RITA MEDICAL SYSTEMS INC
Form 10-Q
November 09, 2004
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 September 30, 2004

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.)**

967 N. Shoreline Blvd.

Mountain View, CA 94043

(Address of principal executive offices, including zip code)

650-314-3400

(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 October 29, 2004, there were 36,787,586 shares of the registrant s Common Stock outstanding.

Table of Contents

INDEX

		Page
PART I. FINANCIAL INFORMATION		
Item 1.	Financial Statements (unaudited)	
	Condensed Consolidated Balance Sheets September 30, 2004 and December 31, 2003	3
	Condensed Consolidated Statements of Operations three and nine months ended September 30, 2004 and 2003	4
	Condensed Consolidated Statements of Cash Flows nine months ended September 30, 2004 and 2003	5
	Notes to Unaudited Condensed Consolidated Financial Statements	6
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	27
Item 4.	Controls and Procedures	27
PART II. OTHER INFORMATION		
Item 1.	Legal Proceedings	28
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	28
Item 3.	Defaults Upon Senior Securities	28
Item 4.	Submission of Matters to a Vote of Security Holders	28
Item 5.	Other Information	28
Item 6.	Exhibits	29
SIGNATURES		32
EXHIBIT INDEX		33

Table of Contents

PART 1. FINANCIAL INFORMATION

Item 1. Financial Statements

RITA MEDICAL SYSTEMS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, unaudited)

	September 30, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 3,070	$ 4,580
Marketable securities	1,043	4,022
Accounts and note receivable, net	6,889	2,990
Inventories	7,742	2,192
Prepaid and other current assets	1,821	1,028
Total current assets	20,565	14,812
Long term marketable securities		933
Long term note receivable, net	274	338
Property and equipment, net	2,107	1,089
Goodwill	91,339	
Intangible assets	31,316	4,814
Other assets	41	47
Total assets	$ 145,642	$ 22,033
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 2,710	$ 757
Accrued liabilities	5,166	2,169
Deferred revenue	648	
Current portion of long term debt	8,271	
Total current liabilities	16,795	2,926
Long term debt, less current portion	9,810	
Deferred maintenance revenue, less current portion	18	23
Other long term liabilities	79	
Total liabilities	26,702	2,949

Stockholders equity		
Common stock	37	18
Additional paid-in capital	205,309	98,037
Accumulated other comprehensive income (loss)	(2)	2
Accumulated deficit	(86,404)	(78,973)
Total stockholders equity	118,940	19,084
Total liabilities and stockholders equity	$ 145,642	$ 22,033

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 September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Sales	$ 7,951	$ 3,865	$ 17,254	$ 12,412
Cost of goods sold	2,821	1,253	6,106	4,530
Gross profit	5,130	2,612	11,148	7,882
Operating expenses:				
Research and development	928	976	2,752	3,395
Selling, general and administrative	6,139	4,182	14,523	13,482
Restructuring charges	1,089		1,089	
Total operating expenses	8,156	5,158	18,364	16,877
Loss from operations	(3,026)	(2,546)	(7,216)	(8,995)
Interest expense	(242)		(242)	
Interest income and other expense, net	10	32	27	157
Net loss	$ (3,258)	$ (2,514)	$ (7,431)	$ (8,838)
Net loss per common share, basic and diluted	$ (0.10)	$ (0.14)	$ (0.33)	$ (0.50)
Shares used in computing net loss per common share, basic and diluted	31,079	17,807	22,399	17,538

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)

	Nine months ended September 30,	
	2004	**2003**
Cash flows from operating activities:		
Net loss	$ (7,431)	$ (8,838)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,587	1,228
Loss on disposal of property and equipment	23	158
Revaluation of common stock warrants for services received		(101)
Amortization of stock-based compensation	103	
Allowance for doubtful accounts	(101)	56
Provision for obsolete inventories	(117)	393
Changes in operating assets and liabilities, net of assets and liabilities acquired:		
Accounts and note receivable	(912)	82
Inventories	282	736
Prepaid and other current assets	(6)	(102)
Accounts payable and accrued liabilities	454	(1,267)
Deferred revenue	643	
Net cash used in operating activities	(5,475)	(7,655)
Cash flows from investing activities:		
Purchase of property and equipment	(509)	(720)
Purchase of marketable securities	(297)	(7,855)
Sales and maturities of marketable securities	4,204	6,560
Net cash used in merger with Horizon Medical Products, Inc.	(224)	
Capitalization of patent litigation costs		(621)
Acquisition of intangibles		(2,650)
Note receivable and other assets	117	106
Net cash provided by (used in) investing activities	3,291	(5,180)
Cash flows from financing activities:		
Proceeds from assumption of short term debt	503	
Principle payments on long term debt	(117)	
Proceeds from issuance of common stock	288	9,274
Net cash provided by financing activities	674	9,274

Net decrease in cash and cash equivalents	(1,510)	(3,561)
Cash and cash equivalents at beginning of period	4,580	6,888
Cash and cash equivalents at end of period	$ 3,070	$ 3,327

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, 2003 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, 2003 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. The combined companies will continue to operate under the name RITA Medical Systems, Inc. The merger was pursued and completed because the management groups and stockholders of each company believe the combined entity will achieve higher sales and profitability than either or both of the pre-merger companies on a stand-alone basis. These factors contributed to a purchase price in excess of the fair value of Horizon s net tangible and intangible assets acquired and, as a result, the Company has recorded goodwill in connection with this transaction.

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 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.

The allocation of purchase price is as follows (in thousands):

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

Table of Contents

The merger was completed on July 29, 2004 and none of Horizon s results of operations prior to that date are included in the Company s condensed consolidated statements of operations for the three or nine month periods ended September 30, 2004. However, the Company has prepared pro forma financial information showing sales and net loss for the combined entity for the three and nine month periods ended September 30, 2004 and September 30, 2003, respectively, as if the merger occurred as of the beginning of the periods presented. This unaudited pro forma financial information is not intended to represent or be indicative of the consolidated results of operations of the Company that would have been reported had the acquisition been completed as of the dates presented and should not be taken as representative of the future consolidated results of operations or financial condition of the Company (in thousands, except per share amounts):

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Sales	$ 9,306	$ 11,410	$ 33,118	$ 32,662
Net loss	$ (6,453)	$ (2,659)	$ (11,981)	$ (10,499)
Net loss per common share, basic and diluted	$ (0.18)	$ (0.07)	$ (0.33)	$ (0.29)

Restructuring costs of $1,089,000, consisting entirely of severance related to the termination of employees to eliminate certain duplicative activities, were incurred in the third quarter of 2004 (see Note 10, Restructuring).

3. Liquidity

As of September 30, 2004, the Company s total assets were $145.6 million, total tangible assets were $23.0 million, total liabilities were $26.7 million, working capital was $3.8 million and cash and cash equivalents totaled $3.1 million. Current and anticipated demand for the Company s products as well as procurement and production affect the need for capital. Also, the Company s merger with Horizon requires significant cash payments over the last three months of 2004 and further requires service of debt, which totaled approximately $18.1 million as of September 30, 2004. Approximately $8.3 million of this debt is current, with $6.5 million coming due in July of 2005. To make our debt payments, we need to sell additional equity or debt securities, obtain an additional credit facility or renegotiate the terms of our debt. 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 the Company and our stockholders, or that we can successfully renegotiate our debt terms. Failure to make timely debt payments may require us to curtail operations, perhaps to a significant extent. In addition, future equity financings could result in dilution to stockholders, and future debt financings could result in certain financial and operational restrictions.

