RITA MEDICAL SYSTEMS INC
Form 424B3
September 13, 2005

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Registration Statement No. 333-128069

PROSPECTUS

RITA MEDICAL SYSTEMS, INC.

2,406,947 Shares of Common Stock

This prospectus relates to the resale of up to 2,406,947 shares of our common stock, par value $0.001 per share, issuable upon conversion of subordinated senior convertible notes held by the selling securityholder identified on page 10 of this prospectus. See "Plan of Distribution" on page 11 of this prospectus for a description of the manner in which shares of common stock may be offered and sold by the selling securityholder under this prospectus. The selling securityholder may be deemed to be an "underwriter," as such term is defined in the Securities Act of 1933.

The selling securityholder identified on page 10 of this prospectus may offer and sell the shares of common stock covered by this prospectus from time to time. We will not receive any of the proceeds from the sale of the shares by the selling securityholder. The selling securityholder will receive all of the proceeds from the sale of the shares and will pay all underwriting discounts and selling commissions, if any, applicable to the sale of the shares. We will pay the expenses of registration of the sale of the shares.

Our common stock trades on the Nasdaq National Market under the symbol "RITA". On September 12, 2005, the last reported sale price of our common stock on the Nasdaq National Market was $3.79 per share.

Beginning on page 3 of this prospectus, we have listed several "RISK FACTORS" which you should consider. You should read the entire prospectus carefully before you make your investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is September 13, 2005.

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, using a “shelf” registration or continuous offering process. Under this shelf registration process, the selling securityholder may from time to time sell the securities described in this prospectus in one or more offerings.

This prospectus provides you with a general description of the securities that the selling securityholder may offer. The selling securityholder may be required to provide you with a prospectus supplement containing specific information about the selling securityholder and the terms of the securities being offered. That prospectus supplement may include additional risk factors or other special considerations applicable to those securities. A prospectus supplement may also add, update or change information in this prospectus. If there is any inconsistency between the information in this prospectus and any prospectus supplement, you should rely on the information in that prospectus supplement. You should read both this prospectus and any prospectus supplement together with the additional information described under the heading “Where You Can Find More Information.”

Unless we have indicated otherwise, references in this prospectus to “RITA,”“we,”“us” and “our” or similar terms are to RITA Medical Systems, Inc. and its consolidated subsidiaries, and references to “Horizon” are to Horizon Medical Products, Inc.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus and the other documents incorporated by reference into this prospectus contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements in this prospectus and the other documents incorporated into this prospectus by reference that are not historical facts are identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Section 27A of the Securities Act of 1933, as amended, or the Securities Act. Forward-looking statements include projections, assumptions or information concerning possible or assumed future actions, events or our results of operations. These statements involve estimates and assumptions based on the judgment of the company's management. A number of risks and uncertainties may cause actual results to differ materially from those suggested by the forward-looking statements.

Forward-looking statements include the information in this prospectus and the other documents incorporated by reference into this prospectus. These statements may be made regarding the business, operations, financial performance and condition, earnings, our prospects and products, as well as regarding our industry generally. These statements may be preceded by, followed by or include the words "believes,""expects,""anticipates,""intends,""plans,""estimates,""should" or similar expressions. We claim the protection of th harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 for all forward-looking statements. We do not undertake any obligation to publicly update any forward-looking statements to reflect subsequent events or circumstances.

Forward-looking statements are not guarantees of performance. You should understand that these factors, in addition to those discussed in "Risk Factors" above and elsewhere in this document, and in the documents that are incorporated by reference into this prospectus, could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in any forward-looking statement.

THE COMPANY

We develop, manufacture and market innovative products for cancer patients including radiofrequency ablation, or RFA, systems for treating cancerous tumors as well as percutaneous vascular and spinal access systems. Our oncology product lines include implantable ports, some of which feature our proprietary VTX(R) technology; tunneled central venous catheters; and stem-cell transplant catheters used primarily in cancer treatment protocols. The proprietary RITA system uses radio frequency energy to heat tissue to a high enough temperature to ablate it or cause cell death. In March 2000, we became the first RFA company to receive specific U.S. Food and Drug Administration, or 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.

