RITA MEDICAL SYSTEMS INC
Form 10-Q
May 10, 2005
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2005

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 000-30959

RITA MEDICAL SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3199149**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

46421 Landing Parkway

Fremont, CA 94538

(Address of principal executive offices, including zip code)

510-771-0400

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes x No ¨

As of April 29, 2005, there were 41,496,759 shares of the registrant s common stock outstanding.

Table of Contents

INDEX

Table of Contents

PART 1. FINANCIAL INFORMATION

Item 1. Financial Statements

RITA MEDICAL SYSTEMS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, unaudited)

	March 31, 2005	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	$ 5,906	$ 12,978
Marketable securities	251	880
Accounts and note receivable, net	6,480	6,410
Inventories	6,881	7,126
Prepaid and other current assets	1,219	792
Total current assets	20,737	28,186
Long term note receivable, net	140	177
Property and equipment, net	1,865	1,966
Goodwill	91,339	91,339
Intangible assets	29,885	30,600
Other assets	139	41
Total assets	$ 144,105	$ 152,309
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 3,700	$ 2,572
Accrued liabilities	2,929	4,159
Current portion of long term debt	708	7,200
Total current liabilities	7,337	13,931
Long term debt, less current portion	9,452	9,632
Other long term liabilities	82	90
Total liabilities	16,871	23,653
Stockholders equity		
Common stock	41	41

Additional paid-in capital	217,158	216,893
Accumulated other comprehensive loss		(2)
Accumulated deficit	(89,965)	(88,276)
Total stockholders equity	127,234	128,656
Total liabilities and stockholders equity	$ 144,105	$ 152,309

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

Table of Contents

RITA MEDICAL SYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data, unaudited)

	Three months ended March 31,	
	2005	**2004**
Sales	$ 11,205	$ 4,644
Cost of goods sold	4,805	1,615
Gross profit	6,400	3,029
Operating expenses:		
Research and development	1,039	843
Selling, general and administrative	6,768	4,366
Restructuring charges	60	
Total operating expenses	7,867	5,209
Loss from operations	(1,467)	(2,180)
Interest expense	(287)	
Interest income and other expense, net	65	10
Net loss	$ (1,689)	$ (2,170)
Net loss per common share, basic and diluted	$ (0.04)	$ (0.12)
Shares used in computing net loss per common share, basic and diluted	41,457	17,998

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

Table of Contents

RITA MEDICAL SYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands, unaudited)

	Three months ended March 31,	
	2005	**2004**
Cash flows from operating activities:		
Net loss	$ (1,689)	$ (2,170)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	970	410
Loss on disposal of property and equipment		13
Amortization of stock-based compensation		107
Allowance for (recovery of) doubtful accounts receivable	(178)	27
Provision for obsolete inventories	101	86
Changes in operating assets and liabilities:		
Accounts and note receivable	108	(43)
Inventories	144	329
Prepaid and other current assets	(427)	232
Accounts payable and accrued liabilities	(102)	(439)
Deferred maintenance revenue	(4)	2
Net cash used in operating activities	(1,077)	(1,446)
Cash flows from investing activities:		
Purchase of property and equipment	(154)	(98)
Purchase of marketable securities	(60)	(404)
Sales and maturities of marketable securities	691	3,770
Note receivable, other assets and other long term liabilities	(65)	23
Net cash provided by investing activities	412	3,291
Cash flows from financing activities:		
Principal payments on debt	(6,672)	
Proceeds from issuance of common stock, net of issuance costs	265	97
Net cash provided by (used in) financing activities	(6,407)	97
Net decrease in cash and cash equivalents	(7,072)	1,942
Cash and cash equivalents at beginning of period	12,978	3,780
Cash and cash equivalents at end of period	$ 5,906	$ 5,722

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

Table of Contents

RITA MEDICAL SYSTEMS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared by RITA Medical Systems, Inc. (the Company) in accordance with accounting principles generally accepted in the United States of America for interim financial information. These principles are consistent in all material respects with those applied in the Company s financial statements contained in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2004, as amended, and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X promulgated by the Securities and Exchange Commission. However, interim financial statements do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all adjustments (all of which are of a normal recurring nature, including the elimination of intercompany accounts) necessary to present fairly the financial position, results of operations and cash flows of the Company for the periods indicated. Interim results of operations are not necessarily indicative of the results to be expected for the full year or any other interim periods. These unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and footnotes thereto for the year ended December 31, 2004 contained in the Company s annual report on Form 10-K.

2. Business Combination

On July 29, 2004, the Company merged with Horizon Medical Products, Inc. (Horizon) in a transaction accounted for under the purchase method of accounting. None of Horizon s results of operations prior to that date are included in the Company s condensed consolidated statements of operations. However, the Company has prepared pro forma financial information showing sales and net loss for the combined entity for the three month period ended March 31, 2004, as if the merger occurred as of January 1, 2004. This unaudited pro forma financial information is presented below in comparison to the Company s unaudited sales and net loss for the three month period ended March 31, 2005, but is not intended to represent or be indicative of the consolidated results of operations of the Company that would have been reported had the acquisition been completed as of January 1, 2004, and should not be taken as representative of the future consolidated results of operations or financial condition of the Company (in thousands, except per share amounts):

	Three months ended March 31,	
	Actual 2005	Pro forma 2004
Sales	$ 11,205	$ 11,730
Net loss	$ (1,689)	$ (3,528)
Net loss per common share, basic and diluted	$ (0.04)	$ (0.10)

Restructuring costs of $1,369,000, consisting entirely of severance related to the termination of employees to eliminate certain duplicative activities, have been incurred since completion of the merger. Of this amount, $60,000 was incurred during the three months ended March 31, 2005 (see Note 11, Restructuring).