4. 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 includes 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 reconciliation of total weighted average outstanding common shares to shares used in determining net loss per share is as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Weighted average shares of common stock outstanding	31,079	17,807	22,399	17,543
Less: weighted-average shares subject to repurchase				(5)
Weighted average shares used in basic and diluted net loss per common share	31,079	17,807	22,399	17,538

The following numbers of shares represented by 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):

	September 30,	
	2004	2003
Effect of potentially dilutive securities:		
Options	7,314	2,307
Warrants	78	25
Total potentially dilutive securities excluded from the computation of net loss per common share as their effect was antidilutive	7,392	2,332

Table of Contents

5. 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 and nine month periods ended September 30, 2004 and 2003, respectively, if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation granted under all of the stock option plans and the Employee Stock Purchase Plan (in thousands, except per share amounts):

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Net loss, as reported	$ (3,258)	$ (2,514)	$ (7,431)	$ (8,838)
Deduct: Total stock-based employee compensation determined under the fair value based method for all awards	(4,428)	(349)	(5,604)	(1,436)
Net loss, pro-forma	$ (7,686)	$ (2,863)	$ (13,035)	$ (10,274)
Basic and diluted net loss per common share:				
As reported	$ (0.10)	$ (0.14)	$ (0.33)	$ (0.50)
Pro-forma	$ (0.25)	$ (0.16)	$ (0.58)	$ (0.59)

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 September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Volatility	76%	76%	76%	76%
Risk-free interest rate	3.57%	3.21%	3.55%	2.74%
Expected life	5 years	5 years	5 years	5 years
Expected dividends	0%	0%	0%	0%

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

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Volatility	60%	70%	60%	70%
Risk-free interest rate	1.18%	2.50%	1.10%	2.95%
Expected life	0.9 years	1.4 years	0.7 years	1.3 years
Expected dividends	0%	0%	0%	0%

6. Inventories

The components of the Company s inventories at September 30, 2004 and December 31, 2003, respectively, were as follows (in thousands):

	September 30, 2004	December 31, 2003
Raw materials	$ 3,253	$ 719
Work-in-process	667	214
Finished goods	3,822	1,259
	$ 7,742	$ 2,192

Table of Contents

7. Intangible assets and related amortization

The Company s intangible assets and related accumulated amortization at September 30, 2004 and December 31, 2003, respectively, were as follows (in thousands):

	September 30, 2004			December 31, 2003		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Capitalized patent defense litigation costs	$ 2,755	$ (533)	$ 2,222	$ 2,755	$ (351)	$ 2,404
Capitalized patent license agreements	2,650	(481)	2,169	2,650	(240)	2,410
Intangible assets recorded at merger with Horizon:						
Customer relationships	16,600	(184)	16,416			
Product technology	6,900	(96)	6,804			
Trademarks	3,000	(50)	2,950			
Isomed distribution contract	700	(29)	671			
Loan closing costs	73	(13)	60			
Non-compete contracts	36	(12)	24			
	$ 32,714	$ (1,398)	$ 31,316	$ 5,405	$ (591)	$ 4,814

The amortization periods of our intangible assets as of September 30, 2004 are as follows:

	Amortization periods of intangible assets
Capitalized patent defense litigation costs	11 years
Capitalized patent license agreements	6 - 12 years
Customer relationships	15 years
Product technology	12 years
Trademarks	10 years
Isomed distribution contract	4 years
Loan closing costs	1 year
Non-compete contracts	4 months

Aggregate amortization expense for the nine months ended September 30, 2004, and estimated amortization expense for the three months ended December 31, 2004 and each of the five years ended December 31, 2005 through 2009 is as follows (in thousands):

Aggregate amortization expense:	
For the nine months ended September 30, 2004	$ 806

Estimated amortization expense:

For the three months ended December 31, 2004	$ 717
For the twelve months ended December 31, 2005	$ 2,744
For the twelve months ended December 31, 2006	$ 2,738
For the twelve months ended December 31, 2007	$ 2,723
For the twelve months ended December 31, 2008	$ 2,647
For the twelve months ended December 31, 2009	$ 2,457

The Company has adopted Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets and Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. Under these standards, the potential impairment of the Company s goodwill will be reviewed at least annually, or more often if changes in business conditions so dictate. No impairment of goodwill has been determined to exist as of September 30, 2004.

8. Debt

The Company has short-term notes payable relating to its insurance coverage. These short-term notes total approximately $1,080,000 as of September 30, 2004.

Also, as part of the merger of RITA and Horizon, the Company assumed the following debts:

Senior Subordinated Convertible Notes (the Senior Notes) were originally issued by Horizon in March 2002, in the amount of $15,033,000. As of September 30, 2004, $14,763,000 was due under the Senior Notes, of which $6,501,000 will come due in July 2005, with the balance coming due in July 2008. The Senior Notes bear interest, payable quarterly, at 6.0% per annum. The interest rate on the Senior Notes will increase to 8.0% on January 29, 2005 and to 14% on July 29, 2005. The Company may prepay the Senior Notes without a penalty prior to their respective maturity dates.

Table of Contents

A Junior Promissory Note (the Junior Note) payable to a major financial institution was originally executed by Horizon in April 2002, in the amount of $2.0 million. As of September 30,2004, $1,595,000 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) was executed by Horizon in 1998. As of September 30, 2004, $643,000 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 scheduled to be fully repaid in March 2006.

Future maturities of debt outstanding as of September 30, 2004 are as follows (in thousands):

Three months ending December 31, 2004	$ 742
Nine months ending December 31,2005	7,529
Three months ending December 31, 2005	178
Twelve months ending December 31,2006	383
Twelve months ending December 31,2007	987
Twelve months ending December 31,2008	8,262
Twelve months ending December 31,2009 and thereafter	
	$ 18,081

9. Deferred maintenance revenue and other deferred revenue

Revenue for maintenance contracts is recognized on a pro-rata basis over the period of the applicable maintenance contract, ranging from 12 to 36 months. Costs are recognized as incurred. The Company had no deferred maintenance revenue during the three and nine month periods ended September 30, 2003. Changes in the Company s deferred maintenance revenue during the three and nine months ended September 30, 2004 were as follows (in thousands):

	Three months ended September 30, 2004	Nine months ended September 30, 2004
Balance at beginning of period	$ 45	$ 45
Add: maintenance contract billings		14
Less: revenue recognized	(8)	(22)
Balance at end of period	37	37
Less: current portion	(19)	(19)
Deferred maintenance revenue, less current portion	$ 18	$ 18

Additionally, during the third quarter of 2004 the Company recorded $648,000 in deferred revenue relating to a shipment to a distributor that was determined not to meet the standard for revenue recognition as defined in the SEC s Staff Accounting Bulletin No. 104, Revenue Recognition.

10. Restructuring

In the third quarter of 2004, in connection with the merger of RITA and Horizon, the Company recorded a restructuring charge of $1,089,000 related to the termination of employees to eliminate certain duplicative activities. These charges were accounted for in accordance with SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. As of September 30, 2004, $245,000 of the severance amounts had been paid and $844,000 has been accrued. The Company expects to pay approximately $370,000 of the remaining severance amounts by the end of the year and the remaining balance during 2005. Additional severance provisions related to further restructuring activities are possible in the fourth quarter of 2004 and 2005.

11. Segment information

As a result of the merger with Horizon, the Company expanded its customer base and portfolio of products, which resulted in two groups of medical oncology products: radiofrequency ablation (RFA) systems, which consist largely of the original RITA products and vascular access systems, which consist largely of the former Horizon products.

Table of Contents

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 executive officer in deciding how to allocate resources and in assessing performance. The Company s chief executive officer 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. For purposes of allocating resources, the Company evaluates the performance of its product groups based only on sales. The Company does not assess the performance of its product groups on measures of income or expenses. Accordingly, the Company operates as one operating segment. Below are the Company s sales by geographic region (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Domestic	$ 6,828	$ 3,312	$ 14,222	$ 9,775
International	1,123	553	3,032	2,637
Total medical oncology product sales	$ 7,951	$ 3,865	$ 17,254	$ 12,412

As mentioned above, the Company has two groups of medical oncology products. Sales for these two groups are as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Radiofrequency ablation products	$ 3,570	$ 3,865	$ 12,873	$ 12,412
Vascular access products	4,381		4,381	
Total medical oncology product sales	$ 7,951	$ 3,865	$ 17,254	$ 12,412

12. 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.