We are a Delaware corporation and are headquartered in Fremont, California with operations in Fremont, California, Manchester, Georgia and Atlanta, Georgia. Our principal executive offices are located at 46421 Landing Parkway, Fremont, California 94538, and our telephone number is (510) 771-0400. Our internet website is www.ritamedical.com. Information set forth on our website is not incorporated by reference into this prospectus.

RISK FACTORS

In addition to the other information included in this prospectus, including the matters addressed in "Cautionary Statement Concerning Forward-Looking Statements," you should consider carefully the following risks related to our common stock before deciding to invest in our shares of common stock. These factors, among others, may cause actual results, events or performance to differ materially from those expressed in any forward-looking statements we make in this prospectus.

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.

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

We have transitioned our California-based manufacturing operations to our Manchester, Georgia location. We have incurred low product yields in our initial production runs of RFA products in Georgia. 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.

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

To date, we have identified material weaknesses in our procurement process which did, prior to adjustment, or could otherwise, result in a material misstatement of our annual or interim financial statements. As a result of these material weaknesses, we have determined that we did not maintain effective internal control over financial reporting as of December 31, 2004. See our disclosure in "Status of Management's Report on Internal Control over Financial Reporting" included in our annual report on Form 10-K, as amended, for the year ended December 31, 2004 for further discussion of these material weaknesses.

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 June 30, 2005, we have less than a full year 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 will be heavily dependent on the RITA system and our line of specialty access catheters in order to achieve our sales goals and our profitability targets. Failure to achieve and grow market acceptance for either product line could harm our business.

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

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

We incurred net losses of $3.1 million during the first six months of 2005, $9.3 million in 2004, $11.1 million in 2003, $13.5 million in 2002, $13.0 million in 2001, $12.8 million in 2000 and $7.5 million in 1999. At June 30, 2005, we had an accumulated deficit of $91.4 million. To become profitable we must increase our sales and continue to limit the growth of our operating expenses. If our sales do not grow, or if expenses grow excessively, we may not be able to achieve or maintain profitability in the future.

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

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

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

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

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

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

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

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

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

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

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products, and yet we may be unable to do so. A number of companies in our market, as well as universities and research institutions, have issued patents and have filed patent applications that relate to the use of radiofrequency energy to ablate soft tissue or to the design or manufacture of implantable vascular products. Under certain circumstances these 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 may be difficult and time consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time consuming and could divert management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against a challenge. In addition, confidentiality agreements executed by our employees, consultants and advisors may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure. If we are unable to protect our intellectual property rights, we could lose market share to our competitors and our business could suffer.

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

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

• the challenge of managing international sales without direct access to the end customer;

• lower average selling prices for our products, due to distributor discounts;

• the risk of inventory build-up by our distributors which could negatively impact sales in future periods;

• obtaining reimbursement for procedures using our devices in some foreign markets;

• the burden of complying with complex and changing foreign regulatory requirements;

• longer accounts receivable collection time;

• 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 18% of our international sales in the first six months of 2005 and 19% of our international sales for the year ended December 31, 2004. International sales accounted for 16% of our total sales in the first six months of 2005 and 16% of our total sales for the year ended December 31, 2004. 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 sell our products in international markets and selected domestic markets through third-party distributors over whom we have limited control, and, if they fail to adequately support our products, our sales could decline. In the past, we have terminated agreements with distributors and although we contracted with replacement distributors, we expended significant time and resources in doing so, and our sales in the affected markets suffered during the transition period that lasted approximately nine months. If our distributors or we terminate other distributor

agreements, we could incur similar or more burdensome expenses, we could expend significant time and resources in finding replacement distributors 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.

