatility	78%	78%	75%
Risk-free interest rate	4.10%	3.55%	3.16%
Expected life	5 years	5 years	5 years
Expected dividends	0%	0%	0%

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

	Years ended December 31,		
	2005	2004	2003
Volatility	60%	60%	70%
Risk-free interest rate	2.20%	1.10%	2.95%
Expected life	0.5 years	0.7 years	1.3 years
Expected dividends	0%	0%	0%

For pro forma purposes, the estimated fair value of stock-based compensation awards to employees is amortized using the straight-line method over the vesting period of the options. As the Company's options generally vest over a four year period, the determination of pro forma net loss and net loss per share reflects the fair value of options granted over the four years ended December 31, 2005. The weighted average per share fair values of options granted under the Company's equity incentive plans were \$2.26, \$2.47 and \$1.87 during the years ended December 31, 2005, 2004 and 2003, respectively.

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

	Years ended December 31,		
	2005	2004	2003
Net loss, as reported	\$ (10,975)	\$ (9,303)	\$ (11,079)
Add: Stock-based employee compensation expense included in reported net loss	98	26	
Deduct: Total stock-based employee compensation determined under fair value based method for all awards	(2,305)	(2,021)	(1,914)
Pro forma net loss	\$ (13,182)	\$ (11,298)	\$ (12,993)
Basic and diluted net loss per common share:			
As reported	\$ (0.26)	\$ (0.35)	\$ (0.63)
Pro forma	\$ (0.32)	\$ (0.43)	\$ (0.74)

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

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

**Net loss per share**

Basic earnings per share is calculated based on the weighted-average number of common shares outstanding during the period less the weighted average number of any common shares subject to repurchase by the Company. Diluted earnings per share further includes the dilutive effect of potential common stock consisting of stock options, warrants and shares issuable upon conversion of convertible debt into shares of common stock

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

provided that the inclusion of such securities is not antidilutive; the Company has reported net losses since its inception and therefore excludes such potentially dilutive securities from its calculation of diluted earnings per share.

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

	<b>Years ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net loss, basic and diluted	\$ (10,975)	\$ (9,303)	\$ 11,079
Weighted-average shares of common stock outstanding	41,778	26,465	17,651
Less: weighted-average shares subject to repurchase			4
Weighted-average shares used in basic and diluted net loss per common share	41,778	26,465	17,647

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

	<b>December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Effect of potential common stock:			
Options outstanding	7,527	7,273	2,675
Warrants outstanding	3,329	3,350	25
Stock issuable upon conversion of Convertible Notes	2,407		
Total potential common stock excluded from the computation of earnings per common share	13,263	10,623	2,700

**Recent accounting pronouncements**

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

In December 2004, the Financial Accounting Standards Board ( FASB ) issued Statement of Accounting Standards (SFAS) No. 123R, Share-Based Payment , which replaces SFAS No. 123. SFAS No. 123R requires public companies to recognize an expense for share-based payment arrangements including stock options and employee stock purchase plans. The statement eliminates a company's ability to account for share-based compensation transactions using APB 25, and generally requires instead that such transactions be accounted for using a fair-value based method. SFAS No. 123R requires an entity to measure the cost of employee services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant, and to recognize the cost over the period during which the employee is required to provide service in exchange for the award. SFAS No. 123R is effective for us in the quarter ending March 31, 2006. Upon adoption of SFAS 123R, companies are allowed to select one of three alternative transition methods, each of which has different financial reporting implications. Management is currently evaluating the transition methods, valuation methodologies and other assumptions for employee stock options in light of SFAS No. 123R. Current estimates of option values using the Black-Scholes method may not be indicative of results from the valuation methodologies we ultimately implement upon adoption of SFAS No. 123R. Although the Company has not yet fully quantified the impact this standard will have on its financial statements, it is likely that the adoption of SFAS No. 123R will have a material impact on its financial position and results of operations.

**Table of Contents**

**RITA MEDICAL SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In March 2005, the SEC released Staff Accounting Bulletin No. 107 ( SAB 107 ), Share-Based Payment, which provides interpretive guidance related to the interaction between SFAS No. 123R and certain SEC rules and regulations. It also provides the SEC staff's views regarding valuation of share-based payment arrangements. Management is currently evaluating the impact SAB 107 will have on the Company's consolidated financial statements.

In November 2005, the FASB issued FASB Staff Position, or FSP, FAS 115-1 and FAS 124-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments, or FSP 115-1, which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and on measuring such impairment loss. FSP 115-1 also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The Company is currently evaluating the effect that the adoption of FSP 115-1 will have on its consolidated results of operations and financial condition but does not expect FSP 115-1 to have a material impact.

Effective April 1, 2004, the SEC adopted Staff Accounting Bulletin No. 105, Application of Accounting Principles to Loan Commitments ( SAB 105 ). SAB 105 clarifies the requirements for the valuation of loan commitments that are accounted for as derivatives in accordance with SFAS No. 133. The Company has no such loan commitments. The Company does not expect the implementation of this new bulletin to have any material impact on its financial position, results of operations and cash flows.

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

In December 2004, the FASB issued Statement SFAS No. 153, Exchanges of Nonmonetary Assets an amendment of APB Opinion No. 29, which amends Opinion 29 by eliminating the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for fiscal periods beginning after June 15, 2005, and implementation is done prospectively. The Company does not expect the implementation of this new standard to have a material impact on its financial position, results of operations or cash flows.