13. Recent accounting pronouncements

The Financial Accounting Standard Board (*FASB*) issued an exposure draft entitled *Share-Based Payment, an Amendment of FASB Statements Nos. 123 and 95.* This exposure draft would require stock-based compensation to employees to be recognized as a cost in the financial statements and that such cost be measured according to the fair value of the stock options. In the absence of an observable market price for the stock awards, the fair value of the stock options would be based upon a valuation methodology that takes into consideration various factors, including the exercise price of the option, the expected term of the option, the current price of the underlying shares, the expected volatility of the underlying share price, the expected dividends on the underlying shares and the risk-free interest rate. The proposed requirements in the exposure draft would be effective for the first fiscal year beginning after June 15, 2005. The FASB intends to issue a final statement in late 2004. We will continue to monitor communications on this subject from the FASB in order to determine the impact on our financial statements.

At its March 2004 meeting, the Emerging Issue Task Force (EITF) reached a consensus recognition and measurement guidance previously discussed under EITF 03-01. The consensus clarifies the meaning of other-than-temporary impairment and its application to investments classified as either available-for-sale or held-to-maturity under FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, and investments accounted for under the cost method or the equity method. The recognition and measurement guidance for which the consensus was reached in the March 2004 meeting is to be applied to other-than-temporary impairment evaluations in reporting periods beginning after June 15, 2004. The Company does not expect the adoption of the disclosure requirements of EITF 03-01 to have a material impact on its financial position, cash flows or results of operations.

14. Commitments and contingencies

In the course of our merger with Horizon, we have incurred commitments for operating leases related to facility rental. Future minimum payments under operating leases are as follows (in thousands):

Payments due in 2004	$ 125
Payments due in 2005	243
Payments due in 2006	205
Payments due in 2007	204
Payments due in 2008	190
Payments due in 2009 and thereafter	243
Total of future minimum operating lease payments	$ 1,210

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, in our joint proxy statement / prospectus, dated June 25, 2004, for the meeting of our stockholders on July 29, 2004 and in our annual report on Form 10-K for the fiscal year ended December 31, 2003. Additionally, factors that might cause actual results to be different from forecasted results may be found in the Factors That May Affect Future Results section of Horizon Medical Products annual report on Form 10-K for their fiscal year ended December 31, 2003 and in their quarterly report on Form 10-Q for their first fiscal quarter ended March 31, 2004. 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 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.

On July 29, 2004, we completed a merger with Horizon Medical Products, Inc. (Horizon). 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. 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. We believe the merger will lead to higher sales and greater profitability due to a larger, more effective sales group, consolidation of manufacturing resulting in lower product costs, and reduced administrative expenses.

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 and nine months ended September 30, 2004 and 2003, and for the years ended December 31, 2003, 2002 and 2001, sets forth some of these measurements:

	Nine months	Years ended December 31,

	Three months ended September 30,		ended September 30,				
	2004	2003	2004	2003	2003	2002	2001
Total sales (in thousands)	$ 7,951	$ 3,865	$ 17,254	$ 12,412	$ 16,607	$ 17,393	$ 14,791
Percentage of sales: United States	86%	86%	82%	79%	80%	74%	54%
Percentage of sales: International	14%	14%	18%	21%	20%	26%	46%
Percentage of sales: Radiofrequency products	45%	100%	75%	100%	100%	100%	100%
Percentage of sales: Vascular access products	55%	0%	25%	0%	0%	0%	0%
Gross margin	65%	68%	65%	64%	63%	60%	59%

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

Table of Contents

areas of the United States. Since completion of the merger, we have begun to distribute our radiofrequency ablation products through some of these domestic distribution partners. However, direct sales will remain the Company s 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 have, to date, introduced our premium-priced Starburst Xli and Xlie families of disposable needles only in this region. 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. Further, some of our distributors in Europe and Japan have been reducing their inventory levels. These factors have resulted in slow growth or even declining volume in some of our international markets. Going forward, we note that the reduction in international inventories experienced in preceding periods seems to have diminished. We expect 2004 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. However, we also note reimbursement approval for our radiofrequency procedure in Japan, effective April 1, 2004, and the receipt of modest orders from our Japanese distributor during the third quarter of 2004. We believe that Japan will once again be an important source of international revenue beginning in 2005.

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 and the percentage of our sales derived from disposable products was growing relative to that of hardware products. Going forward, we expect that more than 90% of our sales will be derived from our disposable products that have higher gross margins than our hardware products. Further, the merger with Horizon expanded our product offering, which should result in additional sales for the company, primarily from the sale of implantable vascular ports used in cancer treatment protocols. During the third quarter of 2004, integration of the two sales groups required training that adversely impacted sales growth and may continue to limit sales growth over the balance of 2004. However, we believe that in 2005 the broader product line and larger sales group resulting from the merger will enable us to increase the efficiency of our selling effort.

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. 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 2003 and the nine months ended September 30, 2004 reflects amortization of capitalized license fees associated with the April 2003 settlement of our patent litigation dispute with Boston Scientific Corporation. We expect these amortization charges to continue through 2015. 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, although we generally expect only modest impacts from such provisions.

Our gross margins reflect our selling prices, our domestic / international mix percentages, our product mix percentages, our production volumes, the costs we pay for vendor manufactured product and our provisions for obsolete inventory. Our gross margin for the three months ended September 30, 2004 was 65%, compared to a gross margin of 68% for the three months ended September 30, 2003. Historically, the gross margin rate for our vascular access products has been lower than that of our radiofrequency ablation products. For this reason, we expect that future company gross margins will, on average, be reduced by inclusion of these products 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 and nine months ended September 30, 2004 and 2003, our Consolidated Statements of Operations for the years ended December 31, 2003, 2002 and 2001, our Unaudited Condensed Consolidated Balance Sheets as of March 31and September 30, 2004, and our Consolidated Balance Sheets as of December 31, 2003, 2002 and 2001:

	Three months ended September 30,		Nine months ended September 30,		Years ended December 31,		
	2004	2003	2004	2003	2003	2002	2001
Research and development expense	$ 928	$ 976	$ 2,752	$ 3,395	$ 4,294	$ 5,052	$ 6,489
Selling, general and administrative expense	6,139	4,182	14,523	13,482	17,418	19,366	16,646
Restructuring charges	1,089		1,089				
Total operating expenses	$ 8,156	$ 5,158	$ 18,364	$ 16,877	$ 21,712	$ 24,418	$ 23,135

				December 31,		
	September 30, 2004	June 30, 2004	March 31, 2004	2003	2002	2001
Cash and cash equivalents	$ 3,070	$ 4,404	$ 6,122	$ 4,580	$ 6,888	$ 7,297
Marketable securities, current and long term	1,043	1,881	1,990	4,955	5,947	16,240
Total cash and marketable securities	$ 4,113	$ 6,285	$ 8,112	$ 9,535	$ 12,835	$ 23,537

Table of Contents

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 and Europe, 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 for the three months ended September 30, 2004 was $0.9 million, or 5% lower than in the prior year period, and little growth is expected over the balance of 2004. Research spending in 2005 is expected to increase modestly, driven by programs aimed at technical innovation of our radiofrequency ablation products. We expect that the merger with Horizon will have only minimal impact on growth in research and development expenses.