In 2002, we significantly increased our allowance for doubtful accounts to address the risk associated with longer collection periods that have arisen principally with our European distributors. Although the deterioration we experienced in international collections in 2002 stabilized in 2003, and has remained stable in 2004 and 2005, 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. 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.

If customers in markets outside the United States experience difficulty obtaining reimbursement for procedures using our products, international sales could decline.

Certain of the markets outside the United States in which we sell our products require that specific reimbursement codes be obtained before reimbursement for procedures using our products can be approved. As a result, in countries where specific reimbursement codes are strictly required and have not yet been issued, reimbursement has been denied on that basis. If our distributors or we are unable to either obtain the required reimbursement codes or develop an effective strategy to resolve the reimbursement issue, physicians in foreign markets may be unwilling to purchase our products, negatively impacting our international revenues.

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

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

There can be no assurance that reimbursement for 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.

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 Chief Financial Officer announced his resignation effective as of October 2005, and a search is being conducted for a replacement. Our future success will depend in part on the continued service of our staff and our ability to identify, hire and retain additional personnel. The markets for qualified management personnel in Northern California, where our headquarters are located, and Georgia, where are primary operating facilities are located, are competitive and expected to remain so. Because the environment for 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 understanding how and when our products should be used. If physicians are not properly trained, they may misuse or ineffectively use our products. Such use may result in unsatisfactory patient outcomes, patient injury and related liability or negative publicity that could have an adverse effect on our product sales.

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

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

• our ability to repay debt;

• our ability to successfully commercialize our products;

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

• conclusions that our internal control over financial reporting are ineffective;

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

• quarterly fluctuations in our results of operations;

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

• product liability claims;

• regulatory developments regarding us or our competitors;

• acquisitions or strategic alliances by us or our competitors;

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

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

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

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

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

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

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

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

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

Sales of our products outside the United States are subject to foreign regulatory requirements that vary from country to country. The time required to obtain approvals from foreign countries may be longer than that required for FDA approval or clearance, and requirements for foreign licensing may differ from FDA requirements. For example, some of our newer RFA products have not received approval in Japan. Any failure to obtain necessary regulatory approvals for our new products in foreign countries could negatively affect revenues.

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

Unless we are exempt, we must obtain the appropriate FDA approval or clearance before we can sell a new medical device in the United States. Obtaining this approval or clearance can be a lengthy and time-consuming process. To date, all of our products have received clearances from the FDA through premarket notification under Section 510(k) of the Federal Food, Drug and Cosmetic Act. However, if the FDA requires us to submit a new premarket notification under Section 510(k) for modifications to our existing products, or if the FDA requires us to go through a lengthier, more rigorous examination than we now expect, our product introductions or modifications could be delayed or canceled which could cause our revenues to be below expectations. The FDA may determine that future products will require the more costly, lengthy and uncertain premarket approval process.

In addition, modifications to medical device products cleared via the 510(k) process may require a new 510(k) submission. We have, in the past, made minor modifications to the RITA system and to our implantable vascular products. Using the guidelines established by the FDA, we have determined that some of these modifications do not require us to file new 510(k) submissions. If the FDA disagrees with our determinations, we may not be able to sell the RITA system or our implantable vascular products until the FDA has cleared new 510(k) submissions for these modifications, or it may require us to recall previously sold products. In addition, we intend to request additional label indications, such as approvals or clearances for the ablation of tumors in additional organs, including lung, uterus and breast, for our current products. The FDA may either deny these requests outright, require additional extensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of approval or clearance. Therefore, obtaining necessary approvals or clearances for these additional applications could be an expensive and lengthy process. In addition, in the course of the FDA process leading to clearance or approval for a new indication, the FDA may request an advisory panel meeting or meetings to discuss the clinical data, the appropriate study design or other criteria for clearance or approval. In the event that the advisory panel advises FDA that the clinical data are inadequate or the study design or other criteria are inappropriate, and the FDA concurs, the FDA clearance or approval process could be lengthened and anticipated revenues from that new indication would be delayed.