3. Liquidity

As of March 31, 2005, the Company s total assets were $144.1 million, total tangible assets were $22.9 million, total liabilities were $16.9 million, working capital was $13.4 million and cash, cash equivalents and marketable securities totaled $6.2 million. Current and anticipated demand for the Company s products as well as procurement and production affect the need for capital. Changes in these or other factors could have a material impact on capital requirements and may require the Company to raise additional capital. While the Company believes that its existing cash resources, including marketable securities, will be sufficient to fund its operating needs for the next twelve months, additional financing may be required for the Company s currently envisioned long term needs. If the Company needs to raise additional financing, it will seek to sell additional equity or debt securities, obtain an additional credit facility or renegotiate debt repayment terms. There can be no assurance that any additional financing will be available on terms acceptable to the Company, or at all. In addition, future equity financings could result in dilution to shareholders, and future debt financings could result in certain financial and operational restrictions. Failure to obtain sufficient funds on acceptable terms when needed, to make timely debt payments, or to achieve our growth or profitability objectives may require us to curtail operations, perhaps to a significant extent.

4. Reclassifications

Certain prior year balances have been reclassified to conform to current year presentation. In the Company s quarterly report on Form 10-Q for the three month period ended March 31, 2004, investments in variable rate debt obligations with interest rate reset

Table of Contents

intervals of less than 90 days were classified as cash equivalents. The Company s Consolidated Statement of Cash Flows for the three months ended March 31, 2004 has been modified from past presentation to give effect to purchases and sales or maturities of such securities in the determination of net cash provided by investing activities. For the three months ended March 31, 2004, net cash provided by investing activities increased by $400,000. The Company s Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2005 and 2004 were not affected by this reclassification.

5. Net loss per share

Basic earnings per share figures are calculated based on the weighted-average number of common shares outstanding during the period less the weighted-average number of any common shares subject to repurchase by the Company. Diluted earnings per share further include the dilutive effect of potentially dilutive securities consisting of stock options and warrants provided that the inclusion of such securities is not antidilutive; the Company has reported net losses and therefore has excluded such potentially dilutive securities from its calculation of diluted earnings per share. The following numbers of shares represented by stock options and warrants (prior to application of the treasury stock method) were excluded from the computation of diluted net loss per share as their effect was antidilutive (in thousands):

	March 31,	
	2005	2004
Effect of potentially dilutive securities:		
Options	7,256	2,743
Warrants	78	25
Total potentially dilutive securities excluded from the computation of net loss per common share as their effect was antidilutive	7,334	2,768

6. Accounting for stock-based compensation

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

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

The following table illustrates the effect on net loss and net loss per common share for the three month periods ended March 31, 2005 and 2004, respectively, if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation granted under all of its stock option plans and its Employee Stock Purchase Plan (in thousands, except per share amounts):

	Three months ended March 31,	
	2005	2004
Net loss, as reported	$ (1,689)	$ (2,170)
Add: Stock-based employee compensation expense included in reported net loss		107
Deduct: Total stock-based employee compensation determined under the fair value based method for all awards	(518)	(809)
Net loss, pro-forma	$ (2,207)	$ (2,872)
Basic and diluted net loss per common share:		
As reported	$ (0.04)	$ (0.12)
Pro-forma	$ (0.05)	$ (0.16)

The determination of stock-based employee compensation, as relating to stock option plans, under the fair value based method used the following weighted average assumptions:

	Three months ended March 31,	
	2005	2004
Volatility	78%	75%
Risk-free interest rate	3.83%	3.13%
Expected life	5 years	5 years
Expected dividends	0%	0%

Table of Contents

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

	Three months ended March 31,	
	2005	2004
Volatility	60%	60%
Risk-free interest rate	1.73%	1.01%
Expected life	0.5	0.5
Expected dividends	0%	0%

7. Inventories

The components of the Company s inventories at March 31, 2005 and December 31, 2004, respectively, were as follows (in thousands):

	March 31, 2005	December 31, 2004
Raw materials	$ 2,686	$ 2,776
Work-in-process	578	682
Finished goods	3,617	3,668
	$ 6,881	$ 7,126

8. Intangible assets and related amortization

The Company s intangible assets and related accumulated amortization at March 31, 2005 and December 31, 2004, respectively, were as follows (in thousands):

	March 31, 2005			December 31, 2004		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Capitalized patent defense litigation costs	$ 2,755	$ (654)	$ 2,101	$ 2,755	$ (593)	$ 2,162
Capitalized patent license agreements	2,650	(641)	2,009	2,650	(561)	2,089
Intangible assets recorded at merger with Horizon:						

Customer relationships	16,600	(738)	15,862	16,600	(461)	16,139
Product technology	6,900	(383)	6,517	6,900	(239)	6,661
Trademarks	3,000	(200)	2,800	3,000	(125)	2,875
Isomed distribution contract	700	(117)	583	700	(73)	627
Loan closing costs	73	(60)	13	73	(32)	41
Non-compete contracts	36	(36)		36	(30)	6
	$ 32,714	$ (2,829)	$ 29,885	$ 32,714	$ (2,114)	$ 30,600

Table of Contents

The amortization periods of our intangible assets as of March 31, 2005 are as follows:

	Amortization periods of intangible assets
Capitalized patent defense litigation costs	9 years
Capitalized patent license agreements	4 -10 years
Customer relationships	14 years
Product technology	11 years
Trademarks	9 years
Isomed distribution contract	3 years
Loan closing costs	4 months