Selling, general and administrative expense for the three months ended September 30, 2004 was $2.0 million higher than in the three months ended September 30, 2003, due to the consolidation of Horizon results and expenses incurred in the integration of the two companies. Also, the merger resulted in recognition of intangible assets, amortization of which will result in charges to selling, general and administrative expense of approximately $180,000 per month for the foreseeable future. However, headcount reductions, particularly in the domestic sales groups, were effected during the third quarter of 2004, and will continue during the fourth quarter of 2004. These headcount reductions should result in expense levels for the combined company that are lower than the sum of expenses for the two companies prior to the merger. However, the severance associated with headcount reductions resulted in a $1.1 million restructuring expense, exclusive of selling, general and administrative expenses, for the three months ended September 30, 2004. Additional severance provisions related to further restructuring activities are possible in the fourth quarter of 2004 and 2005.

In addition to management of our operating expenses, we must continue to conserve our cash and raise additional cash. Our combined total of cash, cash equivalents and marketable securities was $4.1 million as of September 30, 2004, down from $9.5 million as of December 31, 2003. Our net cash used in operating activities for the nine months ended September 30, 2004 was $5.5 million. We have approximately $18.1 million in short term and long term debt as of September 30, 2004, with $6.5 million coming due in July 2005. We must continue to strictly manage our use of cash and will need to raise additional cash through borrowing or sale of equity securities or renegotiate the repayment terms of our debt, in order to support operations and to satisfy our debt obligations over the next twelve months.

We incurred a net loss of $3.3 million for the three months ended September 30, 2004 compared to $2.5 million for the three months ended September 30, 2003. Due to integration costs, the costs associated with research and development programs and our sales and marketing efforts, we expect to incur net losses throughout 2004. Profitability 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.

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, 2003. All of the policies and estimates discussed at that time remain unchanged. However, because the merger with Horizon resulted in goodwill of $91.3 million as of September 30, 2004, management has determined that the Company s accounting policy regarding goodwill should also be considered a critical accounting policy.

Table of Contents

Goodwill and other intangible assets

We account for our goodwill under Statement of Financial Accounting Standards (SFAS) No. 142, Goodwill and Other Intangible Assets. The SFAS No. 142 goodwill impairment model is a two-step process. First, it requires a comparison of the book value of net assets to the fair value of the reporting units that have goodwill assigned to them. If the fair value is determined to be less than book value, a second step is performed to compute the amount of the impairment. Recoverability of the asset is measure by comparison of the asset s carrying amount to future net undiscounted cash flows the asset is expected to generate. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the projected discounted future net cash flows arising from the asset. We test goodwill for impairment during the third quarter of every fiscal year, and when an event occurs or circumstances change such that it is reasonably possible that an impairment may exist.

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 September 30, 2004 and the four preceding fiscal quarters:

	Q3 2004	Q2 2004	Q1 2004	Q4 2003	Q3 2003	Q2 2003
Domestic sales	86%	80%	79%	83%	86%	81%
International sales	14%	20%	21%	17%	14%	19%
Total sales	100%	100%	100%	100%	100%	100%
Cost of goods sold	35%	36%	35%	39%	32%	42%
Gross profit	65%	64%	65%	61%	68%	58%
Operating expenses:						
Research and development	11%	21%	18%	21%	25%	26%
Selling, general and administrative	78%	86%	94%	94%	109%	117%
Restructuring charges	14%	0%	0%	0%	0%	0%
Total operating expenses	103%	107%	112%	115%	134%	143%
Loss from operations	(38)%	(43)%	(47)%	(54)%	(66)%	(85)%
Interest expense	(3)%	0%	0%	0%	0%	0%
Interest income and other expense, net	0%	0%	0%	0%	1%	1%
Net loss	(41)%	(43)%	(47)%	(54)%	(65)%	(84)%

Three months ended September 30, 2004 and 2003

The following table, which sets forth key comparisons of our sales results for the third quarter of 2004 compared to the third quarter of 2003, provides additional information on the impact of the consolidation of our acquired vascular access products upon our results (in thousands):

	Three months ended September 30,			
	2004	2003	Growth	%
Domestic sales:				
Radiofrequency ablation products	$ 2,804	$ 3,312	$ (508)	-15%
Vascular access products	4,024		4,024	
Total domestic sales	$ 6,828	$ 3,312	$ 3,516	106%
International sales:				
Radiofrequency ablation products	$ 766	$ 553	$ 213	39%
Vascular access products	357		357	
Total international sales	$ 1,123	$ 553	$ 570	103%
Total radiofrequency ablation sales	$ 3,570	$ 3,865	$ (295)	-8%
Total vascular access product sales	4,381		4,381	
Total sales	$ 7,951	$ 3,865	$ 4,086	106%

For the three months ended September 30, 2004, our sales rose 106%, to $8.0 million, compared to $3.9 million in the prior period ended September 30, 2003. However, this result was entirely due to inclusion of vascular access products in our results because of the merger with Horizon on July 29, 2004. Sales of our radiofrequency ablation products decreased, compared to the

Table of Contents

prior period, 8% overall, and 15% in our domestic region, because during the third quarter of 2004, integration of two sales groups required training that adversely impacted sales growth. Sales growth may be similarly impacted by training and turnover in sales personnel during the fourth quarter of 2004. However, we note that our shipments during the quarter included an additional $648,000 in product treated as deferred revenue. Also, we believe that in 2005 the broader product line and larger sales group resulting from the merger will enable us to increase the efficiency of our selling effort.

Cost of goods sold for the quarter ended September 30, 2004 was $2.8 million, up from $1.3 million for the quarter ended September 30, 2003, reflecting inclusion of $1.7 million in cost associated with vascular access products and a $0.1 million reduction in cost associated with lower sales of radiofrequency ablation products. Our gross margin rate was 65% in the third quarter of 2004, compared to 68% in the prior period. Historically, the gross margin rate for our vascular access products has been lower than that of our radiofrequency ablation products. For this reason, we expect that future company gross margins may, on average, be reduced by inclusion of these products in our results.

Research and development expenses for the quarter ended September 30, 2004 were $0.9 million, compared to $1.0 million in the third quarter of 2003. Research and development expense for vascular access products was $0.1 million for the quarter, and research and development expense for radiofrequency ablation products was $0.8 million for the quarter, down $0.2 million from the prior period. Development projects underway during the third quarter of 2004 were relatively small and inexpensive, but we expect spending on new and more innovative radiofrequency products to increase in the fourth quarter of 2004 and 2005. Development of vascular access products should have only a minimal impact on growth in research and development expenses.

Selling, general and administrative expenses for the quarter ended September 30, 2004 were $6.1 million, compared to $4.2 million in the third quarter of 2003. About $0.2 million of the increase was due to expenses associated with merger integration and sales training, and approximately $0.2 million of the increase was due to expenses associated with compliance with the Sarbanes-Oxley Act of 2002. Expenses associated with the Sarbanes-Oxley Act of 2002 are expected to increase in the fourth quarter of 2004 and in 2005. Our bad debt expense was about $0.1 million lower in the third quarter of 2004, compared to the third quarter of 2003. The $1.6 million balance of the increase in selling, general and administrative expenses was due to additional headcount in sales and marketing functions as a result of the combination of the two companies.

We incurred restructuring expenses of $1.1 million during the three months ended September 30, 2004, consisting of severance related to the termination of employees to eliminate certain duplicative activities.

Interest expense for the third quarter ended September 30, 2004 was $0.2 million. We had no interest expense in the prior year period. Interest income and other expenses were negligible for the third quarter of 2004 and for the third quarter of 2003.