In December 2004, the FASB issued and made effective two Staff Positions (FSP) that provide accounting guidance on how companies should account for the effect of the American Jobs Creation Act of 2004 that was signed into law on October 22, 2004. In FSP FAS 109-1, Application of FASB Statement No. 109, Accounting for Income Taxes, to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004, the FASB concluded that the special tax deduction for domestic manufacturing, created by the new legislation, should be accounted for as a special deduction instead of a tax rate reduction. As such, the special tax deduction for domestic manufacturing is recognized no earlier than the year in which the deduction is taken on the tax return. FSP FAS 109-2, Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004, allows additional time to evaluate the effects of the

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

new legislation on any plan for reinvestment or repatriation of foreign earnings for purposes of applying FASB Statement No. 109. The Company does not anticipate that this legislation will impact its results of operations or financial condition.

**Table of Contents**

**RITA MEDICAL SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In March 2005, the FASB issued FASB Interpretation (FIN) No. 47, *Accounting for Conditional Asset Retirement Obligations* An Interpretation of FASB Statement No. 143. FIN No. 47 was issued to address diverse accounting practices regarding the timing of liability recognition for legal obligations associated with the retirement of tangible long-lived assets when the timing or method of settlement of the related obligations are conditional on future events. FIN No. 47 concludes that liability should be recognized when incurred if the liability can be reasonably estimated. FIN No. 47 is effective for reporting periods after December 31, 2005. The Company does not believe the adoption of FIN No. 47 will have a material impact on its consolidated financial position, results of operations or cash flows when effective.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* a replacement of APB Opinion No. 20 and FASB Statement No. 3. SFAS No. 154 replaces APB Opinion No. 20, *Accounting Changes*, and FASB Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements* and changes the requirements for the accounting for and reporting of a change in accounting principle. This statement applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. When a pronouncement includes specific transition provisions, those provisions should be followed. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 31, 2005. The Company does not believe the adoption of SFAS No. 154 will have a material effect on its consolidated financial position, results of operations or cash flows.

In June 2005, the EITF issued a draft abstract for EITF Issue No. 05-6, *Determining the Amortization Period for Leasehold Improvements Purchased after Lease Inception or Acquired in a Business Combination*. This draft issue was subsequently finalized. The conclusion of the EITF was that leasehold improvements placed in service significantly after and not contemplated at or near the beginning of the lease term should be amortized over the shorter of the useful life of the assets or a term that includes both required lease periods and renewals that are reasonably assured (as defined in paragraph 5 of Statement 13) as of the date the leasehold improvements are purchased. The Company does not believe the adoption of EITF Issue No. 05-6 will have a material impact on its consolidated financial position, results of operations or cash flows when effective.

In February 2006, the FASB issued final FSP FAS 123R-4 *Classification of Options and Similar Instruments Issued as Employee Compensation That Allow for Cash Settlement upon the Occurrence of a Contingent Event*. The guidance in this FSP FAS 123R-4 amends paragraphs 32 and A229 of FASB Statement No. 123R to incorporate the concept articulated in footnote 16 of FAS 123R. That is, a cash settlement feature that can be exercised only upon the occurrence of a contingent event that is outside the employee's control does not meet the condition in paragraphs 32 and A229 until it becomes probable that the event will occur. Originally under FAS 123R, a provision in a share-based payment plan that required an entity to settle outstanding options in cash upon the occurrence of *any contingent event* required classification and accounting for the share based payment as a liability. This caused an issue under certain awards that require or permit, at the holder's election, cash settlement of the option or similar instrument upon (a) a change in control or other liquidity event of the entity or (b) death or disability of the holder. With this new FSP, these types of cash settlement features will not require liability accounting so long as the feature can be exercised only upon the occurrence of a contingent event that is outside the employee's control (such as an initial public offering) until it becomes probable that event will occur. The guidance in this FSP shall be applied upon initial adoption of Statement 123(R). An entity that adopted Statement 123(R) prior to the issuance of the FSP shall apply the guidance in the FSP in the first reporting period beginning after February 2006. Early application of FSP FAS 123R-4 is permitted in periods for which financial statements have not yet been issued. The Company does not anticipate that this new FSP will have any material impact on its financial condition or results of operations.

**Table of Contents**

**RITA MEDICAL SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In February 2006, the FASB issued SFAS 155 Accounting for Certain Hybrid Financial Instruments, an amendment of FASB Statements No. 133 and 140. This Statement amends FASB Statements No. 133, Accounting for Derivative Instruments and Hedging Activities, and No. 140, Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities. This Statement resolves issues addressed in Statement 133 Implementation Issue No. D1, Application of Statement 133 to Beneficial Interests in Securitized Financial Assets. This Statement:

- a. Permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation
- b. Clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement 133
- c. Establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation
- d. Clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives
- e. Amends Statement 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument.

This Statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. The fair value election provided for in paragraph 4(c) of this Statement may also be applied upon adoption of this Statement for hybrid financial instruments that had been bifurcated under paragraph 12 of Statement 133 prior to the adoption of this Statement. Earlier adoption is permitted as of the beginning of an entity's fiscal year, provided the entity has not yet issued financial statements, including financial statements for any interim period for that fiscal year. Provisions of this Statement may be applied to instruments that an entity holds at the date of adoption on an instrument-by-instrument basis. The Company is in the process of evaluating the impact of SFAS 155.

