

RITA MEDICAL SYSTEMS INC

Form 424B3

August 23, 2004

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Filed Pursuant to Rule 424(b)(3)

Registration No. 333-116378

PROSPECTUS

## RITA MEDICAL SYSTEMS, INC.

### 10,544,037 Shares of Common Stock

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This prospectus relates to the resale of up to 10,544,037 shares of our common stock, par value \$0.001 per share, of which (i) 10,491,387 were issued by us to the selling stockholders identified in this prospectus in connection with our acquisition of Horizon Medical Products, Inc., a Georgia corporation, or Horizon Medical Products, on July 29, 2004, and (ii) 52,650 are issuable upon the exercise of exercise of currently outstanding warrants of Horizon Medical Products assumed by us. See Plan of Distribution on page 13 of this prospectus for a description of the manner in which shares of common stock may be offered and sold by the selling stockholders under this prospectus.

The selling stockholders identified on page 12 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 stockholders. The selling stockholders 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 August 19, 2004, the last reported sale price of our common stock on Nasdaq was \$3.15 per share.

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**Beginning on page 2 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.**

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**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.**

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**The date of this prospectus is August 19, 2004.**

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**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 stockholders 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 stockholders may offer. A selling stockholder may be required to provide you with a prospectus supplement containing specific information about the selling stockholder 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** or **Horizon Medical Products** 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, or the Exchange Act, and Section 27A of the Securities Act of 1933, 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** or similar expressions. We claim the protection of the safe 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** below 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.



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### THE COMPANY

We develop, manufacture and market devices used by physicians to treat patients with solid cancerous or benign tumors. Founded in 1994, we are a publicly held company listed on the Nasdaq National Market under the symbol RITA. Our proprietary system, the RITA System, is a minimally invasive treatment option for cancer patients with unresectable, or inoperable, tumors. The system delivers controlled thermal energy to targeted tissue at a temperature high enough to ablate the tumor, or cause cell death. Our portfolio of products includes disposable electro-surgical devices, radiofrequency generators, introducers and software. On July 29, 2004, we completed the acquisition of Horizon Medical Products, Inc., a Georgia corporation, a company that develops, manufactures and markets vascular access products.

We are a Delaware corporation and are headquartered in Mountain View, California with operations in Mountain View, California and Manchester, Georgia. Our principal executive offices are located at 967 North Shoreline Blvd, Mountain View, California 94013, and our telephone number is (650) 314-3400. Our internet website is [www.ritamedical.com](http://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 may be unable to integrate our operations successfully and realize all of the anticipated benefits of our merger with Horizon Medical Products.**

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

Coordinating geographically disparate organizations, systems and facilities;

Integrating personnel with diverse business backgrounds;

Consolidating corporate and administrative functions;

Consolidating research and development, and manufacturing operations;

Coordinating sales and marketing functions;

Retaining key employees; and

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

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

**If our independent auditor is unable to provide us with an unqualified report as to the adequacy of our internal controls over financial reporting as of December 31, 2004 and future year-ends as required by Section 404 of the Sarbanes-Oxley Act of 2002, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.**

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the company's internal controls over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of such company's internal controls over financial reporting. In addition, the public accounting firm auditing our financial statements must attest to and report on management's assessment of the effectiveness of our internal controls over financial reporting. We are expending significant resources in developing the necessary documentation and testing procedures required by Section 404. Compliance with all of the requirements imposed by Section 404 will be very difficult due at least in part to the changes in processes we expect to make in conjunction with the merger with Horizon Medical Products. If we fail to implement required new or improved controls, or if our independent auditors are not satisfied with our internal controls over financial reporting or with the level at which these controls are documented, operated or reviewed, they may decline to attest to management's assessment or may issue a qualified report. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements, which could cause the market price of our shares to decline.

**We will be heavily dependent on the RITA system and Horizon's line of implantable vascular ports in order to achieve our sales goals. 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, after the date of the Horizon merger, Horizon's line of implantable vascular ports. 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 revenues because we do not have alternative products.