Aggregate amortization expense for the three months ended March 31, 2005, estimated amortization expense for the nine months ending December 31, 2005, and estimated amortization expense for each of the five years ended December 31, 2006 through 2010 is as follows (in thousands):

Aggregate amortization expense:	
For the three months ended March 31, 2005	$ 715
Estimated amortization expense:	
For the nine months ended December 31, 2005	$ 2,052
For the twelve months ended December 31, 2006	$ 2,720
For the twelve months ended December 31, 2007	$ 2,720
For the twelve months ended December 31, 2008	$ 2,647
For the twelve months ended December 31, 2009	$ 2,457
For the twelve months ended December 31, 2010	$ 2,335

9. Goodwill

In accordance with the Company s policy, the potential impairment of the Company s goodwill is reviewed at least annually, or more often if changes in business conditions so dictate. The Company s market capitalization as of March 31, 2005 was approximately $124.0 million, $3.2 million less than the carrying value of the Company s net assets. As of December 31, 2004, the Company s market capitalization exceeded the carrying value of its assets by approximately $31.4 million. The Company believes its market capitalization to be temporarily depressed, reflecting market uncertainty regarding the integration of operations following our merger with Horizon and generally lower valuations of companies in our market sector over the last nine months.

Therefore, the Company does not consider this temporary depression in the market capitalization to be an event or circumstance that would more likely than not reduce the fair value of the Company below the carrying amount. However, if the Company s market capitalization remains at current levels, or decreases, an interim review will be performed for the potential impairment of goodwill, in addition to the Company s annual review performed as of September 30.

10. Debt

The Company has the following debts:

Senior Subordinated Convertible Notes (the Senior Notes): As of March 31, 2005, $8,262,000 was due under the Senior Notes. This balance reflects a prepayment of $6.5 million that the Company made during the quarter ended March 31, 2005. The balance due under the Senior Notes is due in July 2008. The Senior Notes currently bear interest, payable quarterly, at 8.0% per annum. This interest rate will increase to 14% per annum on July 29, 2005. The Company may prepay the Senior Notes without a penalty prior to their respective maturity dates.

Junior Promissory Note (the Junior Note): As of March 31, 2005, $1,460,000 was due under the Junior Note. The Junior Note bears interest at a rate of 6% per annum, is payable monthly and matures in March 2007. The monthly principal payment is $22,500 until maturity at which time a balloon payment of $920,000 is due.

A note payable for the Stepic business purchase (the Stepic Note): As of March 31, 2005, $437,601 was due under the Stepic Note. The Stepic Note bears interest at 8% and calls for monthly interest and principal payments of approximately $38,000. The Stepic Note is due and scheduled to be fully repaid in March 2006.

Table of Contents

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

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

Nine months ending December 31, 2005	$ 527
Three months ending March 31, 2006	180
Nine months ending December 31, 2006	203
Twelve months ending December 31, 2007	988
Twelve months ending December 31, 2008	8,262
Twelve months ending December 31, 2009 and thereafter	
	$ 10,160

11. Restructuring

In the three month period ended March 31, 2005, in connection with the merger of RITA and Horizon, the Company recorded a restructuring charge of $60,000 related to the termination of employees to eliminate certain duplicative activities, primarily in the sales, accounting and operations areas. The total of such charges since July 29, 2004, the day the merger was completed, is $1,369,000. These charges were accounted for in accordance with SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. As of March 31, 2005, approximately $1,238,000 of the severance amounts had been paid and $131,000 remained accrued. The Company expects to pay remaining accrued severance amounts by June 30, 2005.

12. Segment information

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

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

Sales for the Company s two medical oncology product groups for the three month periods ended March 31, 2005 and 2004 are as follows (in thousands):

	Three months ended March 31,	
	2005	2004
Radiofrequency ablation products	$ 4,529	$ 4,644
Specialty access catheter products	6,676	
Total medical oncology product sales	$ 11,205	$ 4,644

Sales for the Company s two domestic and international selling regions for the three month periods ended March 31, 2005 and 2004 are as follows (in thousands):

	Three months ended March 31,	
	2005	2004
Domestic	$ 9,649	$ 3,671
International	1,556	973
Total medical oncology product sales	$ 11,205	$ 4,644

Table of Contents

13. Comprehensive income (loss)

Comprehensive income (loss) generally represents all changes in stockholders equity except those resulting from investments or contributions by stockholders. The Company s unrealized gains and losses on available-for-sale securities represent the only components of comprehensive loss that are excluded from the Company s net loss. These components are not significant individually, or in the aggregate, and therefore, no separate statement of comprehensive loss has been presented.

14. Recent accounting pronouncements

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

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

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

Table of Contents

15. Commitments and contingencies

The Company has commitments for operating leases related to facility rental, including an operating lease signed in February 2005 on a facility to house the Company s headquarters, effective in May 2005. Future minimum payments under operating leases are as follows (in thousands):

Nine months ending December 31, 2005	$ 358
Year ending December 31, 2006	404
Year ending December 31, 2007	383
Year ending December 31, 2008	350
Year ending December 31, 2009	355
Year ending December 31, 2010 and thereafter	116
Total of future minimum operating lease payments	$ 1,966

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

Table of Contents

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

This Management s Discussion and Analysis of Financial Condition and Results of Operations and other parts of this quarterly report on Form 10-Q contain forward-looking statements that involve risks and uncertainties. Words such as anticipates , expects , intends , plans , believes , s estimates , should , and similar expressions identify such forward-looking statements. These statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or forecasted. Factors that might cause such a difference include, but are not limited to, those discussed in the section entitled Factors That May Affect Future Results and those appearing elsewhere in this quarterly report on Form 10-Q and in our annual report on Form 10-K for the fiscal year ended December 31, 2004, as amended. Readers are cautioned not to place undue reliance on these forward-looking statements that reflect management s analysis only as of the date hereof. We assume no obligation to update these forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements.