**NOTE 3: BUSINESS COMBINATION**

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

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

Each Horizon common stockholder received 0.4212 of a share of the Company's common stock for each share of Horizon common stock held. The Company thereby issued approximately 18.7 million shares of its common stock to acquire all issued and outstanding shares of Horizon common stock, and further assumed all outstanding Horizon options and warrants that, upon exercise, will result in the issuance of approximately 3.9 million shares of the Company's common stock. The fair value of shares issued by the Company was approximately \$91.6 million based on a price per share of \$4.896, the Company's average closing price the day the proposed merger was announced (May 13, 2004), the two business days preceding the announcement and the two business days following the announcement. The fair value of options and warrants, all of which were fully vested when assumed by the Company was determined to be approximately \$15.3 million using the Black-

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Scholes valuation model. Costs incurred to effect the merger included as a component of purchase price were \$2.4 million. The total purchase price was approximately \$109.3 million. The fair value of assets acquired, net of liabilities assumed, was approximately \$18.0 million, resulting in goodwill of \$91.3 million. The allocation of purchase price was as follows (in thousands):

Current assets	\$ 10,666
Property and equipment	1,312
Intangible assets	27,309
Goodwill	91,339
Other assets	6
Current liabilities	(11,337)
Debt	(9,928)
Other long term liabilities	(81)
	<hr/>
Purchase consideration	\$ 109,286
	<hr/>

During 2005, the Company recorded an impairment charge of \$5.5 million related to the intangible assets relating to the Horizon merger (see Note 4 Balance Sheet Components )

The merger was completed on July 29, 2004 and none of Horizon's results of operations prior to that date are included in the Company's condensed consolidated statements of operations for the twelve months ended December 31, 2004. The following unaudited pro forma information presents the combined results of operations of the Company and Horizon as if the acquisition had occurred as of the beginning of the years ended December 31, 2004 and 2003 respectively. This unaudited pro forma financial information is not intended to represent or be indicative of the consolidated results of operations of the Company that would have been reported had the acquisition been completed as of the dates presented and should not be taken as representative of the future consolidated results of operations or financial condition of the Company (in thousands, except per share amounts):

	<u>2004</u>	<u>2003</u>
	<u>Unaudited</u>	<u>Unaudited</u>
Sales	\$ 44,079	\$ 44,582
Net loss	\$ (13,853)	\$ (12,748)
Net loss per common share, basic and diluted	\$ (0.37)	\$ (0.35)

Restructuring costs of \$60,000 and \$1,309,000, consisting entirely of severance related to the termination of employees to eliminate certain duplicative activities, were incurred in the year ended December 31, 2005 and 2004, respectively (see Note 13, Restructuring ).

**NOTE 4: BALANCE SHEET COMPONENTS****Marketable securities:**

The Company held no marketable securities at December 31, 2005.

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

<u>Short term marketable securities</u>	<u>Cost Value</u>	<u>Unrealized Loss</u>	<u>Fair Value</u>
Corporate notes	\$ 507	\$ (1)	\$ 506
United States government agency notes	375	(1)	374
	<u>\$ 882</u>	<u>\$ (2)</u>	<u>\$ 880</u>

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The gross realized gains and losses on the Company's short-term marketable securities were minor in all periods presented.

**Accounts Receivable:**

The following is a summary of movements in allowance for doubtful accounts and sales returns during the years ended December 31, 2005 and 2004 (in thousands):

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Beginning balance	\$ 1,237	\$ 1,117
Additions to provision	114	1,420
Recoveries		(694)
Write-offs	(274)	(606)
Ending balance	<u>\$ 1,077</u>	<u>\$ 1,237</u>

**Inventories (in thousands):**

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Raw materials	\$ 2,354	\$ 2,776
Work in progress	703	682
Finished goods	2,323	3,668
	<u>\$ 5,380</u>	<u>\$ 7,126</u>

The following is a summary of the movements in the reserve for excess and obsolete inventory during the years ended December 31, 2005 and 2004 (in thousands):

	December 31,	
	2005	2004
Beginning balance	\$ 1,945	\$ 1,255
Additions to provision for excess, obsolete and expiring inventory	910	1,733
Inventory scrapped	(815)	(1,043)
Ending balance	\$ 2,040	\$ 1,945

**Property and equipment, net (in thousands):**

	December 31,	
	2005	2004
Computer equipment and software	\$ 1,538	\$ 1,464
Furniture and fixtures	347	413
Leasehold improvements	1,394	1,289
Machinery and equipment	3,259	5,223
	6,538	8,389
Less: accumulated depreciation and amortization	(4,579)	(6,423)
	\$ 1,959	\$ 1,966

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Depreciation expense was approximately \$1.2 million, \$1.1 million and \$1.2 million for the years ended December 31, 2005, 2004 and 2003, respectively.

**Intangible assets**

During the fourth quarter of fiscal 2005, due to revised revenue projections of certain of the Company's specialty access products, the Company performed an analysis of its intangible assets 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 whenever events and circumstances indicate that the carrying value of the long-lived assets may not be recoverable. The Company measured the impairment related to its product technology, customer relationships, trademarks and Isomed distribution contract by comparing their net book values to their fair values which we calculated using the projected discounted cash flow method. Based on this analysis, and confirmed by an independent appraisal, the Company recorded impairment of product technology of \$3.6 million, trademarks of \$1.5 million and Isomed distribution contract of \$0.5 million. Of the total charge of \$5.5 million, \$3.6 million was recorded in cost of sales and \$1.9 million as operating expense.