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

We incurred net losses of \$4.2 million in the first six months of 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, 2004, we had an accumulated deficit of \$83.1 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.

We compete directly with two companies in the domestic and international markets: RadioTherapeutics Corporation, a division of Boston Scientific Corporation, and Radionics, Inc., a division of Tyco Healthcare, which is a division of Tyco International. Boston Scientific Corporation 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.

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

### **Alternative therapies could prove to be superior to the RITA system, and physician adoption could be negatively affected.**

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

### **We currently lack long-term data regarding the safety and efficacy of our 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 products in various applications. If the safety or efficacy of our products is questioned, our sales could decline.**

Our 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



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effectiveness of our 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.

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**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. Under certain circumstances these could result in lawsuits against us. Our pending United States and foreign patent applications may not issue or may issue and be subsequently successfully challenged by others. In addition, our pending patent applications include claims to material aspects of our products that are not currently protected by issued patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

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

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

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

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

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

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.



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**We are substantially dependent on two distributors in our international markets, and if we lose either distributor or if either distributor significantly reduces its product demand, our international and total revenues could decline.**

We are substantially dependent on a limited number of significant distributors in our international markets, and if we lose these distributors and fail to attract additional distributors, our international revenues could decline. ITX Corporation, formerly known as Nissho Iwai Corporation, is our primary distributor in Asia. Although it accounted for only 2% of our revenue in the first half of 2004, it accounted for 21% of our international revenues in 2003. M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, accounted for 32% of our international revenue in the first half of 2004 and 22% of our international revenues in 2003. International revenues accounted for 21% of our total revenues for the six months ended June 30, 2004, and these two distributors represented 34% of that total. For the year ended December 31, 2003, international revenues accounted for 20% of our total revenues and these distributors represented 43% of that total. The loss of either distributor or a significant decrease in unit purchases by either distributor could cause our revenues to decline substantially. If we are unable to attract additional international distributors, our international revenues may not grow.

**We may choose to change our business relationships with Horizon's domestic distributors, risking, for a period of time, lower sales and additional costs.**

The integration of our sales efforts with those of Horizon Medical Products will result in re-assessment of the role of Horizon's domestic distributors. If we terminate our relationships with one or more of these distributors, we will incur costs associated with cancellation of our agreements and may experience lower sales while we transition this business to our direct sales force.

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

We sell our products in international markets through third-party distributors over whom we have limited control, and, if they fail to adequately support our products, our sales could decline. During the first quarter of 2003, we terminated our agreements with three of our international distributors and although we contracted with replacement distributors, we expended significant time and resources in doing so, and our sales in the three affected markets suffered during the transition period that we estimate ended September 30, 2003. If our distributors or we terminate other distributor agreements, we could incur similar or more burdensome expenses, we could expend significant time and resources in finding replacement distributors, and our sales could decrease during any related transition period.

We are aware that some of our international distributors have built up inventory of our products. As a result, future sales to these distributors could be negatively impacted. Sales to our Japanese distributor in 2003 and the first six months of 2004 were so affected. In addition, while these distributors have no price protection and no right of return relating to purchased products, if we permit the return of any of these products, we will have to adjust our revenues relating to these products which may also impact our revenue recognition policy on future distributor sales.

In 2002, we significantly increased our allowance for uncollectible accounts to address the risk associated with longer collection periods that have arisen principally with our European distributors. Although the deterioration we experienced in international collections in 2002 stabilized in 2003, and remained stable in the first six months of 2004, we may encounter new difficulties with collections that require further increases in our allowance for uncollectible accounts in the future, and we may require specific accounts to post letters of credit or pay in advance to minimize credit risk to the Company. Additional future increases in our allowance for uncollectible accounts would reduce our profits.