Nine months ended September 30, 2004 and 2003

The following table, which sets forth key comparisons of our sales results for the nine months ended September 30, 2004 compared to the nine months ended September 30, 2003, provides additional information on the impact of the consolidation of our acquired vascular access products upon our results (in thousands):

	Nine months ended September 30,

	2004	2003	Growth	%
Domestic sales:				
Radiofrequency ablation products	$ 10,198	$ 9,775	$ 423	4%
Vascular access products	4,024		4,024	
Total domestic sales	$ 14,222	$ 9,775	$ 4,447	45%
International sales:				
Radiofrequency ablation products	$ 2,675	$ 2,637	$ 38	1%
Vascular access products	357		357	
Total international sales	$ 3,032	$ 2,637	$ 395	15%
Total radiofrequency ablation sales	$ 12,873	$ 12,412	$ 461	4%
Total vascular access product sales	4,381		4,381	
Total sales	$ 17,254	$ 12,412	$ 4,842	39%

Table of Contents

For the nine months ended September 30, 2004, our sales rose $4.4 million, or 39%, to $17.3 million, compared to $12.4 million in the prior period ended September 30, 2003. Inclusion of vascular access products comprised $4.3 million of the increase. Sales of our radiofrequency ablation products increased 4% overall, and 4% in our domestic region. During the third quarter of 2004, integration of two sales groups required training that adversely impacted sales growth. Sales growth may be similarly impacted by training and turnover in sales personnel during the fourth quarter of 2004. However, we note that our shipments during the quarter included an additional $648,000 in product treated as deferred revenue. Also, we believe that in 2005 the broader product line and larger sales group resulting from the merger will enable us to increase the efficiency of our selling effort.

Cost of goods sold for the nine months ended September 30, 2004 was $6.1 million, up from $4.5 million for the nine months ended September 30, 2003, reflecting inclusion of $1.7 million in cost associated with vascular access products and a $0.1 million reduction in cost associated with radiofrequency ablation products. Our gross margin rate was 65% in the nine months ended September 30, 2004, compared to 64% in the prior period. Historically, the gross margin rate for our vascular access products has been lower than that of our radiofrequency ablation products. For this reason, we expect that future company gross margins may, on average, be reduced by inclusion of these products in our results.

Research and development expenses for the nine months ended September 30, 2004 were $2.8 million, compared to $3.4 million in the third quarter of 2003. Research and development expense for vascular access products was $0.1 million for the nine months ended September 30, 2004. Research and development expense for radiofrequency ablation products was $2.6 million for the nine months ended September 20, 2004, down $0.7 million from the prior period, including $0.4 million in reduced patent legal expenses. Development projects underway during the nine months ended September 30, 2004, were relatively small and inexpensive, but we expect spending on new and more innovative radiofrequency products to increase in the fourth quarter of 2004 and 2005. Development of vascular access products should have only a minimal impact on growth in research and development expenses.

Selling, general and administrative expenses for the nine months ended September 30, 2004 were $14.5 million, compared to $13.5 million in the nine months ended September 30, 2003. About $0.2 million of the increase was due to expenses associated with merger integration and sales training, offset by a $0.2 million reduction in bad debt expenses. Also, approximately $0.3 million of the increase was due to expenses associated with compliance with the Sarbanes-Oxley Act of 2002. Expenses associated with the Sarbanes-Oxley Act of 2002 are expected to grow in the fourth quarter of 2004 and in 2005. The $0.7 million balance of the increase in selling, general and administrative expenses was due to additional headcount in sales and marketing functions as a result of combining the two companies.

We incurred restructuring expenses of $1.1 million during the nine months ended September 30, 2004, all during the third quarter of 2004, consisting of severance related to the termination of employees to eliminate certain duplicative activities.

Interest expense for the nine months ended September 30, 2004 was $0.2 million. We had no interest expense in the prior year period. Interest income and other expenses were negligible for the nine months ended September 30, 2004, and approximately $0.2 million for the nine months ended September 30, 2003.

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 offering costs. 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 (see below), which 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. On July 29, 2004, the date we completed our merger with Horizon, we assumed approximately $17.7 million in Horizon s outstanding debt.

The merger with Horizon was accounted for under the purchase method of accounting. The combined companies will continue to operate under the name RITA Medical Systems, Inc. Each Horizon common stockholder received 0.4212 of a share of our common stock for each share of Horizon common stock held. We 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 our common stock. The fair value of shares we issued 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

Table of Contents

announcement and the two business days following the announcement. The fair value of options and warrants we assumed 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.

As of September 30, 2004, we had $3.1 million of cash and cash equivalents, $1.0 million of marketable securities and $3.8 million of working capital.

For the nine months ended September 30, 2004, net cash used in operating activities was $5.5 million principally due to our net loss of $7.4 million, offset by non-cash charges of $1.5 million, including depreciation and amortization, provisions to reserves for uncollectible accounts and inventory, and expenses associated with options granted to consultants. Approximately $1.4 million in cash was provided in the first nine months ended September 30, 2004 by changes in working capital accounts, with a $0.5 million increase in accounts payable and accrued liabilities, a $0.3 million reduction in inventories and a $0.6 million increase in deferred revenue offset by a $0.9 million increase in accounts receivable. The increase in accounts payable and accrued liabilities was primarily due to costs incurred, but not yet paid, in conjunction with the Horizon merger. Approximately $0.2 million of cash has been used in the acquisition of Horizon and approximately $0.9 million remains to be paid. Remaining investing activities include $0.5 million in purchases of property and equipment and maturities and net sales of investment instruments, which provided $3.9 million in cash in support of operations. Financing activities for the year provided $0.7 million in cash, generally through the issuance of common stock in conjunction with the exercise of stock options and the completion of short term notes used to finance insurance.

We have, from time to time, financed equipment through capital and operating leases. As of September 30, 2004, we had no future minimum payments due under capital leases. Our future minimum payments under operating leases, including those assumed in the course of the Horizon merger, are as follows (in thousands):

Payments due in 2004	$ 125
Payments due in 2005	243
Payments due in 2006	205
Payments due in 2007	204
Payments due in 2008	190
Payments due in 2009 and thereafter	243
Total of future minimum operating lease payments	$ 1,210

As of September 30, 2004, we have approximately $18.1 million in long and short term debt. Maturities of these debt obligations are as follows (in thousands):

Three months ending December 31, 2004	$ 742
Twelve months ending December 31, 2005	7,707
Twelve months ending December 31, 2006	383
Twelve months ending December 31, 2007	987
Twelve months ending December 31, 2008	8,262
Twelve months ending December 31, 2009 and thereafter	

	$ 18,081

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.

We believe our September 30, 2004 balances of cash and cash equivalents, coupled with the sale of marketable securities, will be sufficient to satisfy our operating cash requirements for the next twelve months, but insufficient to meet our scheduled debt payments, principally the $6.5 million of debt coming due in July 2005. Therefore, we will need to sell additional equity or debt securities, or 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 the Company and our stockholders, or that we will be successful in renegotiating debt repayment terms. Failure to make timely debt payments may require us to curtail operations, perhaps to a significant extent.

Table of Contents

Recent Accounting Pronouncements

The Financial Accounting Standard Board (FASB) issued an exposure draft entitled *Share-Based Payment, an Amendment of FASB Statements Nos. 123 and 95.* This exposure draft would require stock-based compensation to employees to be recognized as a cost in the financial statements and that such cost be measured according to the fair value of the stock options. In the absence of an observable market price for the stock awards, the fair value of the stock options would be based upon a valuation methodology that takes into consideration various factors, including the exercise price of the option, the expected term of the option, the current price of the underlying shares, the expected volatility of the underlying share price, the expected dividends on the underlying shares and the risk-free interest rate. The proposed requirements in the exposure draft would be effective for the first fiscal year beginning after June 15, 2005. The FASB intends to issue a final statement in late 2004. We will continue to monitor communications on this subject from the FASB in order to determine the impact on our financial statements.

At its March 2004 meeting, the Emerging Issue Task Force (EITF) reached a consensus recognition and measurement guidance previously discussed under EITF 03-01. The consensus clarifies the meaning of other-than-temporary impairment and its application to investments classified as either available-for-sale or held-to-maturity under FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, and investments accounted for under the cost method or the equity method. The recognition and measurement guidance for which the consensus was reached in the March 2004 meeting is to be applied to other-than-temporary impairment evaluations in reporting periods beginning after June 15, 2004. The Company does not expect the adoption of the disclosure requirements of EITF 03-01 to have a material impact on its financial position, cash flows or results of operations.