Overview

We develop, manufacture and market innovative products for cancer patients, including radiofrequency ablation (RFA) systems for treating cancerous tumors as well as percutaneous vascular and spinal access systems. In 2001, we commercially launched our StarBurst XLi family of disposable devices and significantly expanded our direct domestic sales organization and our international distribution network. In 2002, the XLi family of disposable devices gained wide acceptance with our customers in the United States. In 2003, we introduced our next generation in infusion technology, the Xli-Enhanced (Xlie) disposable device. The Xlie device builds upon our established infusion expertise, making the ablation process easier and more efficient than it was with previous generations of our devices.

On July 29, 2004, the Company merged with Horizon Medical Products, Inc. (Horizon) in a transaction accounted for under the purchase method of accounting. None of Horizon s results of operations prior to that date are included in the Company s condensed consolidated statements of operations. We believe the merger will lead to higher sales and greater profitability than either or both of the pre-merger companies on a standalone basis due to a larger, more effective sales group, consolidation of manufacturing resulting in lower product costs, and reduced administrative expenses.

Horizon operated as a specialty medical device company focused on manufacturing and marketing vascular products, particularly oncology product lines including implantable vascular ports, tunneled catheters and stem cell transplant catheters used in cancer treatment protocols (collectively, specialty access catheter or SAC products). Each Horizon common stockholder received 0.4212 of a share of the Company s common stock for each share of Horizon common stock held. The Company thereby issued approximately 18.7 million shares of its common stock to acquire all issued and outstanding shares of Horizon common stock, and further assumed all outstanding Horizon options and warrants that, upon exercise, will result in the issuance of approximately 3.9 million shares of the Company s common stock. The fair value of shares issued by the Company was approximately $91.6 million based on a price per share of $4.896, the Company s average closing price the day the proposed merger was announced (May 13, 2004), the two business days preceding the announcement and the two business days following the announcement. The fair value of options and warrants, all of which were fully vested when assumed by the Company was determined to be approximately $15.4 million using the Black-Scholes valuation model. Costs incurred to effect the merger and to be included as a component of purchase price were $2.3 million. The total purchase price was approximately $109.3 million. The fair value of assets acquired, net of liabilities assumed, was approximately $18.0 million, resulting in goodwill of $91.3 million.

Table of Contents

Management relies on certain statistical measurements to assess trends in sales growth and the effectiveness of our selling strategies. The following table, derived from our Consolidated Statements of Operations and other unaudited data for the three months ended March 31, 2005 and 2004, and for the years ended December 31, 2004, 2003 and 2002, sets forth some of these measurements:

	Three months ended March 31,		Years ended December 31,		
	2005	2004	2004	2003	2002
Total sales (in thousands)	$ 11,205	$ 4,644	$ 28,215	$ 16,607	$ 17,393
Percentage of sales: United States	86%	79%	84%	80%	74%
Percentage of sales: International	14%	21%	16%	20%	26%
Percentage of sales: Radiofrequency products	40%	100%	62%	100%	100%
Percentage of sales: Vascular access products	60%	0%	38%	0%	0%
Gross margin	57%	65%	60%	63%	60%

Consolidation of Horizon s results did not begin until the closing date of the merger, July 29, 2004. Therefore, the percentages shown for historical periods must be used with caution, as they may not be indicative of future results. In particular, the percentage of sales attributable to vascular access products is expected to be higher in future periods.

Prior to completion of the Horizon merger, our products were sold in the United States exclusively through our direct sales force and internationally through distribution partners. Horizon, in contrast, made use of domestic distribution partners in selected areas of the United States. Since completion of the merger, we have begun to distribute our radiofrequency ablation products through two of these domestic distribution partners. However, direct sales will remain our predominant mode of domestic distribution for the foreseeable future.

Our sales in the United States are more profitable than our sales in international markets because direct selling, which avoids distributor discounts, permits higher average selling prices for our products. Accordingly, we have made significant investments in our domestic sales force in an effort to increase sales growth in the United States, and we introduced our premium-priced Starburst Xli and Xlie families of disposable needles in this region earlier than in Europe or other regions. These actions have resulted in a growing percentage of sales derived from the domestic market. The merger with Horizon should permit wider and even more efficient coverage of the domestic market, further strengthening this trend. In contrast, our international markets in Europe and Japan have relatively more restrictive reimbursement conditions than those in the United States, which combined with our distributor discounts, limit our average selling prices in these markets. We expect 2005 sales growth in the United States to continue to outpace international growth because we believe the principle impact of the Horizon merger will be upon the domestic market and because introduction of premium products to our international distributors will have a relatively small impact on growth due to pricing limitations.

Prior to completion of the Horizon merger, essentially all of our sales came from the sale of our disposable devices and radiofrequency generators used in the treatment of cancerous liver tumors. The merger with Horizon expanded our product offering and has resulted in additional sales, primarily from the specialty access catheter and port product lines used in cancer treatment protocols. Going forward, we expect that nearly 95% of our sales will be derived from our RFA and SAC disposable products, with the balance of our sales coming from hardware products. We believe that the broader product line and larger sales group resulting from the merger will enable us to increase the efficiency of our selling effort in 2005 and beyond.