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

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

### **If third-party payors do not reimburse health care providers for use of the RITA system, purchases could be delayed and our revenues could decline.**

Physicians, hospitals and other health care providers may be reluctant to purchase our products if they do not receive coverage or adequate reimbursement for the cost of procedures using our products from third-party payors, such as Medicare, Medicaid and private health insurance plans. If physicians believe that using our system will add cost to a procedure but will not add sufficient offsetting economic or clinical benefits, physician adoption of our products could be delayed. Even though the American Medical Association has established CPT codes relating to liver procedures and bone tumor procedures, some third-party payors still may not cover or reimburse adequately for liver or bone tumor procedures using our products. We are aware of liver procedures using our system where the patient's insurance has denied coverage. In addition, there are no assigned CPT codes for radiofrequency ablation of tumors in organs other than liver or bone. Further, we believe the advent of the Medicare fixed payment schedules has made it difficult to receive adequate liver reimbursement for procedures using our products in the outpatient setting. Medicare reimbursement levels for procedures using our products are highest when our products are used in an in-patient setting. If there is a trend toward the use of our products on an outpatient basis or if coverage continues to be denied or reimbursement levels continue to be inadequate, physician use of our products could decline which would cause our revenues to decline.

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

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

### **We may 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 may be subject to product liability lawsuits. To date, we have not been subject to a product liability claim; however, 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.

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### **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 due to market uncertainty about our ability to successfully integrate the operations of Horizon Medical Products and manage our cash during the process of integrations. Our stock price may also fluctuate for a number of other reasons including:

failure of the public market to support the valuation established in our initial public offering or our 2003 private placement transaction;

our ability to successfully commercialize our products;

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

quarterly fluctuations in our results of operations;

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

product liability claims;

regulatory developments regarding us or our competitors;

acquisitions or strategic alliances by us or our competitors;

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

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

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

### **We have limited experience manufacturing our disposable devices in substantial quantities, and if we are unable to hire sufficient additional personnel or to purchase additional equipment or are otherwise unable to meet customer demand, our business could suffer.**

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. In addition, we intend to consolidate our manufacturing



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operations with Horizon Medical Products over the balance of 2004. 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.

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**We may be required to relocate, or choose to relocate, to a new facility in 2005. If so, we will incur moving expenses, and our business will suffer.**

The operating lease on our current facility was to expire in August of 2004, but we have negotiated an extension through January of 2005. We believe that during the third or fourth quarters of 2004 we will be able to either renew the lease on our existing facility, or lease alternative space, at commercially reasonable terms. If we choose to relocate to a new facility, we will incur normal and customary moving costs that will reduce our profitability.

**We are dependent on two suppliers as the only sources of a component that we use in our 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 June 30, 2003, we qualified a second supplier. However, a disruption in the supply of this component is still possible and could negatively affect revenues. If we were unable to remedy a disruption in supply of this component within twelve months, we could be required to redesign the handle of our disposable devices, which could divert engineering resources from other projects or add to product costs. In addition, a new or supplemental filing with applicable regulatory authorities may require clearance prior to our marketing a product containing new materials. This clearance process may take a substantial period of time, and we may be unable to obtain necessary regulatory approvals for any new material to be used in our products on a timely basis, if at all. This could also create supply disruptions that could negatively affect our business.

**We are dependent on two suppliers as our only sources of an accessory device used in conjunction with our Starburst XLi and Xlie lines of disposable devices, and any disruption in the supply of these devices could negatively affect our revenues.**

Until December 2002, we had only one supplier available to provide us with accessory infusion pumps used in conjunction with our Starburst XLi line of disposable devices. Our Starburst Xlie product line, introduced in 2003, also requires an accessory infusion pump. During the quarters ended September 30, 2002 and December 31, 2002, we experienced shortages in the supply of accessory infusion pumps. In December 2002, we qualified a new accessory infusion pump from our existing supplier for which we now have approval from UL and conditional approval from TUV for use in the United States and Europe. Also in December 2002, we qualified a second supplier of an accessory infusion pump, although we have not yet shipped this product to our customers commercially. Although we were able to remedy this supply disruption, future disruptions in the supply of this component are still possible and, in that event, our business could suffer through lower revenues or higher costs. Additionally, we have limited experience with both the primary and alternative pump and if either pump fails to perform as desired, revenues could be negatively affected.