The following table sets forth the activity in the Company's intangible assets as of December 31, 2004 and 2005 (in thousands):

<u>Gross Carrying Amount</u>	<u>December 31,</u> <u>2004</u>	<u>Additions</u>	<u>Impairments</u>	<u>December 31,</u> <u>2005</u>
Capitalized patent defense litigation costs	\$ 2,755	\$	\$	\$ 2,755
Capitalized patent license agreements	2,650	1,154		3,804
Loan closing costs		127		127
<b>Patent and loan related intangibles</b>	<b>5,405</b>	<b>1,281</b>		<b>6,686</b>
Intangible assets recorded at merger with Horizon:				
Customer relationships	16,600			16,600
Product technology	6,900		(4,410)	2,490
Trademarks	3,000		(1,920)	1,080
Isomed distribution contract	700		(700)	
Loan closing costs	73			73
Non-compete contracts	36			36
<b>Acquisition related intangibles</b>	<b>27,309</b>		<b>(7,030)</b>	<b>20,279</b>
<b>Intangible assets, at cost</b>	<b>\$ 32,714</b>	<b>\$ 1,281</b>	<b>\$ (7,030)</b>	<b>\$ 26,965</b>



**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

<u>Accumulated Amortization</u>	<u>December 31, 2004</u>	<u>Additions</u>	<u>Impairments</u>	<u>December 31, 2005</u>
Capitalized patent defense litigation costs	(593)	(243)		(836)
Capitalized patent license agreements	(561)	(371)		(932)
Loan closing costs		(18)		(18)
	<u>(1,154)</u>	<u>(632)</u>		<u>(1,786)</u>
Intangible assets recorded at merger with Horizon:				
Customer relationships	(461)	(1,107)		(1,568)
Product technology	(239)	(576)	815	
Trademarks	(125)	(300)	425	
Isomed distribution contract	(73)	(175)	248	
Loan closing costs	(32)	(41)		(73)
Non-compete contracts	(30)	(6)		(36)
	<u>(960)</u>	<u>(2,205)</u>	<u>1,488</u>	<u>(1,677)</u>
Acquisition related intangibles	(960)	(2,205)	1,488	(1,677)
Total accumulated amortization	(2,114)	\$ (2,837)	\$ 1,488	(3,463)
Intangible assets, net	<u>\$ 30,600</u>			<u>\$ 23,502</u>

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

The capitalized patent license agreements include a license acquired during 2005 from EMcision Limited Incorporated (EMcision), the settlement of the Company's suit against RadioTherapeutics and suits brought against the Company by Boston Scientific Corporation and several related parties. In May 2005 the Company capitalized \$1.2 million related to cash payments of \$250,000, an additional liability to pay \$500,000 and issuance of 150,000 shares of its common stock valued at \$403,500 to EMcision to acquire patent license agreement to sell the HABIB 4X resection device. Also, in April 2003, the Company capitalized \$2,650,000 in payments made to acquire patent license agreements from Boston Scientific and the other opposing litigants.

Loan closing costs of \$127,000 associated with the Company's August 5, 2005 private placement of convertible debt have been capitalized as an intangible asset. The net carrying value of the asset was \$109,000 as of December 31, 2005.

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

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

The following table presents details of the amortization expense of intangible assets as reported in the Consolidated Statements of Operations (in thousands):

	Years ended December 31,		
	2005	2004	2003
Cost of goods sold	\$ 947	\$ 560	\$ 240
Research and development	243	242	240
Selling, general and administrative	1,588	689	
Interest expense	59	32	
	<u>\$ 2,837</u>	<u>\$ 1,523</u>	<u>\$ 480</u>

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The weighted average remaining life for the intangible assets was approximately 12 years at December 31, 2005. Estimated amortization expense of the intangible assets for each of the five years ended December 31, 2006 through 2010 and thereafter is as follows (in thousands):

<u>For the twelve months ended December 31,</u>	<u>Estimated Intangible Assets Amortization</u>
2006	\$ 2,161
2007	2,161
2008	2,143
2009	2,031
2010	1,909
Thereafter	13,097
<b>Total</b>	<b>\$ 23,502</b>

**Accrued liabilities (in thousands):**

	<u>December 31,</u>	
	<u>2005</u>	<u>2004</u>
Payroll and related expenses	\$ 911	\$ 2,170
Accrued vacation	357	280
Accrued legal and audit expenses	250	491
Accrued sales and franchise taxes	306	403
Accrued patent license costs	500	
Other accrued liabilities	982	815
	<b>\$ 3,306</b>	<b>\$ 4,159</b>

**Debt**

On August 5, 2005, the Company 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 the Company. No warrants or other securities were issued in conjunction with the

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

Purchase Agreement and the Company incurred no financing costs other than normal and customary legal and other professional expenses. The New Notes are convertible into shares of the Company's 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, the Company 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

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

A note payable for the Stepic business purchase (the Stepic Note ) was executed by Horizon in 1998. At July 29, 2004, the date of the Horizon merger, \$710,542 of the Stepic Note remained due. At December 31, 2005 and 2004, \$112,693 and \$541,658, respectively, was due under the Stepic Note. Prior to its repayment in January of 2006, the Stepic Note bore interest at 8% and called for monthly interest and principal payments of approximately \$38,000.