Our manufacturing costs consist of raw materials, including generators and ancillary hardware components produced for us by third-party suppliers, labor to produce our disposable devices and to inspect incoming, in-process and finished goods, sterilization performed by an outside service provider and general overhead expenses. Our manufacturing costs are volume-dependent, and our unit costs should decrease as our production volumes increase. The ongoing integration of our manufacturing operations in our Manchester, Georgia location should result in lower costs in the future from the use of less expensive labor and economies of scale. However, the process of integration resulted in costs during the first quarter of 2005, including training costs and the expense of duplicate facilities that resulted in a 57% margin rate for the quarter, lower than management s long-term expectations for the business. This integration process will continue during the second quarter of 2005, negatively affecting margins for the period. We also believe we have the opportunity to reduce the cost of our vendor-supplied hardware products through higher order volumes or product redesign. Besides manufacturing costs, our cost of goods sold for the three months ended March 31, 2005 reflects amortization of intangible assets relating to product technology acquired in the merger. Our cost of goods sold for both of the three month periods ended March 31, 2005 and 2004 reflect amortization charges arising from the 2003 settlement of patent litigation. We expect these amortization charges to continue through 2016. Further, our cost of goods sold also includes provisions to our reserve for obsolete inventory. Technology in our marketplace has evolved rapidly and we have, from time to time, recognized relatively high expenses related to obsolete inventory as our product line has changed. We may experience similar product changes and related obsolete inventory provisions in the future.

Our gross margins reflect our selling prices, our domestic / international mix percentages, our product mix percentages, our production volumes, the prices we pay for vendor manufactured product and our provisions for obsolete inventory. Our gross margin

Table of Contents

for the quarter ended March 31, 2005, was 57%, compared to a gross margin of 65% for the quarter ended March 31, 2004. We believe that the 57% gross margin in the first quarter of 2005 reflects unusual costs associated with the integration of our manufacturing operations and is therefore lower than our long-term expectations for the business. However, historically, the gross margin rate for our specialty access catheter products has been lower than that of our radiofrequency ablation products. Also, amortization of our product technology related intangible assets will negatively impact cost of goods sold. Future gross margins may, therefore, be lower than our historical gross margin rates because of inclusion of these products and expenses in our results.

In addition to the selling statistics discussed above, management relies on certain measurements to assess the effectiveness of our operations. The following tables sets forth some of these measurements, derived from our Unaudited Condensed Consolidated Statements of Operations for the three months ended March 31, 2005 and 2004, our Consolidated Statements of Operations for the years ended December 31, 2004, 2003 and 2002, our Unaudited Condensed Consolidated Balance Sheets as of March 31, 2005 and 2004 and our Consolidated Balance Sheets as of December 31, 2004, 2003 and 2002 (in thousands):

	Three months ended March 31,		Years ended December 31,		
	2005	2004	2004	2003	2002
Research and development expense	$ 1,039	$ 843	$ 3,787	$ 4,294	$ 5,052
Selling, general and administrative expense	6,768	4,366	20,637	17,418	19,366
Restructuring charges	60		1,309		
Total operating expenses	$ 7,867	$ 5,209	$ 25,733	$ 21,712	$ 24,418

	March 31,	December 31,		
	2005	2004	2003	2002
Cash and cash equivalents	$ 5,906	$ 12,978	$ 4,580	$ 6,888
Marketable securities, current and long term	251	880	4,955	5,947
Total cash and marketable securities	$ 6,157	$ 13,858	$ 9,535	$ 12,835

If we are to become profitable, we must continue to manage our operating expenses. Our operating expenses consist of product development costs, clinical trial expenses, patent litigation expenses, sales and marketing expenses related to our selling efforts in the United States, Europe and Asia, and administrative expenses, including the costs associated with our status as a public company, professional service expenses and our provisions for uncollectible accounts. Changes in these expenses are determined by the breadth of our new product development portfolio, the number of headcount we maintain in our selling and administrative functions, the scope of our marketing efforts, the costs we incur in defense of our patents and intellectual property rights and the extent to which credit issues and economic conditions constrain our ability to collect our receivables.

Research spending in the quarter ended March 31, 2005 was $1.0 million, compared to $0.8 million in the quarter ended March 31, 2004. Research spending in 2005 is expected to increase modestly, driven by programs aimed at technical innovation of our radiofrequency ablation products and the introduction of new implantable ports and access catheters.

Selling, general and administrative in quarter ended March 31, 2005 was $6.8 million, compared to $4.4 million in the quarter ended March 31, 2004. The primary reasons for the increase were the consolidation of Horizon results and the expenses incurred in the integration of the two companies. Also, the merger resulted in recognition of intangible assets relating to trademarks, customer relationships and our distribution contract with Medtronic, amortization of which will result in charges to selling, general and administrative expense of $1.4 million to $1.6 million per year through 2014. Furthermore, we incurred significant costs related to compliance with the Sarbanes-Oxley Act of 2002. We incurred restructuring expenses of $60,000 during the quarter ended March 31, 2005, consisting of severance related to the termination of employees to eliminate certain duplicative activities. The total of such restructuring charges since the merger is $1,369,000, and we believe our restructuring is now essentially complete.

In addition to management of our operating expenses, we must continue to conserve our cash. Our combined total of cash, cash equivalents and marketable securities was $6.2 million as of March 31, 2005, compared to $13.9 million at December 31, 2004. Our net cash used in operating activities for the quarter ended March 31, 2005 was $1.1 million. We had approximately $10.2 million in short term and long term debt as of March 31, 2004. This figure reflects our payment of $6.5 million of our outstanding debt, plus accrued interest, in February 2005. We may in the future need to raise additional cash through borrowing or sale of equity securities or to renegotiate the payment terms of our debt.