**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 revenues.**

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

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

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

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



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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 to execute on our business plan. If we are successful in raising capital through the sale of common stock, it will result in dilution of our existing stockholders, and if we are unsuccessful in raising additional capital, we may not be able to execute on our business plan and our results of operations may suffer.**

We may seek to raise additional capital through the sale of our securities. It is expected that the offering proceeds, if raised, would be used, among other things, to retire debt assumed in the merger with Horizon Medical Products, including \$14.7 million of outstanding senior subordinated notes of Horizon, and to execute our business plan. Any such sale of stock will reduce the proportionate ownership and voting power of our existing stockholders and may result in a reduction of the market price of our common stock. If we are unable to raise additional capital on acceptable terms, or at all, our liquidity may suffer as assumed debts mature and we may be limited in our ability to execute our business plan, negatively affecting both results of operations and our stock price.

**Our executive officers and directors own a large percentage of our voting stock and could exert significant influence over matters requiring stockholder approval.**

Our executive officers and directors, and their respective affiliates, owned approximately 10 percent of our outstanding common stock as of June 30, 2004. After completion of the merger on July 29, 2004, our executive officers and directors, and their respective affiliates, owned approximately 26% of our outstanding common stock. 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.

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**USE OF PROCEEDS**

The selling stockholders will receive all of the net proceeds from the sale of the shares of our common stock covered by this prospectus. We will not receive any of the proceeds from the resale of any of these securities.

The selling stockholders will pay any underwriting fees or discounts, and any fees and expenses of counsel retained by them, incurred in connection with the resale of the shares covered by this prospectus. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including fees and expenses of our counsel and accountants.

**DESCRIPTION OF WARRANTS**

In connection with the acquisition of Horizon, we assumed all warrants of Horizon outstanding immediately prior to the merger, and such warrants automatically became exercisable to purchase our common stock. Each warrant assumed by us is now exercisable for 0.4212 of a share of our common stock for each share of Horizon common stock issuable under such warrant. This prospectus relates to the following warrants to purchase up to 52,650 shares of our common stock:

Warrant to purchase 10,530 shares of our common stock with an exercise price of \$2.90 per share and an expiration date of July 11, 2011.

Warrant to purchase 21,060 shares of our common stock with an exercise price of \$2.21 per share and an expiration date of December 31, 2005.

Warrant to purchase 21,060 shares of our common stock with an exercise price of \$1.64 per share and an expiration date of June 30, 2006.

**Table of Contents****SELLING STOCKHOLDERS**

We are registering for resale pursuant to this prospectus and as required in connection with our acquisition of Horizon and pursuant to that certain Agreement and Plan of Merger by and among us, Hornet Acquisition Corp. and Horizon dated as of May 12, 2004 (i) shares of our common stock acquired by the selling stockholders and (ii) shares of our common stock issuable upon the exercise of Horizon warrants assumed by us.

This table is prepared based on information supplied to us by the selling stockholders and assumes the sale of all of the resale shares. The number of shares beneficially owned by each selling stockholder is determined under rules promulgated by the Securities and Exchange Commission, and is not necessarily indicative of beneficial ownership for any other purpose.

We do not know how long the selling stockholders will hold the shares before selling them, and except as noted below, we currently have no agreements, arrangements or understandings with any of the selling stockholders regarding the sale of any of the shares. The shares offered by this prospectus may be offered from time to time by the stockholders listed below.

The applicable percentages of ownership listed below are based on 36,743,836 shares of our common stock outstanding as of August 5, 2004.

Information about the selling stockholders may change over time. Any changed information given to us by the selling stockholders will be set forth in prospectus supplements if and when necessary.