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

Future maturities of debt outstanding as of December 31, 2005 are as follows (in thousands):

	Outstanding as of December 31, 2005	Principal amounts due in the years ending December 31,		
		2006	2007	2008
New Notes	\$ 9,700	\$	\$	\$ 9,700
Stepic Note	113	113		
	<u>\$ 9,813</u>	<u>\$ 113</u>	<u>\$</u>	<u>\$ 9,700</u>

In January 2006, the Company entered into a revolving credit agreement of up to \$7.0 million with CapitalSource Finance LLP (see Note 15: Subsequent Event: Revolving Credit Agreement ). As of the date of this report on Form 10-K, no borrowings have been made under this revolving credit agreement.

**NOTE 5: GOODWILL**

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

The Company's merger with Horizon in fiscal year 2004 resulted in goodwill, which is the excess of purchase price over the fair value of assets acquired, of \$91.3 million. There were no changes to goodwill during the year ended December 31, 2005. Based on the results of its annual impairment test in accordance with SFAS No. 142, the Company determined that no impairment on the carrying value of its goodwill existed as of its annual impairment test date of October 31, 2005 and 2004. As of those dates, the Company's market capitalization exceeded its net book value and therefore no further analysis was required.

During the fourth quarter of 2005, due to revised revenue projections of certain of the Company's specialty access products, the Company performed an analysis of its intangible assets in accordance with SFAS 144 and recorded an impairment charge of \$5.5 million as a result of this analysis (see Note 4 - Balance Sheet Components). This was considered a possible indicator of impairment of goodwill, and the Company re-performed its goodwill impairment test as of December 31, 2005. As of December 31, 2005, the Company's market capitalization exceeded its net book value and therefore no further analysis was required.

Although the Company's market capitalization was higher than its net book value at October 31, 2005 and at December 31, 2005, its market capitalization has dropped below its net book value in the past and could do so in the future. If the Company's market capitalization drops below its net book value and/or there are indicators of

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

impairment either at its next impairment test date of October 31, 2006 or at interim basis, the Company may be required to perform an additional impairment assessment, which includes the analysis of discounted future cash flows which management believes to be an important factor in determination of the Company's sole reporting unit. This analysis takes into consideration certain assumptions on revenue growth and operating expenses. Since these financials assumptions are subject to variability, the impairment evaluation could result into a charge to earnings.

**NOTE 6: COMMITMENTS AND CONTINGENCIES****Litigation**

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

**Off-Balance Sheet Arrangements**

The Company had no off-balance sheet arrangements as of December 31, 2005.

**Operating Leases**

As of December 31, 2005, the Company had commitments under operating leases for its facilities in Fremont, California, Manchester, Georgia and Atlanta, Georgia, as well as for office and other equipment. All of the facility leases are non-cancelable. The leases pertaining to the Manchester, Georgia and Fremont California facilities expire in 2010. Rent expense was approximately \$588,000, \$597,000 and \$539,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

Future minimum payments under operating leases are as follows (in thousands):

Year ending December 31,	
2006	\$ 409
2007	386

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

2008	354
2009	355
2010 and thereafter	101
	<hr/>
Total of future minimum payments	\$ 1,605
	<hr/>

### NOTE 7: STOCKHOLDERS EQUITY

#### Private placement of common shares

As part of the November 24, 2004, Stock and Warrant Purchase Agreements, the Company sold an aggregate of 4,363,634 shares of its unregistered common stock at a per share price of \$2.75 and warrants to purchase an aggregate of 3,272,724 shares of its common stock which are initially exercisable at a price of \$4.00 per share, netting approximately \$11.1 million after issuance fees and expenses. The issuance was deemed to be exempt from registration under the Securities Act.

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

**Table of Contents**

**RITA MEDICAL SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Warrants**

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

On July 29, 2004, the Company completed its merger with Horizon. Under the terms of the merger agreement, the Company assumed 125,000 Horizon warrants, which were converted into warrants exercisable for 52,650 shares of the Company's common stock at an average price of \$2.11 per share. In 2005, 21,060 of these warrants were exercised in a net issuance exchange for 9,521 shares of the Company's common stock. In 2006, 21,060 of these warrants will expire and the remaining 10,530 will expire in 2011. Their aggregate fair value of approximately \$201,000 was recorded as part of the purchase price described in Note 3, Business Combination, using fair values determined under the Black-Scholes valuation model.

As part of the November 24, 2004 Stock and Warrant Purchase Agreements, the Company issued warrants to purchase an aggregate of 3,272,724 shares of its common stock. The warrants have an initial exercise price of \$4.00 per share and expire on November 24, 2009. The warrants provide for adjustment of the number and kind of securities purchasable upon exercise of the warrants, as well as for adjustment of the per share exercise price, upon the occurrence of certain specified events. These specified events include, without limitation, the payment by the Company of a dividend or a distribution on its common stock in shares of common stock, the consolidation or merger of the Company with another entity in which the Company is not the surviving entity, and the recapitalization, reclassification or reorganization of the capital stock of the Company. The warrants also contain an anti-dilution adjustment provision which provides for an adjustment in the per share exercise price in the event that the Company issues and sells shares of its common stock for per share consideration that is less than the exercise price then in effect, subject to customary limitations and exclusions, but in no event will the per share exercise price for the warrant be adjusted to less than \$3.23.