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

- Coordinating geographically disparate organizations, systems and facilities;
- Integrating personnel with diverse business backgrounds;
- Consolidating corporate and administrative functions;
- Consolidating research and development, and manufacturing operations;

Coordinating sales and marketing functions;

Retaining key employees; and

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

The process of integrating our operations with those of Horizon Medical Products 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 Medical Products could harm our business, results of operations, financial condition or prospects after the merger.

If our evaluation of internal controls is not completed in time for our registered public accountants to complete their assessment in a timely basis, this may impact the reliability of our internal controls over financial reporting.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, beginning with our fiscal year ending December 31, 2004, we will be required to include in our annual report on Form 10-K an assessment of the effectiveness of our internal controls over financial reporting together with a report from our independent registered public accountants on management s assessment of the effectiveness of our internal controls over financial reporting. While we are expending significant resources in developing the necessary documentation and testing procedures required by Section 404, to date, we have experienced significant delays in executing against our internal Section 404 project plan. Furthermore, compliance with all of the requirements imposed by Section 404 will be very difficult for us due at least in part to the changes in processes we are making in conjunction with the merger with Horizon Medical Products. In the third quarter of 2004, we received a letter from our independent registered public accountants in which they indicate that they might not be able to timely attest to our evaluation of our internal controls if we are unable to complete our assessment in a timely fashion. We recognize that our internal Section 404 project plan contains many time-critical milestones and that our efforts during the fourth quarter of 2004 will be critical to our completion of our assessment. If our evaluation of internal controls is not completed in time for our independent registered public accountants to complete their assessment in a timely basis, this may impact the reliability of our internal controls over financial reporting.

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

Unless we are able to renegotiate our debt repayment terms, we will need to raise additional capital to satisfy our scheduled debt payments. We will seek to raise additional capital through the sale of our securities or by obtaining an additional credit facility. If additional funds are raised through the issuance of debt securities, these securities could have rights, preferences and privileges senior to holders of common stock, and the terms of this debt could impose restrictions on our operations. Any such sale of equity or convertible debt securities will reduce the proportionate ownership and voting power of our existing stockholders and may result in a reduction of the market price of our common stock. In addition, a credit facility or a debt financing could result in certain financial and operational restrictions. If we are unable to raise additional capital on acceptable terms, or at all, or to renegotiate our debt repayment terms our liquidity may suffer as assumed debts mature and we may become in default of our debt agreements. We may be limited in our ability to execute our business plan, negatively affecting both results of operations and our stock price.

We will be heavily dependent on the RITA system and Horizon s line of implantable vascular ports 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.

Table of Contents

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

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

We incurred net losses of $7.4 million in the first nine months of 2004, $11.1 million in 2003, $13.5 million in 2002, $13.0 million in 2001, $12.8 million in 2000 and $7.5 million in 1999. At September 30, 2004, we had an accumulated deficit of $86.4 million. To become profitable we must increase our sales and continue to limit the growth of our operating expenses. If our sales do not grow, or if expenses grow excessively, we may not be able to achieve or maintain profitability in the future.

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

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

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

In the market for implantable 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, and physician adoption 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 system or to have less severe

side effects than those resulting from our system, physician adoption of our products could be negatively affected and our revenues could decline.

We currently lack long-term data regarding the safety and efficacy of our 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.

Table of Contents

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products, and yet we may be unable to do so. A number of companies in our market, as well as universities and research institutions, have issued patents and have filed patent applications that relate to the use of radiofrequency energy to ablate soft tissue. Under certain circumstances these could result in lawsuits against us. Our pending United States and foreign patent applications may not issue or may issue and be subsequently successfully challenged by others. In addition, our pending patent applications include claims to material aspects of our products that are not currently protected by issued patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

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

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

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

- the challenge of managing international sales without direct access to the end customer;
- 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 (for example, our distributor in Japan has built up a significant inventory of product in anticipation of the receipt of reimbursement approvals);
- 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 two distributors in our international markets, and if we lose either distributor or if either distributor significantly reduces its product demand, our international and total revenues could decline.

We are substantially dependent on a limited number of significant distributors in our international markets, and if we lose these distributors and fail to attract additional distributors, our international revenues could decline. ITX Corporation, formerly known as Nissho Iwai Corporation, is our primary distributor in Asia. Although it accounted for only 4% of our international revenue in the first nine months of 2004, it accounted for 21% of our international revenues in 2003. M.D.H. s.r.l. Forniture Ospedaliere, our distributor in Italy, accounted for 23% of our international revenue in the first nine months of 2004 and 22% of our international revenues in 2003. International revenues accounted for 18% of our total revenues for the nine months ended September 30, 2004, and these two distributors represented 28% of that total. For the year ended December 31, 2003, international revenues accounted for 20% of our total revenues and these distributors represented 43% of that total. The loss of either distributor or a significant decrease in unit purchases by either distributor could cause our revenues to decline substantially. If we are unable to attract additional international distributors, our international revenues may not grow.

Table of Contents

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, 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 2003 and the first nine months of 2004, and to a domestic distributor in the three months ended September 30, 2004, were so affected. In addition, while these distributors have no price protection and no right of return relating to purchased products, if we permit the return of any of these products, we will have to adjust our revenues relating to these products which may also impact our revenue recognition policy on future distributor sales.

In 2002, we significantly increased our allowance for uncollectible accounts to address the risk associated with longer collection periods that have arisen principally with our European distributors. Although the deterioration we experienced in international collections in 2002 stabilized in 2003, and remained stable in the first nine months of 2004, we may encounter new difficulties with collections that require further increases in our allowance for uncollectible accounts in the future, and we may require specific accounts to post letters of credit or pay in advance to minimize credit risk to the Company. Further, we may, in the future, terminate relationships with some of the domestic distributors utilized by Horizon prior to the merger, making collection of accounts receivable with these customers difficult. We believe our allowance for uncollectible accounts sufficiently reflects this possibility, but additional provisions to the allowance for uncollectible accounts are could be required. Additional future increases in our allowance for uncollectible 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.

The Company s business is dependent upon reimbursement from government programs, such as Medicare and Medicaid, and the Company may face limitations on such third-party reimbursement, which could harm the Company s operating results.

In the United States, the Company s 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.

Reimbursement of procedures implanting the Company s vascular access ports and catheter products is currently covered under a DRG. There can be no assurance that reimbursement for such implantation will continue to be available, or that future reimbursement policies of third-party payors will not adversely affect the Company s ability to sell its products on a profitable basis. Failure by hospitals and other users of the Company s products to obtain reimbursement from third-party payors, or changes in government and private third-party payors policies toward reimbursement for procedures employing the Company s products, would have a material adverse effect on the Company s business, results of operations and financial condition.

Table of Contents

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.

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 Medical Products and manage our cash during the process of integrations. 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;

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.

Table of Contents

We have limited experience manufacturing our disposable devices in substantial quantities, and if we are unable to hire sufficient additional personnel or to purchase additional equipment or are otherwise unable to meet customer demand, our business could suffer. Also, we are consolidating our manufacturing operations at our 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 with Horizon s by March 2005, or are otherwise unable to meet customer demand for our products, our business could suffer.

We may be required to relocate, or choose to relocate, to a new facility in 2005. If so, we will incur moving expenses, and if we become unable to meet customer demand, our business could suffer.

The operating lease on our facility in California was to expire in August of 2004, but we have negotiated an extension through January 2005. We believe that during the fourth quarter of 2004 we will be able to either renew the lease on our existing facility, or lease alternative space, at commercially reasonable terms. If we choose to relocate to a new facility, we will incur normal and customary moving costs and may experience an interruption in our manufacturing operations. If we become unable to meet customer demand for our products, our business could suffer.