Selling Stockholders(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)	Number of Shares of Common Stock Beneficially Owned After the Offering(4)	Percentage of Shares of Common Stock Owned	
				Before Offering of the Resale Shares(5)	After Offering of the Resale Shares(6)
Harold Blue(7)	108,890	108,890	0	*	*
Commonwealth Associates Group Holdings, LLC(8)	4,750,743	59,046	4,691,697	12.9%	12.7%
ComVest Venture Partners, L.P.(9)	4,201,470	4,201,470	0	11.4%	*
Commonwealth Associates, L.P.	86,624	86,624	0	*	*
Epoch Financial Group, Inc.	10,530	10,530	0	*	*
Michael S. Falk(10)	4,750,743	403,603	4,347,140	12.9%	11.8%
Lippert/Heilshorn & Associates, Inc.	21,060	21,060	0	*	*
Lippert/Heilshorn & Associates, Inc.	21,060	21,060	0	*	*
Marshall B. Hunt(11)	3,163,716	994,869	2,168,847	8.6%	5.9%
Hunt Family Investments, L.L.P.(12)	484,047	484,047	0	1.3%	*
L. Bruce Maloy	12,636	12,636	0	*	*
Medtronic, Inc.(13)	3,032,640	3,032,640	0	8.2%	*
Robert Priddy(14)	1,066,772	561,332	505,440	2.9%	1.5%
RMC Capital, LLC(15)	505,440	505,440	0	1.3%	*
Robert R. Singer	12,636	12,636	0	*	*



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Robert D. Tucker(16)	28,154	28,154	0	*	*
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\* Less than 1.0%

Represents shares of our common stock issuable upon the exercise of Horizon warrants assumed by us.