**NOTE 8: STOCK OPTIONS**

**2005 Stock and Incentive Plan**

The Company adopted the 2005 Stock and Incentive Plan ( 2005 Plan ) subsequent to stockholder approval at the Company's annual stockholder meeting in June 2005. This plan was implemented to replace the Company's 2000 Stock Plan to expand the types of equity awards permitted under the equity compensation plans and to take tax deductions for certain equity compensation paid to executive officers under Section 162(m) of the Internal Revenue Code of 1986, as amended. The Company reserved for issuance a maximum of 5,591,390 shares of the Company's common stock under the 2005 Plan, which included approximately 5.2 million shares for issuance of shares of common stock for options granted under the 2000 Stock Plan and 400,000 additional shares of common stock for issuance under the 2005 Plan. The types of awards that may be granted under the 2005 Plan include restricted stock grants, restricted stock units, stock appreciation rights, stock purchase rights, and other similar types of awards as well as cash awards. Up to 400,000 shares of common stock may be granted under the 2005 Plan as restricted

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

stock grants, stock purchase rights and restricted stock units or any similar type of award that does not require the participant to pay the Company an amount equal to the fair market value of the common stock as of the award grant date. The maximum number of shares subject to awards that may be granted to any one participant under the 2005 Plan during any single fiscal year of the Company is 1.0 million shares and the maximum value of any cash award granted under the 2005 Plan is \$500,000. The 2005 Plan will expire in 2015 unless it is terminated earlier pursuant to its terms. The average vesting period of options granted under this plan has been 4 years.

**Table of Contents**

**RITA MEDICAL SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2000 Director s Stock Option Plan**

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

**2000 Stock Plan**

Prior to its termination subsequent to the Company s adoption of the 2005 Plan, the 2000 Stock Plan provided for the grant of incentive stock options to employees and non-statutory stock options and stock purchase rights to employees, directors and consultants. A total of 2,000,000 common shares were originally available for issuance under this plan at its inception in 2000. A total of 810,292 common shares were available for issuance as of December 31, 2004. Future increases to the shares available for issuance occurred on the first day of each fiscal year through 2005 in the amount of the lesser of 1,000,000 shares, 7% of the Company s outstanding common stock on the last day of the preceding fiscal year or a lower number as determined by the board of directors. Incentive stock options granted under this plan had an exercise price of at least 100% of the fair market value of the common stock on the date of the grant, and at least 110% of the fair market value of the common stock if the options were awarded to an employee who held more than 10% of the total voting power of all classes of the Company s stock. Options granted under this plan became exercisable and vest on a cumulative basis at the discretion of the board of directors and generally expire ten years from the date of grant. The average vesting period of options granted under this plan was approximately 4 years.

**1998 Incentive Stock Plan**

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

**1994 Incentive Stock Plan**

Under the 1994 Incentive Stock Plan, options were granted to employees and non-employees at prices determined by the board of directors to be not lower than 85% of the fair market value of the common stock for non-statutory stock options or 100% of the fair market value of the common stock for incentive stock options. For individuals who at the time of grant owned stock representing more than 10% of the voting power of all classes of outstanding stock, options were granted at prices not lower than 110% of the fair value of the common stock for both non-statutory and incentive stock options. Options granted under this plan become exercisable and vest on a cumulative basis at the discretion of

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

the board of directors and generally expire ten years from the date of grant. The average vesting period of options granted under this plan was approximately 4 years. The Company's board of directors has determined that no future grants will be made under this plan.

Table of Contents

## RITA MEDICAL SYSTEMS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Shares Available	Options Outstanding		
		Shares	Aggregate Exercise Price	Weighted Average Exercise Price
Balances, December 31, 2002	891	2,725	\$ 12,029	\$ 4.41
Shares reserved	1,000			
Options granted	(1,724)	1,724	5,118	2.97
Options exercised		(714)	(1,029)	1.44
Options canceled	1,001	(1,060)	(5,607)	5.29
Balances, December 31, 2003	1,168	2,675	10,511	3.93
Shares reserved	1,000			
Options assumed in merger		3,814	7,452	1.95
Options granted	(1,455)	1,455	4,909	3.37
Options exercised		(244)	(546)	2.24
Options canceled	391	(427)	(2,090)	4.89
Balances, December 31, 2004	1,104	7,273	20,236	2.78
Shares reserved	1,900			
Options granted	(1,806)	1,806	6,389	3.54
Options exercised		(1,088)	(2,808)	2.58
Options canceled	403	(464)	(2,368)	5.10
Balances, December 31, 2005	1,601	7,527	\$ 21,449	\$ 2.85

**Stock Options: Options outstanding and exercisable**

Options outstanding, from all plans, and exercisable as of December 31, 2005 are as follows by exercise price ranges (in thousands, except per share data):

Range of Exercise Prices	Options Outstanding	Options Exercisable

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

	<u>Number Outstanding</u>	<u>Weighted- Average Remaining Contractual Life</u>	<u>Weighted- Average Exercise Price</u>	<u>Number Outstanding</u>	<u>Weighted- Average Exercise Price</u>
\$0.50 to \$ 1.07	1,814	6.12 years	\$ 1.06	1,814	\$ 1.06
\$1.19 to \$ 1.94	463	2.18 years	\$ 1.73	463	\$ 1.73
\$2.12 to \$ 2.52	1,049	6.28 years	\$ 2.41	703	\$ 2.35
\$2.57 to \$ 3.07	966	8.55 years	\$ 2.89	370	\$ 2.89
\$3.09 to \$ 3.42	1,367	8.74 years	\$ 3.26	416	\$ 3.19
\$3.43 to \$ 3.92	804	9.04 years	\$ 3.76	186	\$ 3.70
\$4.03 to \$ 6.75	942	6.87 years	\$ 4.56	488	\$ 4.86
\$8.02 to \$34.73	122	4.84 years	\$ 13.28	120	\$ 13.35
	<u>7,527</u>	<u>7.07 years</u>	<u>\$ 2.85</u>	<u>4,560</u>	<u>\$ 2.51</u>

At December 31, 2005, 2004 and 2003, the Company had approximately 4,560,000, 4,888,000, and 740,000 options exercisable at weighted average exercise prices of \$2.51, \$2.58, and \$5.36, respectively.