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 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 sources of an accessory device used in conjunction with our Starburst XLi and Xlie lines of disposable devices, and any disruption in the supply of these devices could negatively affect our revenues.

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 revenues 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 revenues.

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

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.

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

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

Unless we are exempt, we must obtain the appropriate FDA approval or clearance before we can sell a new medical device in the United States. Obtaining this approval or clearance can be a lengthy and time-consuming process. To date, all of our products have received clearances from the FDA through premarket notification under Section 510(k) of the Federal Food, Drug and Cosmetic Act. However, if the FDA requires us to submit a new premarket notification under Section 510(k) for modifications to our existing products, or if the FDA requires us to go through a lengthier, more rigorous examination than we now expect, our product introductions or modifications could be delayed or canceled which could cause our revenues to be below expectations. The FDA may determine that future products will require the more costly, lengthy and uncertain premarket approval process. In addition, modifications to medical device products cleared via the 510(k) process may require a new 510(k) submission. We have made minor modifications to our system. Using the guidelines established by the FDA, we have determined that some of these modifications do not require us to file new 510(k) submissions. If the FDA disagrees with our determinations, we may not be able to sell the RITA system until the FDA has cleared new 510(k) submissions for these modifications, or it may require us to recall previously sold products. In addition, we intend to request additional label indications, such as approvals or clearances for the ablation of tumors in additional organs, including lung, uterus and breast, for our current products. The FDA may either deny these requests outright, require additional extensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of approval or clearance. Therefore, obtaining necessary approvals or clearances for these additional applications could be an expensive and lengthy process. In addition, in the course of the FDA process leading to clearance or approval for a new indication, the FDA may request an advisory panel meeting or meetings to discuss the clinical data, the appropriate study design or other criteria for clearance or approval. In the event that the advisory panel advises FDA that the clinical data are inadequate or the study design or other criteria are inappropriate, and the FDA concurs, the FDA clearance or approval process could be lengthened and anticipated revenues from that new indication would be delayed.

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

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

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

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

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

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

assumption of liabilities of the acquired company.

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

Table of Contents

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

Our executive officers and directors, and their respective affiliates, own approximately 5% of our outstanding common stock as of October 29, 2004. 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.

Table of Contents

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, 2003, filed on March 15, 2004.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Based on our management s evaluation (with the participation of our principal executive officer and principal financial officer), as of the end of the period covered by this report, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)) are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Changes in Internal Controls

During the third quarter of 2004, we began integrating our accounting operations in our Georgia location. Further, we began implementing changes in our internal controls aimed at satisfying perceived gaps in our control structure as indicated by our initial compliance efforts with the Sarbanes-Oxley Act of 2002. We believe these changes will not have a material negative impact on the Company s internal control over financial reporting.

Sarbanes-Oxley Section 404 Compliance

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, beginning with our fiscal year ending December 31, 2004, we will be required to include in our annual report on Form 10-K an assessment of the effectiveness of our internal controls over financial reporting together with a report from our independent registered public accountants on management s assessment of the effectiveness of our internal controls over financial reporting. Our internal control report must include the following: (1) a statement of management s responsibility for establishing and maintaining adequate internal control over financial reporting, (2) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting, (3) management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004, including a statement as to whether or not internal control over financial reporting is effective, and (4) a statement that our independent registered public accountants have issued an attestation report on management s assessment of internal control over financial reporting.

Management acknowledges its responsibility for establishing and maintaining internal controls over financial reporting and seeks to continually improve those controls. In addition, in order to achieve compliance with Section 404 of the Act within the required timeframe, the Company has been conducting a process to document and evaluate its internal controls over financial reporting since March 2004. In this regard, the Company has dedicated significant internal resources, engaged outside consultants and adopted a detailed project plan to: (1) assess and document the adequacy of internal control over financial reporting; (2) take steps to improve control processes where required; (3) validate through testing that controls are functioning as documented; and (4) implement a continuous reporting and improvement process for internal control over financial reporting. We believe our process for documenting, evaluating and monitoring our internal control over financial reporting is consistent with the objectives of Section 404 of the Act.

To date, we have experienced significant delays in executing against our project plan. Furthermore, compliance with all of the requirements imposed by Section 404 of the Act will be very difficult for us due at least in part to the changes in processes we are making in conjunction with the merger with Horizon Medical Products. In the third quarter of 2004, we received a letter from our independent registered public accountants in which they indicate that they might not be able to timely attest to our evaluation of our internal controls if we are unable to complete our assessment in a timely fashion. We recognize that our internal Section 404 project plan contains many time-critical milestones and that our efforts during the fourth quarter of 2004 will be critical to our completion of our assessment. If our evaluation of our internal controls is not completed in time for our independent registered public accountants to complete their assessment on a timely basis, this may impact the reliability of our internal controls over financial reporting.

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.

(a) On July 29, 2004, the Annual Meeting of Stockholders of RITA Medical Systems, Inc. was held in Menlo Park, California.

(b) An election of Class I directors was held with the following individuals being elected to our Board of Directors to serve until our annual meeting of stockholders for the year ending December 31, 2007:

Vincent Bucci	(14,630,031 votes in favor, 1,361,937 votes withheld)
Scott Halsted	(15,223,464 votes in favor, 768,504 votes withheld)

Upon consummation of the merger with Horizon Medical Products, Inc., which occurred immediately following the Annual Meeting, the following individuals comprised our Board of Directors:

Harold Blue	Class I director
Vincent Bucci	Class I director
Scott Halsted	Class I director
John Gilbert	Class II director
Wesley E. Johnson, Jr.	Class II director
James E Brands	Class II director
Joseph DeVivo	Class III director
Randy Lindholm	Class III director
Robert D. Tucker	Class III director

(c) Other matters voted upon and approved at the Annual Meeting and the number of affirmations, negative votes cast and abstentions with respect to each such matter were as follows:

Approval of the issuance of shares of our common stock pursuant to the Agreement and Plan of Merger, dated as of May 12, 2004, by and among RITA, Hornet Acquisition Corp. and Horizon Medical Products, Inc.:

9,989,973 votes in favor	493,182 votes opposed	23,640 votes abstaining	5,485,173 broker non-votes

Approval of amendment to our certificate of incorporation to increase the number of authorized shares of our common stock from 100,000,000 to 150,000,000 and to clarify the authority of our board of directors to fix the terms of preferred stock:

9,978,198 votes in favor	676,086 votes opposed	52,511 votes abstaining	5,485,173 broker non-votes

Ratification of the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2004:

15,692,201 votes in favor	222,896 votes opposed	76,871 votes abstaining

Item 5. Other Information. Not applicable.

Table of Contents

Item 6. Exhibits

(a) Exhibits:

10.46^ Lease Agreement dated as of July 1, 1996 between The Development Authority of the City of Manchester and Horizon Medical Products, Inc., filed as Exhibit 10.9 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.

10.47^ Amendment to Lease Agreement dated November 2, 1999 between The Development Authority of the City of Manchester and Horizon Medical Products, Inc., filed as Exhibit 10.10 to the Form 10-K of Horizon Medical Products, Inc. dated March 29, 2000 (SEC File No. 000-24025) and incorporated herein by reference.

10.48^ Lease Agreement dated as of August 29, 1997 between The Development Authority of the City of Manchester and Horizon Medical Products, Inc., filed as Exhibit 10.10 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.

10.49^ 1998 Stock Incentive Plan, filed as Exhibit 10.11 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.

10.50^ Equity Agreement, dated as of February 17, 1993, by and between CarboMedics, Inc. and Horizon Medical Products, Inc., as amended, filed as Exhibit 10.23 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.