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

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

• diversion of management’s attention from our core business objectives and other business concerns;

• failure to integrate efficiently businesses or technologies acquired in the future with our pre-existing business or technologies;

• potential loss of key employees from either our pre-existing business or the acquired business;

• dilution of our existing stockholders as a result of issuing equity securities; and

• assumption of liabilities of the acquired company.

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

We may need to raise additional capital in the future resulting in dilution to our stockholders.

We may need to raise additional funds for our business operations and to execute our business strategy. We may seek to sell additional equity or debt securities or to obtain an additional credit facility. The sale of additional equity or convertible debt securities could result in additional dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights that are senior to holders of common stock and could contain covenants that would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, if at all. Failure to obtain sufficient funds on acceptable terms when needed or to make timely debt payments may require us to curtail operations, perhaps to a significant extent.

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

Our executive officers and directors, and their respective affiliates, own approximately 4.6% of our outstanding common stock as of June 30, 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.

USE OF PROCEEDS

The proceeds from the sale of the shares of common stock offered pursuant to this prospectus are solely for the account of the selling securityholder. As such we will not receive any of the proceeds from the sale of these shares. As of September 12, 2005, the last sale price of our common stock on the Nasdaq National Market was $3.79.

TRANSACTIONS WITH SELLING SECURITYHOLDER

On August 5, 2005, we issued in a private placement subordinated Senior Convertible Notes with an aggregate principal amount of $9.7 million to Atlas Master Fund, Ltd. The notes are convertible into shares of our common stock at an initial conversion price of $4.03 per share of common stock. The conversion price is subject to adjustment in certain circumstances. The notes bear interest at a rate of 6.5% per year, which interest is payable semi-annually on December 15 and June 15 each year, beginning December 15, 2005, and are due on August 5, 2008. During the occurrence of an “Event of Default” under the notes, the notes will bear interest at a rate of 12% per year. The notes are subordinate in right of payment to our existing “Senior Debt”, which as of September 1, 2005 consists of the Agreement by and among Steven Picheny, Howard Fuchs and the Company dated as of March 14, 2002, as amended. The notes will also be subordinate in right of payment to a working capital line in an amount not to exceed $10 million into which we may enter in the future.

If on the maturity date of the notes, the closing price of our common stock has been at or above 102% of the then current conversion price for at least 10 consecutive business days immediately preceding August 5, 2008, then any remaining principal outstanding under the notes shall automatically be converted into shares of our common stock, subject to certain conditions set forth in the notes.

SELLING SECURITYHOLDER

The following table sets forth certain information as of August 26, 2005 with respect to the selling securityholder. We are unable to determine the exact number of shares that actually will be sold by the selling securityholder. We do not know how long the selling securityholder will hold the shares before selling them. We assume the selling securityholder will sell all shares offered by such selling securityholder in this prospectus.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that entity named in the table below have sole voting and investment power with respects to all shares of common stock that it beneficially owns, subject to applicable community property laws. We have based our calculation of the percentage of beneficial ownership on 41,827,313 shares of common stock outstanding on August 26, 2005.

Except as indicated in “Transactions with Selling Securityholder” on page 9 of this prospectus, or by the footnotes below, the selling securityholder has not had any material relationship with us or any of our predecessors or affiliates within the last three years. Except as indicated by the footnotes below, the selling securityholder is not a broker-dealer or affiliate of broker-dealers. The selling securityholder acquired the shares being offered in this prospectus in the ordinary course of business and at the time of acquisition the selling securityholder had no direct or indirect agreements or understandings with any person to distribute such shares. Information about the selling securityholder may change over time. Any changed information given to us by the selling securityholder will be set forth in prospectus supplements if and when necessary.

Selling Securityholder [1]	Number of Shares of Common Stock Beneficially Owned Before the Offering [2]	Number of Shares of Common Stock to be Resold in the Offering [3]	Shares Offered by this Prospectus	Percentage of Shares of Common Stock Owned	
				Before Offering of the Resale Shares	After Offering of