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2000 Employee Stock Purchase Plan**

The Company's 2000 employee stock purchase plan was adopted in the second quarter of 2000. A total of 650,000 common shares were initially reserved for issuance under this plan. Automatic increases occurred on the first day of 2002, 2003, 2004, and 2004 and will occur on the first day of each year until 2010, in amounts equal to the lesser of 650,000 shares, 4% of the Company's outstanding common stock on the last day of the preceding year, or such lesser number that board of directors determines. This plan permits employees to purchase common shares at a price equal to the lower of 85% of the fair market value of the common stock at the beginning of each offering period or the end of each offering period. Employee purchases are nonetheless limited to 15% of eligible cash compensation, and other restrictions regarding the amount of annual purchases also apply. As of December 31, 2005, there have been 420,660 shares issued under this plan and 879,243 shares available for issuance under this plan.

**Stock-based compensation**

During the years ended December 31, 2005, 2004, and 2003, the Company recorded approximately \$98,000, \$26,000 and \$0, respectively, in employee stock-based compensation expense as selling, general and administrative expenses. These expenses related to options granted to consultants, options granted to certain employees in consideration of contractual rights waived and acceleration of stock options for certain terminated employees. Such stock compensation expense has been recognized over the vesting periods of the related options, generally four years. Option grants to a director in compensation for consulting services were made in 2004 and 2003. (See Note 10, "Related Party Transactions").

**NOTE 9: INCOME TAXES**

No provisions for federal income taxes were recorded during the years ended December 31, 2005 and 2004, as the Company incurred net operating losses during these years.

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

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Net operating loss carryforwards	\$ 40,432	\$ 38,525

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

Capitalized research and development costs	901	1,371
Research and development credit	1,534	1,225
Other	2,757	2,466
	<u>          </u>	<u>          </u>
Gross deferred tax assets	45,624	43,587
Deferred tax liability intangible assets	(7,198)	(10,478)
	<u>          </u>	<u>          </u>
Total deferred tax assets	38,426	33,109
Less: Valuation allowance	(38,426)	(33,109)
	<u>          </u>	<u>          </u>
Net deferred tax assets	\$	\$
	<u>          </u>	<u>          </u>

At December 31, 2005, the Company had federal and state net operating loss carryforwards of approximately \$111.3 million and \$55.2 million, respectively, available to offset future taxable income. The Company's federal and state operating loss carryforwards expire between 2008 and 2025 and between 2006 and 2015, respectively, if not utilized.

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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

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

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Tax at federal statutory rate	34.0%	34.0%	34.0%
State, net of federal benefit	(3.9)	6.0	6.0
Other	(0.5)		
Deferred tax assets not benefited	(30.7)	(39.0)	(38.0)
Federal research and development credits	1.1	(1.0)	(2.0)
	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

**NOTE 10: RELATED PARTY TRANSACTIONS**

During the years ended December 31, 2004 and 2003 the Company received professional services relating to the administration of its clinical trials as well as regulatory advice from a firm in which one of the Company's directors serves as an officer. The Company has recognized expenses relating to the services received from this firm of approximately \$14,000, \$55,000 for the years ended December 31, 2004 and 2003, respectively. No such professional services were received in 2005.

In April 2003, a member of the Company's Board of Directors began providing consulting services to the Company. In 2003, this board member was paid approximately \$164,000 and was granted options to purchase 35,000 shares of the Company's common stock under his consulting agreement. In 2004, this board member was granted options to purchase an additional 10,000 shares of the Company's common stock in connection with his consulting services. The Company is recognizing the expense of all of the options granted to this board member for consulting services using the Black-Scholes valuation model. This expense totaled \$21,000 and \$94,000 for the years ended December 31, 2005 and 2004, respectively.

**NOTE 11: SEGMENT INFORMATION**

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

Operating segments are defined as components of an enterprise of which separate financial information is available and it is evaluated regularly by the Company's chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker reviews financial information on a consolidated basis, accompanied by disaggregated information about sales by groups of similar products for purposes of making operating decisions and assessing financial performance. However, significant expenses such as research and development and corporate administration are not allocated to product groups or geographical regions, but rather are employed by the entire enterprise. For this reason, the Company's

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

chief operating decision maker evaluates resource allocation on an enterprise-wide basis, and not on a product or geographic basis. Accordingly, the Company has concluded that it operates in only one reportable segment, the medical oncology products business.