10.51^ Second Amended License Agreement dated January 1, 1995 between Dr. Sakharam D. Mahurkar and NeoStar Medical® Technologies, filed as Exhibit 10.26 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.

10.52^ License Agreement dated July 1995 between Dr. Sakharam D. Mahurkar and Strato®/Infusaid TM Inc., filed as Exhibit 10.27 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.

10.53^ Additional License Agreement dated January 1, 1997 between Dr. Sakharam D. Mahurkar and Horizon Medical Products, Inc., filed as Exhibit 10.28 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.

10.54^ Note Purchase Agreement among Horizon Medical Products, Inc., ComVest Venture Partners, L.P. and certain Additional Note Purchasers dated March 1, 2002, filed as Exhibit 10.1 to the Form 8-K/A of Horizon Medical Products, Inc., filed on July 3, 2002 (SEC File Number 001-15459) and incorporated herein by reference.

10.55^ Senior Subordinated Convertible Note payable by Horizon Medical Products, Inc. to ComVest Venture Partners, L.P., dated March 16, 2002, filed as Exhibit 10.57 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.

10.56^ Senior Subordinated Convertible Note payable by Horizon Medical Products, Inc. to Medtronic, Inc., dated March 16, 2002, filed as Exhibit 10.58 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.

10.57^ Form of Senior Subordinated Convertible Note payable by Horizon Medical Products, Inc. to certain additional parties, dated March 16, 2002, filed as Exhibit 10.59 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.

10.58^ Junior Subordinated Promissory Note payable by ComVest Venture Partners, L.P. to Bank of America, dated March 15, 2002 and assumed by Horizon Medical Products, Inc. on March 15, 2002, filed as Exhibit 10.60 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.

10.59^

Non-Qualified Stock Option Agreement between Horizon Medical Products, Inc. and Marshall B. Hunt, dated March 15, 2002, for the purchase of 1,000,000 shares of the common stock of Horizon Medical Products, Inc. at an option price of $0.45 per share, filed as Exhibit 10.66 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.

Table of Contents

10.60^ Non-Qualified Stock Option Agreement between Horizon Medical Products, Inc. and Marshall B. Hunt, dated March 15, 2002, for the purchase of 2,500,000 shares of the common stock of Horizon Medical Products, Inc. at an option price of $0.45 per share, filed as Exhibit 10.67 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.

10.61^ Non-Qualified Stock Option Agreement between Horizon Medical Products, Inc. and William E. Peterson, Jr., dated March 15, 2002, for the purchase of 1,000,000 shares of the common stock of Horizon Medical Products, Inc. at an option price of $0.45 per share, filed as Exhibit 10.69 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.

10.62^ Agreement between Horizon Medical Products, Inc., Steven Picheny and Howard Fuchs, dated March 14, 2002, filed as Exhibit 10.71 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2001, dated April 16, 2002 (SEC File Number 001-15459) and incorporated herein by reference.

10.63^ Amendment No. 1 to Note Purchase Agreement, dated as of June 10, 2002, by and among Horizon Medical Products, Inc., ComVest Venture Partners, L.P. and the Additional Note Purchasers (incorporated by reference to Exhibit 10.2 to the Form 10-Q of Horizon Medical Products, Inc. for the three months ended June 30, 2002).

10.64^ Amendment No. 2 to Note Purchase Agreement, dated as of July 29, 2002, by and among Horizon Medical Products, Inc., ComVest Venture Partners, L.P. and the Additional Note Purchasers (incorporated by reference to Exhibit 10.3 to the Form 10-Q of Horizon Medical Products, Inc. for the three months ended June 30, 2002).

10.65^ Common Stock Purchase Warrant, dated as of September 26, 2002, by and between Horizon Medical Products, Inc. and Epoch Financial Group, Inc. (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of Horizon Medical Products, Inc. dated November 14, 2002).

10.66^ Common Stock Purchase Warrant, dated as of September 26, 2002, by and between Horizon Medical Products, Inc. and Lippert/Heilshorn & Associates, Inc. (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of Horizon Medical Products, Inc. dated November 14, 2002).

10.67^ Amendment to Option Agreement, dated November 15, 2002, between Horizon Medical Products, Inc. and Marshall B. Hunt (incorporated by reference to Exhibit 10.43 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. dated March 28, 2003).

10.68^ Lease Agreement, entered into as of December 15, 2000, by and between The Development Authority of the City of Manchester and Horizon Medical Products, Inc. (incorporated by reference to Exhibit 10.48 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. dated March 28, 2003).

10.69^ Exclusive Distribution Agreement, dated April 15, 2003, between Horizon Medical Products, Inc. and Medtronic, Inc. (incorporated by reference to Exhibit 10.2 of the Quarterly Report filed on Form 10-Q of Horizon Medical Products, Inc. dated August 14, 2003).

10.70^ Common Stock Purchase Warrant between Lippert/Heilshorn & Associates, Inc., dated June 30, 2003 (incorporated by reference to Exhibit 10.5 of the Quarterly Report filed on Form 10-Q of Horizon Medical Products, Inc. dated August 14, 2003).

10.71^ Amendment No. 1 to Note Purchase Agreement, dated October 21, 2003, by and among Horizon Medical Products, Inc., ComVest Venture Partners, L.P., Medtronic, Inc., and certain Additional Note Purchasers (incorporated by reference to Exhibit 10.1 of the Current Report filed on Form 8-K of Horizon Medical Products, Inc. dated November 12, 2003).

10.72^ Amended and Restated Securityholders Agreement, dated October 21, 2003, by and among Horizon Medical Products, Inc., ComVest Venture Partners, L.P., Medtronic, Inc., Standard Federal Bank National Association and Marshall B. Hunt (incorporated by reference to Exhibit 10.2 of the Current Report filed on Form 8-K of Horizon Medical Products, Inc. dated November 12, 2003).

10.73^ Stock Option Agreement, dated October 21, 2003, between Horizon Medical Products, Inc. and Marshall Hunt (incorporated by reference to Exhibit 10.5 of the Current Report filed on Form 8-K of Horizon Medical Products, Inc. dated November 12, 2003).

Table of Contents

10.74^	Stock Option Agreement, dated October 21, 2003, between Horizon Medical Products, Inc. and Robert Wenzel (incorporated by reference to Exhibit 10.6 of the Current Report filed on Form 8-K of Horizon Medical Products, Inc. dated November 12, 2003).
10.75^	Form of Bonus Agreement dated November 1, 2003, between Horizon Medical Products, Inc. and Robert Singer, L. Bruce Maloy and Elaine Swygert (incorporated by reference to Exhibit 10.61 to the Annual Report on Form 10-K of Horizon Medical Products, Inc. for the year ended December 31, 2003).
10.76	Separation Agreement and Release of Claims, executed on or about August 20, 2004, between the Company, Horizon Medical Products, Inc. and Robert J. Wenzel.
10.77	Amendment to Agreement, dated August 6, 2004, among the Company, Horizon Medical Products, Inc., Steven Picheny and Howard Fuchs.
10.78^	Equity Agreement, dated as of February 17, 1993, by and between CarboMedics, Inc. and Horizon Medical Products, Inc., as amended, filed as Exhibit 10.23 to the Form S-1 of Horizon Medical Products, Inc. dated April 14, 1998 (SEC File No. 333-46349) and incorporated herein by reference.
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	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, of Chief Executive Officer
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, of Chief Financial Officer

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

Table of Contents

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: November 9, 2004

Table of Contents

EXHIBIT INDEX

10.76	Separation Agreement and Release of Claims, executed on or about August 20, 2004, between the Company, Horizon Medical Products, Inc. and Robert J. Wenzel.
10.77	Amendment to Agreement, dated August 6, 2004, among the Company, Horizon Medical Products, Inc., Steven Picheny and Howard Fuchs.
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	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, of Chief Executive Officer
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, of Chief Financial Officer