- (1) This table is based upon information supplied to us by the selling stockholders.
- (2) Under the rules of the SEC, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of such security, or investment power, which includes the power to dispose of or to direct the disposition of such security. Under these rules, more than one person may be deemed to be a beneficial owner of the same securities and a person may be deemed to be a beneficial owner of securities as to which he or she has no economic or pecuniary interest. Except as set forth in the footnotes below, the persons named below have sole voting and investment power with respect to all shares of our common stock shown as being beneficially owned by them. A person also is deemed to be a beneficial owner of any securities which that person has the right to acquire within 60 days. Therefore, the number includes shares of common stock issued to the selling stockholders in connection with our acquisition of Horizon and shares of common stock issuable upon the exercise of any options or warrants held by such selling stockholder that were not exercised prior to the acquisition.
- (3) Represents shares of common stock issued to the selling stockholders in our acquisition of Horizon.
- (4) Assumes that the selling stockholders sell all of the shares of common stock available for sale.
- (5) The percentage of shares owned is determined based upon the sum of (i) 18,039,158 shares of our common stock issued and outstanding as of July 29, 2004 and (ii) the issuance of an aggregate of 18,704,678 shares of our common stock at the effective time of the merger.
- (6) Assumes that the selling stockholders sell all of the shares of our common stock available for resale.
- (7) Harold Blue is a director of RITA and President of Commonwealth Group Holdings, LLC.
- (8) Commonwealth Associates Group Holdings, LLC, or CAGH, wholly owns ComVest Management, LLC, which is the general partner of ComVest Venture Partners, L.P., or ComVest. In addition, CAGH wholly owns Commonwealth Management LLC which is the General Partner of Commonwealth Associates, L.P., or Commonwealth. CAGH may be deemed to beneficially own 4,750,743 shares of our common stock. This number includes 59,046 shares of our common stock beneficially held by such entity as well as 4,201,470 and 86,624 shares of our common stock beneficially owned by ComVest and Commonwealth, respectively. This number also includes 403,603 shares of our common stock with respect to which Mr. Falk has sole power to dispose of.
- (9) The general partner of ComVest is ComVest Management, LLC, which is wholly owned by CAGH. ComVest may be deemed to be the beneficial owner of 4,201,470 shares of our common stock. ComVest and Mr. Falk may be deemed to share voting and disposition powers with respect to such 4,201,470 shares of our common stock beneficially held by ComVest. ComVest is party to a Lock-up Agreement with us and Horizon dated May 12, 2004 pursuant to which it has agreed to certain limitations on the number of shares of our common stock that it may sell during any three-month period following the effective time of the merger.
- (10) Mr. Falk is the Chairman of CAGH. Only Mr. Falk has the authority to vote or dispose of the shares. Mr. Falk may be deemed to be the beneficial owner of an aggregate of 4,750,743 shares of our common stock, as follows: Mr. Falk may be deemed to beneficially own the 4,201,470 shares of our common stock beneficially owned by ComVest (ComVest and Mr. Falk may be deemed to share such voting and disposition powers with respect to such 4,201,470 shares of our common stock), 86,624 shares of our common stock beneficially owned by Commonwealth and 59,046 shares of our common stock beneficially owned by CAGH. In his capacity as Chairman and controlling equity owner of CAGH, Mr. Falk may be deemed to share indirect voting and dispositive power with respect to such entities' shares and may therefore be deemed to be the beneficial owner of such securities. Finally, Mr. Falk has the sole power to dispose of an aggregate of 403,603 shares of our common stock.
- (11) Includes 484,047 shares of our common stock owned by Hunt Family Investments, L.L.P., a Georgia limited liability limited partnership of which Mr. Hunt is the managing general partner. Mr. Hunt is party to a Lock-up Agreement with us and Horizon dated May 12, 2004 pursuant to which he has agreed to certain limitations on the number of shares of our common stock that he may sell during any three-month period following the effective time of the merger.
- (12) Mr. Hunt is the managing partner of Hunt Family Investments, L.L.P.
- (13) Medtronic, Inc. is party to a Lock-up Agreement with us and Horizon dated May 12, 2004 pursuant to which it has agreed to certain limitations on the number of shares of our common stock that it may sell during any three-month period following the effective time of the merger.
- (14) In addition to the 505,440 shares of our common stock beneficially owned by RMC Capital, LLC, which Mr. Priddy beneficially owns as a manager of RMC Capital, Mr. Priddy may be deemed to beneficially own an additional 561,332 shares of our common stock, over which Mr. Priddy maintains sole voting and dispositive power.
- (15) Mr. Priddy is manager of RMC Capital, LLC.
- (16) Mr. Tucker is a director of RITA.

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**PLAN OF DISTRIBUTION**

We are registering for resale up to (i) 10,491,387 shares of our common stock issued by us to certain selling stockholders identified in this prospectus in connection with our acquisition of Horizon and (ii) 52,650 shares of our common stock issuable by us to certain selling stockholders identified in this prospectus upon the exercise of Horizon warrants assumed by us in connection with our acquisition of Horizon. See section titled Selling Stockholders. The selling stockholders may offer and sell, from time to time, some or all of the shares of common stock covered by this prospectus. We have registered the shares of common stock covered by this prospectus for offer and sale by the selling stockholders so that those shares may be freely sold to the public by them. Registration of the shares of common stock covered by this prospectus does not mean, however, that those shares necessarily will be offered or sold. We are not aware of any plan of distribution for the resale of our common stock by the selling stockholders. We will not receive any of the proceeds from the sale by the selling stockholders of any of the shares covered by this prospectus.

**LEGAL MATTERS**

The validity of the issuance of the common stock offered hereby has been passed upon us by Heller Ehrman White & McAuliffe LLP, 2775 Sand Hill Road, Menlo Park, California 94025.

**EXPERTS**

The consolidated financial statements of RITA Medical Systems, Inc. incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2003 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The consolidated financial statements and the related financial statement schedule of Horizon Medical Products, Inc. as of December 31, 2002 and 2003 and for each of the two years in the period ended December 31, 2003 incorporated by reference in this prospectus have been audited by Grant Thornton LLP, independent registered public accountants, as stated in their report, given on the authority of said firm as experts in auditing and accounting.