We incurred a net loss of $1.7 million for quarter ended March 31, 2005 compared to $2.2 million for the quarter ended March 31, 2004. Profitability further depends on, among other things, our success in expanding product usage in our current markets and in developing new markets, as well as the successful integration of Horizon s operations. To the extent current or new markets do not materialize in accordance with our expectations, our sales could be lower than expected and we may be unable to achieve or sustain profitability.

In the first quarter of 2006, we expect to implement SFAS No. 123R. We have not yet been able to determine the impact of SFAS No. 123R on our results in 2006, or in subsequent years, but we expect to incur significant charges as a result of adoption of the standard.

Table of Contents

Critical Accounting Policies and Estimates

Our critical accounting policies and estimates were discussed in our annual report on Form 10-K for the fiscal year ended December 31, 2004. All of the policies and estimates discussed at that time remain unchanged.

Results of Operations

The following table sets forth the percentage of net revenue represented by certain items in our Condensed Consolidated Statements of Operations for the quarter ended March 31, 2005 and the four preceding fiscal quarters:

	Q1 2005	Q4 2004	Q3 2004	Q2 2004	Q1 2004
Domestic sales	86%	86%	86%	80%	79%
International sales	14%	14%	14%	20%	21%
Total sales	100%	100%	100%	100%	100%
Cost of goods sold	43%	47%	35%	36%	35%
Gross profit	57%	53%	65%	64%	65%
Operating expenses:					
Research and development	9%	9%	11%	21%	18%
Selling, general and administrative	60%	56%	78%	86%	94%
Restructuring charges	1%	2%	14%	0%	0%
Total operating expenses	70%	67%	103%	107%	112%
Loss from operations	(13)%	(14)%	(38)%	(43)%	(47)%
Interest expense	(3)%	(3)%	(3)%	0%	0%
Interest income and other expense, net	1%	0%	0%	0%	0%
Net loss	(15)%	(17)%	(41)%	(43)%	(47)%

Three months ended March 31, 2005 and 2004

The following table, which sets forth key comparisons of our sales results for the first quarter of 2005 compared to the first quarter of 2004, provides additional information on the impact of the consolidation of our acquired vascular access products upon our results (in thousands):

	Three months ended March 31,

	2005	2004	Growth	%
Domestic sales:				
Radiofrequency ablation products	$ 3,602	$ 3,671	$ (69)	-2%
Specialty access catheter products	6,047		6,047	
Total domestic sales	$ 9,649	$ 3,671	$ 5,978	163%
International sales:				
Radiofrequency ablation products	$ 927	$ 973	$ (46)	-5%
Specialty access catheter products	629		629	
Total international sales	$ 1,556	$ 973	$ 583	60%
Total radiofrequency ablation sales	$ 4,529	$ 4,644	$ (115)	-2%
Total specialty access catheter products	6,676		6,676	
Total sales	$ 11,205	$ 4,644	$ 6,561	141%

For the quarter ended March 31, 2005, sales totaled $11.2 million, an increase of 141% or $6.6 million from $4.6 million in the first quarter of 2004. Sales of specialty access catheter products acquired in the merger with Horizon explained all of this increase,

Table of Contents

adding $6.7 million to our sales, while sales of our radiofrequency ablation products decreased $0.1 million or 2% compared to the quarter ended March 31, 2004. Domestic sales of radiofrequency ablation products were also 2% lower in 2005 than in 2004. International sales of radiofrequency ablation products were 5% lower in 2005 than in 2004. For the quarter ended March 31, 2005, domestic sales represented 86% of total sales, compared to 79% in the first quarter of 2004.

Cost of goods sold for the quarter ended March 31, 2005 was $4.8 million, up from $1.6 million for the quarter ended March 31, 2004, primarily reflecting inclusion of $2.8 million in cost associated with SAC product sales. The remainder of the cost increase was due to a $0.1 million increase in patent-related amortization and $0.3 million in net costs associated with integration of our manufacturing operations following the Horizon merger. Our gross margin rate was 57% in the first quarter of 2005, compared to 65% in the prior period. We believe that the 57% gross margin in the first quarter of 2005 reflects unusual costs associated with the integration of our manufacturing operations and is therefore lower than our long-term expectations for the business. However, historically, the gross margin rate for our specialty access catheter products has been lower than that of our radiofrequency ablation products. Also, amortization of our product technology related intangible assets will negatively impact cost of goods sold. Future gross margins may, therefore, be lower than our historical gross margin rates because of inclusion of these products and expenses in our results.

Research and development expenses for the quarter ended March 31, 2005 were $1.0 million, compared to $0.8 million in the first quarter of 2004. This increase was primarily due to inclusion of research and development expenses for specialty access products that totaled $0.2 million for the quarter. Expenses associated with clinical trial work, specifically investigations into the use of our technology in the fields of kidney and breast cancer, also increased modestly.

Selling, general and administrative expenses for the quarter ended March 31, 2005 were $6.8 million, compared to $4.4 million in the first quarter of 2004. Of this $2.4 million increase, approximately $0.5 million is due to increased audit expenses, including costs incurred in compliance with the Sarbanes-Oxley Act of 2002. Increased sales and marketing expenses reflecting headcount increases and programs after the Horizon merger totaled $1.1 million for the firs quarter of 2005, including the $60,000 in restructuring expense. Another $0.4 million of the increase for the period resulted from amortization of merger-related intangible assets. Corporate expenses, including public company expenses, rent and insurance, were $0.4 million higher in the first quarter of 2005 than in the preceding period, again due to operational changes stemming from the Horizon merger. Our bad debt expense was about $0.2 million lower in the first quarter of 2005, compared to the first quarter of 2004.