The following table presents sales information for the Company's two product groups for the years ended December 31, 2005, 2004 and 2003 (in thousands):

	Years Ended December 31,		
	2005	2004	2003
<b>Sales:</b>			
Radiofrequency ablation products	\$ 20,483	\$ 17,553	\$ 16,607
Specialty access catheter products	25,958	10,662	
<b>Total</b>	<b>\$ 46,441</b>	<b>\$ 28,215</b>	<b>\$ 16,607</b>

Sales for geographic regions reported below are based upon the customers' locations. Following is a summary of the geographic information related to revenues and long-lived assets for the years ended December 31, 2005, 2004 and 2003 (in thousands):

	Years Ended December 31,		
	2005	2004	2003
<b>Sales:</b>			
United States	\$ 39,343	\$ 23,612	\$ 13,274
Italy	1,041	883	726
Japan	484	437	535
Other	5,573	3,283	2,072
<b>Total</b>	<b>\$ 46,441</b>	<b>\$ 28,215</b>	<b>\$ 16,607</b>

Years Ended December 31,		
2005	2004	2003

Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

<b>Long-lived assets:</b>			
United States	\$ 1,799	\$ 1,966	\$ 1,089
Europe	160		
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Total</b>	<b>\$ 1,959</b>	<b>\$ 1,966</b>	<b>\$ 1,089</b>
	<u>          </u>	<u>          </u>	<u>          </u>

In the years ended December 31, 2005, 2004 and 2003, the Company had no customers accounting for 10% or more of its sales. In the year ended December 31, 2005 the Company had one customer accounting for 11% of its outstanding accounts and notes receivable. In the year ended December 31, 2004, the Company had no customers accounting for 10% or more of its outstanding accounts and notes receivable.

**NOTE 12: EMPLOYEE BENEFIT PLAN**

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

**Table of Contents****RITA MEDICAL SYSTEMS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****NOTE 13: RESTRUCTURING**

The Company accounts for restructuring in accordance with SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. In connection with the merger of RITA and Horizon, the Company recorded total restructuring charge of \$1,369,000 of which \$60,000 was recorded in the year ended December 31, 2005 and \$1,309,000 in the year ended December 31, 2004 to eliminate certain duplicative activities, primarily in the sales, accounting and operations areas. As of December 31, 2005, \$1,356,000 of the accrued amount has been paid and \$13,000 remains unpaid. The Company completed the cash payments related to the workforce reduction in January 2006.

**NOTE 14: QUARTERLY RESULTS OF OPERATIONS (UNAUDITED):**

The following table sets forth selected items from the Company's consolidated statements of operations for each of the eight quarters ended December 31, 2005. This data has been derived from unaudited consolidated financial statements that, in the opinion of the Company's management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of such information when read in conjunction with our annual audited consolidated financial statements and notes thereto appearing elsewhere in this Form 10-K. The operating results for any quarter are not necessarily indicative of results for any future period. (In thousands, except per share amounts.)

	Quarter Ended							
	Dec. 31, 2005	Sept. 30, 2005	June 30, 2005	Mar. 31, 2005	Dec. 31, 2004	Sept. 30, 2004	June 30, 2004	Mar. 31, 2004
Sales	\$ 12,090	\$ 11,191	\$ 11,955	\$ 11,205	\$ 10,961	\$ 7,951	\$ 4,659	\$ 4,644
Gross profit	2,726	6,669	7,332	6,400	5,867	5,130	2,989	3,029
Net loss	(7,194)	(705)	(1,387)	(1,689)(a)	(1,872)(a)	(3,258)(a)	(2,003)	(2,170)
Net loss per common share, basic and diluted	\$ (0.17)	\$ (0.02)	\$ (0.03)	\$ (0.04)	\$ (0.05)	\$ (0.10)	\$ (0.11)	\$ (0.12)
Shares used in computing net loss per common share, basic and diluted.	42,302	41,794	41,548	41,457	38,574	31,079	18,025	17,998

(a) Net loss during the quarters ended March 31, 2005, December 31, 2004 and September 30, 2004 include restructuring charges of \$60, \$220 and \$1,089, respectively. Restructuring charges are discussed in Note 13, Restructuring.

**NOTE 15: SUBSEQUENT EVENT: REVOLVING LINE OF CREDIT AGREEMENT**

On January 31, 2006, the Company 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 the Company to borrow

## Edgar Filing: RITA MEDICAL SYSTEMS INC - Form 10-K

at any time is limited to the aggregate of (i) varying percentages of the amount of the Company's eligible receivables and (ii) varying percentages of the amount of the Company's eligible finished goods inventory. The applicable percentages are determined based on the level of the Company's EBITDA (as defined in the Credit Agreement) for the prior quarter and its inventory turns ratio. In addition, the amount otherwise available to borrow based on the aforementioned criteria is required to be reduced by a required liquidity reserve of \$1,000,000 to \$1,500,000 depending on the level of the Company's EBITDA (as defined in the Credit Agreement) for the prior quarter. The principal available for the Company 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 the tangible and intangible assets of the Company and its subsidiaries. The Credit Agreement provides for the use of

**Table of Contents**

**RITA MEDICAL SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

a lockbox for the collection of the Company's 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 the Company (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 quarter.

The Credit Agreement contains affirmative covenants that require the Company to promise, among other things, to deliver financial statements and other financial information to CapitalSource, to maintain its insurance policies, to allow inspection of its 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 its inventory. The Credit Agreement also contains negative covenants that will limit the ability of the Company 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 its charter documents, transfer its 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 property of the Company and its subsidiaries 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.

The Company 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. The Company 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 daily average amount of the balances under the revolving credit facility outstanding during the preceding month, from (ii) \$7,000,000. Additionally, the Company is obligated to pay a termination fee of up to \$210,000 if it terminates the Credit Agreement prior to its expiration. The Company has not yet made any borrowings under the revolving credit facility.