The consolidated financial statements of Horizon Medical Products, Inc. for the year ended December 31, 2001 incorporated in this prospectus by reference to the Current Report on Form 8-K of RITA Medical Systems, Inc. dated August 9, 2004 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any of these reports, statements or other information at the Securities and Exchange Commission's public reference room located

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at 450 Fifth Street, N.W., Washington D.C. 20549. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the public reference room. Our Securities and Exchange Commission filings are also available to the public from commercial document retrieval services and at the web site maintained by the Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov).

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**INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

The Securities and Exchange Commission allows us to incorporate by reference information into this prospectus, meaning that we can disclose important information by referring to another document filed separately with the Securities and Exchange Commission. The information incorporated by reference is deemed to be part of this prospectus, except for any information superseded by information in, or incorporated by reference in, this prospectus. This prospectus incorporates by reference the documents set forth below that we have previously filed with the Securities and Exchange Commission.

<b>RITA MEDICAL SYSTEMS, INC. SECURITIES AND EXCHANGE COMMISSION FILINGS</b>	<b>PERIOD / FILING DATE</b>
Annual Report on Form 10-K, as amended	Fiscal Year ended December 31, 2003
Quarterly Reports on Form 10-Q	Three months ended March 31, 2004 and three months ended June 30, 2004
Current Reports on Form 8-K	Filed on January 13, 2004, January 21, 2004, February 11, 2004, February 19, 2004, March 5, 2004, March 11, 2004, March 24, 2004, April 1, 2004, April 29, 2004, May 10, 2004, May 14, 2004, June 3, 2004, June 9, 2004, June 28, 2004, July 9, 2004, July 30, 2004, August 3, 2004 and August 9, 2004.
The description of our common stock contained in the Registration Statement on Form 8-A filed pursuant to Section 12 of the Exchange Act, and any amendment or report filed with the Securities and Exchange Commission for the purpose of updating such description.	Filed on July 7, 2000
The description of our Preferred Share Purchase Rights contained in the Registration Statement on Form 8-A filed pursuant to Section 12 of the Exchange Act, and any amendment or report filed with the Securities and Exchange Commission for the purpose of updating such description.	Filed on August 7, 2001
We are also incorporating by reference additional documents that it has filed with the Securities and Exchange Commission under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus and the earliest of (i) the date of final sale by persons covered by this registration statement of all of our common stock registered on this registration statement, (ii) the date upon which all of our common stock registered on this registration statement is saleable without registration pursuant to Rule 145 under the Securities Act, excluding in each, any information furnished pursuant to Item 9 or Item 12 (or, as of and after August 23, 2004, Item 7.01 or Item 2.02) of any current report on Form 8-K.	

You can obtain any of these documents through us or the Securities and Exchange Commission. Documents incorporated by reference are available from us, without charge. You may obtain documents incorporated by reference in this prospectus by requesting them in writing or by telephone from us at the following address:

RITA Medical Systems, Inc.  
  
967 North Shoreline Boulevard  
  
Mountain View, CA 94043

Attention: Corporate Secretary

(650) 314-3400

**WE HAVE NOT AUTHORIZED ANY DEALER, SALES PERSON OR OTHER PERSON TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS OR ANY PROSPECTUS SUPPLEMENT. YOU MUST NOT RELY ON ANY UNAUTHORIZED INFORMATION. THIS PROSPECTUS IS NOT AN OFFER OF THESE SECURITIES IN ANY STATE WHERE AN OFFER IS NOT PERMITTED. THE INFORMATION IN THIS PROSPECTUS AS OF THE DATE ON THE FRONT OF THIS DOCUMENT. YOU SHOULD NOT ASSUME THAT THIS PROSPECTUS IS ACCURATE AS OF ANY OTHER DATE.**