Interest expense, net of interest and other income, for the first quarter ended March 31, 2005 was $0.2 million. We had no net interest expense in the prior year period.

Liquidity and Capital Resources

Prior to August 2000, we financed our operations principally through private placements of convertible preferred stock, raising approximately $37.9 million net of expenses. On August 1, 2000, we completed our initial public offering of 3.6 million common shares at a price of $12 per share, raising approximately $39.0 million net of expenses. All outstanding convertible preferred shares were converted to common shares at that time. To a lesser extent, we also financed our operations through equipment financing and other loans that were fully repaid as of December 31, 2002. In January of 2003, we raised an additional $8.3 million, net of expenses, through a private placement of our common shares. In November of 2004, we raised an additional $11.1 million, net of expenses, through a second private placement of our common shares and warrants to purchase our common shares. As of March 31, 2005, we had $5.9 million of cash and cash equivalents, $0.3 million of marketable securities and $13.4 million of working capital.

For the quarter ended March 31, 2005, net cash used in operating activities was $1.1 million principally due to our net loss of $1.7 million, offset by non-cash charges of $0.9 million, including depreciation and amortization, stock-based compensation and provisions to reserves for uncollectible accounts receivable and inventory. Stock-based compensation for the quarter was essentially zero, resulting from the impact of decreases in our stock price on the revaluation of consultant options. Approximately $0.3 million in cash was used in the quarter by changes in working capital accounts, primarily a $0.4 million increase in prepaid expenses offset by cash provided in other working capital accounts. During the quarter, $0.4 million was provided by investing activities, with net sales of marketable securities providing $0.6 million offset by $0.2 million used in purchase of property and equipment. Financing activities for the quarter used $6.4 million in cash, primarily reflecting $6.7 million in debt payments made during the quarter. The impact of debt payment on our cash used in financing activities was offset by $0.3 million raised by the issuance of common stock in conjunction with the exercise of stock options.

Table of Contents

We have, from time to time, financed equipment through capital and operating leases. Also, in the course of the Horizon merger, we acquired debt, the balance of which was $10.2 million as of March 31, 2005. As of March 31, 2005, we had no future minimum payments due under capital leases. Future minimum payments due under operating leases, including the 2005 operating lease we have entered regarding our new headquarters space in Fremont, California, and debt agreements were as follows (in thousands):

	Operating Leases	Debt	Total
Nine months ending December 31, 2005	$ 358	$ 527	$ 885
Year ending December 31, 2006	404	383	787
Year ending December 31, 2007	383	988	1,371
Year ending December 31, 2008	350	8,262	8,612
Year ending December 31, 2009	355		355
Year ending December 31, 2010 and thereafter	116		116
Total of future minimum operating lease payments	$ 1,966	$ 10,160	$ 12,126

Our capital requirements depend on numerous factors including our research and development expenditures, expenses related to selling, general and administrative operations and working capital to support business growth. Our net cash used in operating activities was $1.1 million for the quarter ended March 31, 2005. We expect that our net cash used in operating activities will not increase, on a quarterly basis, for the remaining quarters of 2005. Our cash used in the purchase of property and equipment was $154,000 for the three months ended March 31, 2005. We expect cash used in the purchase of property and equipment to be approximately $0.8 million for the year ended December 31, 2005. Our balance of cash, cash equivalents and marketable securities on March 31, 2005 was $6.2 million. Although it is difficult for us to predict future liquidity requirements with certainty, we believe that our current balances of cash, cash equivalents and marketable securities will satisfy our cash requirements for at least the next 12 months. During or after this period, if cash generated by operations is insufficient to satisfy our liquidity requirements, we may need to sell additional equity or debt securities, obtain an additional credit facility or renegotiate debt repayment terms. There can be no assurance that additional financing will be available to us or, if available, that such financing will be available on terms favorable to us and our stockholders, or that we will be successful in renegotiating debt repayment terms. Failure to obtain sufficient funds on acceptable terms when needed, to make timely debt payments, or to achieve our growth or profitability objectives may require us to curtail operations, perhaps to a significant extent.

Recent Accounting Pronouncements

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

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

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

Table of Contents

Factors That May Affect Future Results

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

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

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

- Coordinating geographically disparate organizations, systems and facilities;
- Integrating personnel with diverse business backgrounds;
- Consolidating corporate and administrative functions;
- Consolidating research and development, and manufacturing operations;
- Coordinating sales and marketing functions;
- Retaining key employees; and
- Preserving research and development, collaboration, distribution, marketing, promotion and other important relationships of the companies.

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

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 are consolidating our manufacturing operations at our Manchester, Georgia location and, prior to September 30, 2004, personnel at that location had essentially no experience in manufacturing our radiofrequency ablation disposable devices.

To be successful, we must manufacture our products in substantial quantities in compliance with regulatory requirements at acceptable costs. If we do not succeed in manufacturing quantities of our disposable devices that meet customer demand, we could lose customers and our business could suffer. At the present time, we have limited high-volume manufacturing experience. Our manufacturing operations are currently focused on the in-house assembly of our disposable devices. As we increase our manufacturing volume and the number of product designs for our disposable devices, the complexity of our manufacturing processes will increase. Because our manufacturing operations are primarily dependent upon manual assembly, if demand for our system increases we will need to hire additional personnel and may need to purchase additional equipment. If we are unable to sufficiently staff and equip our manufacturing operations, particularly considering our plans to consolidate our manufacturing operations in our Manchester, Georgia location by the end of the second quarter of 2005, 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 are in the process of transitioning of our California-based manufacturing operations to our Manchester, Georgia location. We have incurred normal and customary moving costs and have also incurred integration costs, including training expenses and 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 costs associated with moving our RFA manufacturing to 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.

Table of Contents

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 $1.7 million during the first quarter 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 March 31, 2005, we had an accumulated deficit of $90.0 million. To become profitable we must increase our sales and continue to limit the growth of our operating expenses. If our sales do not grow, or if expenses grow excessively, we may not be able to achieve or maintain profitability in the future.

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

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

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

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

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

Alternative therapies could prove to be superior to the RITA radiofrequency ablation system or implantable 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

Table of Contents

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

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

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

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

- the challenge of managing international sales without direct access to the end customer;
- lower average selling prices for our products, due to distributor discounts;
- the risk of inventory build-up by our distributors which could negatively impact sales in future periods;
- obtaining reimbursement for procedures using our devices in some foreign markets;
- the burden of complying with complex and changing foreign regulatory requirements;
- longer accounts receivable collection time;
- 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 20% of our international sales in the first quarter of 2005 and 19% of our international in 2004. International sales accounted for 14% of our total sales in the first quarter 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 built up inventory of our products. As a result, future sales to these distributors could be negatively impacted. Sales to our Japanese distributor in 2004 and 2003 and to a domestic distributor in the three months ended September 30, 2004 were so affected. In addition, while our distributors have no price protection and may only return undamaged products per our return policies, if we permit the return of products in excess of our provision for returns, we will have to adjust our revenues relating to these products. This may also impact our revenue recognition policy on future distributor sales.

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

Table of Contents

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

We are subject to, and may in the future be subject to, costly and time-consuming product liability actions.

We manufacture medical devices that are used on patients in both minimally invasive and open surgical procedures and, as a result, we are and may in the future be subject to product liability lawsuits. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, we could have to pay any amount awarded by a court in excess of policy limits. Finally, even a meritless or unsuccessful product liability claim could be time consuming and expensive to defend and could result in the diversion of management s attention from managing our core business.

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.

Table of Contents

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

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

- our ability to repay debt;
- our ability to successfully commercialize our products;
- our ability to comply with Section 404 of the Sarbanes-Oxley Act of 2002;
- conclusions that our internal control over financial reporting are ineffective;
- announcements regarding patent litigation or the issuance of patents to us or our competitors;
- quarterly fluctuations in our results of operations;
- announcements of technological or competitive developments by us or our competitors;
- product liability claims;
- regulatory developments regarding us or our competitors;
- acquisitions or strategic alliances by us or our competitors;
- changes in estimates of our financial performance or changes in recommendations by securities analysts; and
- general market conditions, particularly for companies with small market capitalizations.

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

We 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 through lower sales or higher costs.

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

We are dependent on two third-party suppliers to produce our 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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

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

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We assumed fixed rate borrowings in conjunction with our merger with Horizon Medical Products. These borrowings will increase our interest expense. Also, changes in interest rates will affect the fair market value of these borrowings. Except for these factors, our market risk disclosures have not changed significantly from those set forth in Management s Discussion and Analysis of Financial Condition and Results of Operations in our Form 10-K for the year ended December 31, 2004, as amended.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of Company management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to the Securities Exchange Act of 1934 Rules 13a-15(b) and 15d-15(b). Based upon, and as of the date of this evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were not effective, because the material weaknesses discussed in the Company s annual report on Form 10-K for the year ended December 31,

2004, as amended, have not yet been fully remediated. In light of these material weaknesses, the Company performed additional analysis and other post-closing procedures to ensure that the consolidated financial statements were prepared in accordance with generally accepted accounting principles. Accordingly, management believes that the financial statements included in this report fairly present in all material respects our financial condition, results of operations and cash flows for the periods presented.

Changes in Internal Control Over Financial Reporting

The material weaknesses identified and discussed in the Company s annual report on Form 10-K for the year ended December 31, 2004, as amended, have resulted in changes in the Company s internal control over financial reporting during the quarter ended March 31, 2005, that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Although not yet complete, during the quarter ended March 31, 2005, we continued the following actions to remediate the material weaknesses we identified to be present as of December 31, 2004**:**

- Hiring of additional personnel, permitting enhanced segregation of duties and additional review;
- Additional training of staff;
- Identification of procedural improvements in our accounting processes;
- Enhancement of procedures for timely submission of invoices, particularly those received in California, to our Georgia-based accounting department.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings. Not applicable.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds. Not applicable.

Item 3. Defaults Upon Senior Securities. Not applicable.

Item 4. Submission of Matters to a Vote of Security Holders. Not applicable.

Item 5. Other Information. Not applicable.

Item 6. Exhibits

(a) Exhibits:

31.1	Rule 13a-14(a) / 15d-14(a) Certification of Chief Executive Officer
31.2	Rule 13a-14(a) / 15d-14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

RITA MEDICAL SYSTEMS, INC

By: /S/ Joseph DeVivo

Joseph DeVivo

President and Chief Executive Officer

Date: May 10, 2005

Table of Contents

EXHIBIT INDEX

(a) Exhibits:

31.1	Rule 13a-14(a) / 15d-14(a) Certification of Chief Executive Officer
31.2	Rule 13a-14(a) / 15d-14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer