NOVOSTE CORP /FL/
Form 10-Q
May 07, 2004
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2004

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

For the transition period from _____ to _____.

0-20727

(Commission File Number)

Novoste Corporation

(Exact Name of Registrant as Specified in Its Charter)

Florida	**59-2787476**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
3890 Steve Reynolds Blvd. Norcross, GA	**30093**
(Address of Principal Executive Offices)	**(Zip Code)**

(770) 717-0904

(Registrant s telephone, 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 requirements for the past 90 days.

(Item 1) Yes x No ¨

(Item 2) Yes x No ¨

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

As of March 31, 2004 there were 16,331,068 shares of the registrant s common stock outstanding.

Table of Contents

NOVOSTE CORPORATION

FORM 10-Q

INDEX

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

NOVOSTE CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands, except number of shares data)

	March 31, 2004 (unaudited)	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,494	$ 33,177
Short-term investments	4,756	6,225
Accounts receivable, net of allowance of $351 and $442, respectively	2,891	5,206
Inventory, net	2,612	2,439
Prepaid expenses and other current assets	368	480
Total current assets	42,121	47,527
Property and equipment, net	6,475	6,997
Radiation and transfer devices, net	5,778	6,304
Other assets	408	579
Total assets	$ 54,782	$ 61,407
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,045	$ 1,492
Accrued expenses	5,025	6,483
Unearned revenue	142	188
Total current liabilities	6,212	8,163
Shareholders equity:		
Preferred stock, $.01 par value, 5,000,000 shares authorized; no shares issued and outstanding		
Common stock, $.01 par value, 25,000,000 shares authorized; 16,373,997 and 16,371,997 shares issued, respectively	164	164
Additional paid-in capital	187,914	187,880
Accumulated other comprehensive income	640	733
Accumulated deficit	(139,916)	(135,302)
Treasury stock, at cost, 42,929 shares	(172)	(172)
Unearned compensation	(60)	(59)
Total shareholders equity	48,570	53,244
Total liabilities and shareholders equity	$ 54,782	$ 61,407

See accompanying notes.

Table of Contents

NOVOSTE CORPORATION

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per-share data)

	Three Months Ended March 31,	
	2004	**2003**
Net sales	$ 7,025	$ 20,705
Cost of sales	3,876	7,066
Gross margin	3,149	13,639
Operating expenses:		
Research and development	2,290	3,358
Sales and marketing	3,427	5,934
General and administrative	2,124	2,318
Total operating expenses	7,841	11,610
Income (loss) from operations	(4,692)	2,029
Interest income	87	113
Interest expense		(7)
Other income (expense)	(9)	2
Total other income	78	108
Net income (loss)	$ (4,614)	$ 2,137
Net income (loss) per share - Basic	$ (0.28)	$ 0.13
Weighted average shares outstanding - Basic	16,331	16,269
Net income (loss) per share - Diluted	$ (0.28)	$ 0.13
Weighted average shares outstanding - Diluted	16,331	16,836

See accompanying notes.

Table of Contents

NOVOSTE CORPORATION

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Three Months Ended March 31,	
	2004	**2003**
Cash flows from operating activities:		
Net income (loss)	$ (4,614)	$ 2,137
Adjustments to reconcile net income (loss) to net cash (used in) operating activities:		
Depreciation and amortization of property and equipment	670	878
Stock based compensation expense	26	65
Depreciation of radiation and transfer devices	1,099	2,459
Provision for doubtful accounts	(55)	30
Changes in assets and liabilities:		
Accounts receivable	2,361	(1,910)
Inventory	(184)	337
Prepaid expenses and other current assets	111	(74)
Other assets	164	178
Accounts payable	(439)	(582)
Accrued expenses	(1,454)	(2,767)
Unearned revenue	(46)	(1,133)
Net cash (used in) operating activities	(2,361)	(382)
Cash flows from investing activities:		
Maturity/sale of short-term investments	3,504	4,339
Purchase of short-term investments	(2,035)	(3,894)
Purchase of property and equipment, net	(152)	(381)
Purchase of radiation and transfer devices	(573)	(712)
Net cash provided by (used in) investing activities	744	(648)
Cash flows from financing activities:		
Proceeds from issuance of common stock	7	429
Repayment of capital lease obligations		(72)
Net cash provided by financing activities	7	357
Effect of exchange rate changes on cash	(73)	62
Net (decrease) in cash and cash equivalents	(1,683)	(611)
Cash and equivalents at beginning of period	33,177	21,928
Cash and cash equivalents at end of period	$ 31,494	$ 21,317
Supplemental disclosure of cash flow information:		
Cash paid for interest	$	$ 7

See accompanying notes.

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004

NOTE 1. BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and in accordance with instructions to Article 10 of Regulation S-X. Accordingly, such consolidated financial statements do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of management, all normal and recurring adjustments considered necessary for a fair presentation of Novoste s financial results and condition have been included.

The operating results of the interim periods presented are not necessarily indicative of the results to be achieved for the year ending December 31, 2004. The accompanying unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2003, included in Novoste s 2003 Annual Report on Form 10-K filed with the Securities and Exchange Commission.

The consolidated financial statements include the accounts of Novoste Corporation and its wholly owned subsidiaries incorporated in August 1998 in the Netherlands, in December 1998 in Belgium, in February 1999 in Germany, in January 2000 in France and a dedicated sales corporation incorporated in the state of Florida in March 2002. Significant inter-company transactions and accounts have been eliminated.

Novoste sells its catheters with no right of return except in cases of product malfunction or shipping errors. On August 19, 2002, Novoste initiated a voluntary recall of the Beta-Rail 3.5F Delivery Catheter (the 3.5F catheter) inventory from its customers. The recall related to the discovery by Novoste of a small number of catheter-tip separations in the 3.5F catheter product. An extensive evaluation and improvement program was initiated. A pre-market approval supplement was submitted to the U.S. Food and Drug Administration (FDA) on October 15, 2002, describing the improvements to the product and manufacturing processes and requesting approval for re-launch of the product. The FDA approved the re-launch on January 6, 2003.

In connection with the re-launch, Novoste exchanged 5.0F catheters for 3.5F catheters with a number of its customers. The exchange of these catheters was completed by September 2003 and all related reserves have been eliminated since that time. However, in the quarter ended March 31, 2003, Novoste had recorded a reserve of approximately $1,000,000 to recognize the 5.0F catheters purchased prior to March 31, 2003, that were expected to be returned in the future for exchange to 3.5F catheters.

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES

Novoste s significant accounting policies are included in the audited financial statements and notes thereto for the year ended December 31, 2003 included in Novoste s 2003 Annual Report on Form 10-K filed with the Securities and Exchange Commission.

Table of Contents

Novoste accounts for grants of stock options and restricted stock under the recognition and measurement principles of Accounting Principles Board Option No. 25, *Accounting for Stock Issued to Employees* and related interpretations. The following table illustrates the effect on net income and earnings per share if Novoste had applied the fair value recognition provisions of FASB Statement No.123, *Accounting for Stock-Based Compensation* (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2004	**2003**
Net income (loss), as reported	$ (4,614)	$ 2,137
Add: Total stock-based employee compensation expense included in net income (loss)	26	65
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(576)	(1,208)
Pro forma net income (loss)	$ (5,164)	$ 994
Earnings per share (Basic and Diluted):		
As reported	$ (0.28)	$ 0.13
Pro forma	$ (0.32)	$ 0.06

IMPACT OF RECENTLY ISSUED ACCOUNTING STANDARDS

In January 2003, the FASB issued FASB Interpretation No. 46, *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51*, which requires a new approach in determining if a reporting entity should consolidate certain legal entities, including partnerships, limited liability companies, or trusts, among others, collectively defined as variable interest entities, or VIE s. A legal entity is considered a VIE if it does not have sufficient equity at risk to finance its own activities without relying on financial support from other parties. If the legal entity is a VIE, then the reporting entity that is the primary beneficiary must consolidate it. Even if a reporting entity is not obligated to consolidate a VIE, then certain disclosures must be made about the VIE if the reporting entity has a significant variable interest. Certain transition disclosures are required for all financial statements issued after January 31, 2003. The on-going disclosure and consolidation requirements are effective for all interim financial periods beginning after June 15, 2003. There is no impact of FIN 46 on our results of operations or financial condition.

NOTE 3. CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Cash equivalents are comprised of certain highly liquid investments with maturities of less than three months. In addition to cash equivalents, Novoste has investments in commercial paper and other securities that are classified as short-term. All securities are considered as available-for-sale and reported at fair value, with the unrealized gains and losses reported as a component of Other Comprehensive Income (Loss) on the consolidated statements of shareholders equity. The amortized cost of debt securities in this category, if significant, is adjusted for amortization included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, of which there were none, would be included in interest income. Realized gains and losses are included in interest income and are determined on a specific identification basis. Interest and dividends on securities classified as available-for-sale are included in interest income.

7

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004

(continued)

NOTE 4. ACCOUNTS RECEIVABLE

Accounts receivable at March 31, 2004 and December 31, 2003 include receivables due from product sales and amounts due under lease arrangements to hospitals relating to radiation and transfer devices (See Note 7 to the unaudited consolidated financial statements). The carrying amounts reported in the consolidated balance sheets for accounts receivable approximate their fair value.

There were no significant concentrations of credit risk at March 31, 2004. Novoste performs periodic credit evaluations of its customers financial condition and generally does not require collateral. Management records estimates of expected credit losses and returns of product sold. Net bad debt recovery for the three-month period ended March 31, 2004 was $55,000 as compared to bad debt expense of $30,000 in the three-month period ended March 31, 2003. Bad debt recoveries occurred as aged accounts receivables balances declined.

NOTE 5. INVENTORIES

Inventories are stated at the lower of cost or market value on a first-in, first-out (FIFO) basis and are comprised of the following (in thousands):

	March 31, 2004	December 31, 2003
Raw materials	$ 2,407	$ 2,442
Work in process	154	124
Finished goods	1,159	1,115
Inventory, gross	3,720	3,681
Less: Inventory reserve	(1,108)	(1,242)
Inventory, net	$ 2,612	$ 2,439

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment are comprised of the following (in thousands):

	March 31, 2004	December 31, 2003
Furniture and fixtures	$ 1,209	$ 1,211
Office equipment	4,202	4,142
Laboratory equipment	937	991
Leasehold improvements	2,208	2,208
Production equipment	8,222	8,205
Property and equipment, gross	16,778	16,757
Less: Accumulated depreciation and amortization	(10,303)	(9,760)
Property and equipment, net	$ 6,475	$ 6,997

NOTE 7. RADIATION AND TRANSFER DEVICES

Novoste retains ownership of the radiation source trains (RSTs) and transfer devices (TDs). Depreciation of the costs of these assets is taken over the estimated useful life using the straight-line method and is recorded in cost of sales. Depreciation begins at the time the Beta-Cath System is placed into service. Novoste classifies the annual agreements with Novoste s customers to license the use of radiation and transfer devices as operating leases. Income is recognized ratably over the length of the lease. At March 31, 2004, deferred revenue under these leases approximated $142,000.

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004

(continued)

Radiation and transfer devices subject to operating leases, stated at cost, less accumulated depreciation, are comprised of the following (in thousands):

	March 31, 2004	December 31, 2003
Radiation and transfer devices, gross	$ 24,276	$ 25,554
Less: Accumulated depreciation	(18,498)	(19,250)
Radiation and transfer devices, net	$ 5,778	$ 6,304

During 2001, Novoste estimated the useful lives of these assets to be eighteen months based upon the information available at that time. During January 2002, Novoste determined that based upon the latest information available the estimated useful lives of RSTs were twelve months and the TDs were three years. Accordingly, depreciation was recorded over the updated estimates lives starting at the beginning of the first quarter 2002. Given the pace of change of this medical technology, these estimates have changed from time to time as new information about the markets and applications is received.

In June 2002, Novoste decided to phase out the 5.0F diameter catheter systems, resulting in an impairment charge of $5,065,000 and other related charges of $1,835,000 (See Note 14 to unaudited consolidated financial statements) to adjust the carrying value of these assets to their fair value. The remaining fair value was being amortized on a straight-line basis over the remaining useful life, then estimated to end March 31, 2003.

In August 2002, Novoste initiated a voluntary recall of 3.5F diameter catheters. To meet patient needs, the 5.0F catheter system was reinstalled in sites where the 3.5F catheter system had previously supplanted the 5.0F catheter system. Notwithstanding its return to widespread active use, the 5.0F catheter system was still expected to be replaced by a redesigned 3.5F catheter system early in 2003. The new design for the 3.5F catheter system was submitted to the FDA on October 15, 2002 and was approved by the FDA for re-launch on January 6, 2003.

At December 31, 2002, approximately $1,650,000 of unamortized costs for the 5.0F catheter assets remained. During the first quarter of 2003, despite the re-launch of the newly designed 3.5F catheter system in January, it became apparent that the 5.0F assets would be utilized beyond the previously estimated termination date, and in fact, remained in active use through December 31, 2003. Factors leading to an extended life included: (a) the time required to convert customers to 3.5F catheter systems following the recall, (b) the time required to complete training on the new 3.5F catheter replacement systems, and (c) allocations of 3.5F catheter systems to customer sites based on availability, customer preference and volume potential. Accordingly, the remaining value of the 5.0F catheter assets was amortized through December 31, 2003, rather than through March 31, 2003, as previously estimated. The result of this change in the estimated useful life reduced amortization expense in the first quarter of 2003 by $1,237,000, and increased amortization expense by $413,000 for subsequent quarters in 2003. The impact of this change

in estimate of useful lives of the 5.0F catheter in the three months ended March 31, 2004 and 2003 is $0 and $1,237,000, respectively, or $.07 per share for the three months ended March 31, 2003.

NOTE 8. RECEIVABLE FROM OFFICERS

In October 2001, Novoste adopted a split-dollar life insurance plan for all officers. Pursuant to the plan, Novoste matched officer contributions to the plan and also provided an advance for related payroll taxes. The payroll advance was reflected as a receivable from officers on the balance sheet. The advances were unsecured and subject to the life insurance company s ability to repay Novoste in the future from the available funds. In accordance with the plan agreement, if an officer left Novoste for any reason, retired or in any way terminated or withdrew from plan, the life insurance company would be obligated to repay Novoste for the tax advances prior to settlement of account with the officer. Novoste has ceased accepting further contributions to the plan from executive officers. All officers who participated in the plan have withdrawn from the plan. $164,000 of the outstanding balance was refunded to Novoste in the first quarter of 2003, and the remainder of the balance was refunded to Novoste in April 2003. At March 31, 2004 the balance of the receivables from officers was $0.

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004

(continued)

NOTE 9. ACCRUED EXPENSES

Significant items of accrued expenses are as follows (in thousands):

	March 31, 2004	December 31, 2003
Salaries, wages and benefits	$ 1,170	$ 2,353
Radiation and disposals	1,620	1,598
Clinical trials	705	783
Operating expenses and royalties	583	643
Professional fees	578	584
Due to customers	248	310
Sales and use taxes	121	212
	$ 5,025	$ 6,483

NOTE 10. LINE OF CREDIT

In August 2001, Novoste obtained a $10,000,000 revolving line of credit. Novoste may borrow an amount not to exceed the borrowing base as defined in the loan agreement, which is principally based on domestic accounts receivable. Interest on outstanding balances is payable on the first of each month, calculated on the outstanding balance, and accrues at a rate of the bank s prime rate plus 1%. Novoste granted a first priority security interest in substantially all assets of Novoste to the lender. By agreement between Novoste and the lender, the maturity date of the original loan agreement between parties was extended to February 28, 2003, and by further agreement, the maturity date has been extended to May 27, 2004. As part of the earlier modification in February 2003, the tangible net worth covenant was lowered, and the interest rate was changed to a base of the bank s prime rate, or 4.25%, plus 1%.

Novoste also has letters of credit available under the revolving line of credit. The lender will issue or has issued letters of credit for Novoste s account subject to certain limitations; however, all such issued letters of credit may not exceed $500,000 in the aggregate. At March 31, 2004 and 2003, Novoste had no outstanding borrowings or letters of credit.

NOTE 11. SEGMENT INFORMATION

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information* requires the reporting segment information based on the information provided to Novoste s chief operating decision maker for purposes of making decisions about allocating resources and assessing performance. Novoste s business activities represented by a single industry segment, the manufacture and distribution of medical devices. For management purposes, Novoste is segmented into two geographic areas: United States and the Rest of the World (Europe, Canada, Asia and South America).

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004

(continued)

The following is a summary of selected financial information by reportable segment as of, and for the three months ended, March 31, 2004 and 2003 (in thousands):

Net sales

	United States	Rest of World	Consolidated
2004	$ 5,959	$ 1,066	$ 7,025
2003	19,299	1,406	20,705

Net Income (Loss)

	United States	Rest of World	Consolidated
2004	$ (4,566)	$ (48)	$ (4,614)
2003	2,100	37	2,137

Long-lived assets

	United States	Rest of World	Consolidated
2004	$ 11,499	$ 754	$ 12,253
2003	17,346	2,505	19,851

Total assets

	United States	Rest of World	Consolidated
2004	$ 51,604	$ 3,178	$ 54,782
2003	60,368	5,299	65,667

Novoste s total assets outside of the United States consist principally of cash and cash equivalents, accounts receivable and office equipment.

NOTE 12. EARNINGS PER SHARE

The following table sets forth the computation of basic and diluted earnings per share for the three-month periods ended March 31, 2004 and 2003 (in thousands, except per-share data):

	Three Months Ended March 31,	
	2004	**2003**
Numerator:		
Net income (loss)	$ (4,614)	$ 2,137
Denominator:		
Weighted-average shares outstanding	16,331	16,269
Dilutive effect of stock options and unvested restricted stock		567
Weighted-average shares outstanding, assuming dilution	16,331	16,836
Net income (loss) per share:		
Basic	$ (0.28)	$ 0.13
Diluted	$ (0.28)	$ 0.13

The basic and diluted income or loss per share is computed based on the weighted average number of common shares outstanding. Weighted average shares outstanding, assuming dilution, includes the incremental shares that would be issued upon the assumed exercise of stock options. For the calculation of the three months ended March 31, 2004, all stock options representing approximately 2.9 million shares of Novoste common stock were excluded, as they would be anti-dilutive. Of these, approximately 1.8 million shares had an exercise price higher than the average price of Novoste s common stock for that period.

For the three months ended March 31, 2003, approximately 1.2 million shares were excluded, as their exercise price was higher than the average price of Novoste s common stock for that period.

These options could be dilutive in the future if there is an increase in the price of Novoste common stock.

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004

(continued)

NOTE 13. SHAREHOLDERS EQUITY

Changes in shareholders equity consisted of the following (in thousands):

	Three Months Ended March 31,	
	2004	**2003**
Shareholders equity at beginning of period	$ 53,244	$ 52,765
Proceeds from exercise of stock options ranging from $3.20 to $6.65 per share	7	429
Amortization of unearned compensation	27	65
Revaluation of variable stock awards	(4)	
Amortization of fair market value of stock options to non employees	3	
Comprehensive income:		
Unrealized loss on held-for-sale securities		(20)
Translation adjustment	(93)	61
Net income (loss)	(4,614)	2,137
Total comprehensive income	(4,707)	2,178
Shareholders equity at end of period	$ 48,570	$ 55,437

NOTE 14. IMPAIRMENT CHARGES

Novoste accounts for long-lived assets in accordance with the provisions of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. SFAS No. 144 requires long-lived assets and certain identifiable intangibles to be reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If assets are impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount of fair value, less costs to sell.

In March 2002, Novoste began commercial distribution of a newer, smaller Beta-Cath System utilizing a 3.5F diameter catheter. Original plans were to introduce the product slowly; however, the smaller diameter system allows physicians to provide better and more comprehensive treatment to their patients, and demand for the new product exceeded expectations and the first-year goal of installed sites was achieved in less than four months. While the older, larger 5.0F diameter Beta-Cath Systems are still serviceable, during the second quarter 2002, Novoste decided to concentrate marketing and development efforts on the 3.5F diameter Beta-Cath System. Accordingly, Novoste evaluated the ongoing value of the 5.0F catheter systems that are equipped to use with 30mm and 40mm radiation source trains. Based on this evaluation, Novoste determined that the transfer devices and radiation source trains, which were long-lived assets with a carrying amount of $8.6 million, were no longer recoverable and wrote them down to their estimated fair value of $3.5 million, and accrued $1.8 million for related expenses, resulting in an impairment and other related charges of $6.9 million for the second quarter of 2002. Fair value was based on expected future net cash flows to be generated by the transfer devices and radiation source trains during their remaining service lives, discounted at the risk-free rate of interest. The remaining fair value was amortized ratably over the estimated useful life of these assets.

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004

(continued)

On August 19, 2002, Novoste announced the recall of all 3.5F diameter catheter products (See Note 1 to the unaudited consolidated financial statements). As a result, demand for the 5.0F diameter system increased significantly to service the patients needing vascular brachytherapy. This increase demand provided cash flow in excess of the carrying value. Following the re-launch of a redesigned 3.5F catheter system in January 2003, the 5.0F systems continued to be utilized, but at a declining rate as 3.5F systems returned to use. The revenue of the 5.0F systems continued to exceed carrying value and Novoste concluded that these would remain in active use through December 31, 2003. At March 31, 2004 no costs remained to be amortized for the 5.0F impaired assets.

NOTE 15. TERMINATION COSTS

In March 2004, Novoste announced a reduction in force to eliminate 84 positions to align Novoste s staffing with current market conditions. Novoste anticipates that total one-time termination costs of $716,000 related to this reduction will be incurred. Fifty-nine of the employees involved in the reduction terminated employment with Novoste during the three months ended March 31, 2004. The costs associated with termination of those employees are included within operating expense in the unaudited consolidated statements of operations for the first quarter of 2004. The remaining 25 employees are scheduled to leave Novoste between April 2004 and July 2004. Termination costs associated with these persons will be recorded as their employment with Novoste ends.

Thirty-seven employees located in the U.S. were terminated during the quarter ended March 31, 2003, to align Novoste s staffing with market conditions at the time. One-time termination costs of $196,000 were included in general and administrative expense on the consolidated statement of operations for the first quarter of 2003.

Termination costs activity consisted of the following:(in thousands):

	Three Months Ended March 31,	
	2004	2003
Paid during the quarter	$ 359	$ 196
Accrued, but not paid by the end of the quarter	111	
	$ 470	$ 196

In addition to the termination costs of $470,000 recorded in the first quarter 2004, Novoste expects to incur future costs of $246,000 related to the March 2004 reduction in force.

NOTE 16. RELATED PARTY TRANSACTIONS

On December 23, 2002, Novoste signed a Distribution Agreement with Orbus Medical Technologies, Inc., (Orbus) a manufacturer of cardiology products. Novoste s Chief Executive Officer, Mr. Al Novak, is also the Chairman of Orbus. During the first quarter of 2004, Novoste purchased $52,000 of product from Orbus at normal commercial prices. As of March 31, 2004, Novoste has prepaid $107,000 for future product purchases. During the three months ended March 31, 2004, Novoste had net sales from this product line of $135,000, or 2% of total revenues.

NOTE 17. SUBSEQUENT EVENTS

Novoste announced on April 22, 2004, that it had signed an asset purchase agreement with Guidant Corporation (Guidant) pursuant to which Novoste will acquire information regarding Guidant s vascular brachytherapy business, including the customer list of Guidant in the United States and Canada. Under the terms of the agreement, during an established transition period, which is expected to be six months, Guidant and Novoste will jointly cooperate to transition the Guidant customers to Novoste products for any customer that wishes to continue vascular brachytherapy. Guidant will discontinue its vascular brachytherapy business in the United States and Canada over the six-month period. Additionally, Guidant has agreed to not compete in the vascular brachytherapy market in the United States and Canada for a period of five years. Novoste paid the sum of $2,500,000 to Guidant at the signing of the transaction and has agreed to pay additional earn out payments equal to 5%, on net sales to customers on the Guidant customer list that transition to Novoste s products for a period of six months after the closing date of the Guidant transaction. After this six month transition period, the additional earn out paid to Guidant will be at a rate of 5% on all U.S. and Canadian net sales of Novoste vascular brachytherapy products up to a maximum of $4,000,000.

Table of Contents

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

In this Form 10-Q, Novoste, the Company, we, us and our refer to Novoste Corporation. Beta-Cath®, Corona®, and the Novoste® logo are trademarks of Novoste.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The forward-looking statements in this Form 10-Q are made under the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended. Our operating results and financial condition have varied and may in the future vary significantly depending on a number of factors. Statements in this Form 10-Q which are not strictly historical statements, including, without limitation, statements regarding management s expectations for future growth and plans and objectives for future management and operations, domestic and international marketing and sales plans, product plans and performance, research and development plans, management s assessment of market factors, as well as statements regarding our strategy and plans, constitute forward-looking statements that involve risks and uncertainties. In some cases these forward-looking statements can be identified by the use of words such as may, will, should, expect, project, predict, potential or the ne these words or comparable words. The factors listed under Certain Factors Which May Affect Future Results in this Form 10-Q, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this report and presented elsewhere by management from time to time. Such factors, among others, may have a material adverse effect upon our business, financial condition, and results of operations. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future global events or otherwise. Accordingly, you are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they are made.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Novoste s discussion and analysis of its financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires that we adopt and follow certain accounting policies. Certain amounts presented in the financial statements have been determined based upon estimates and assumptions. Although we believe that our estimates and assumptions are reasonable, actual results will differ and the difference could be material.

We have included below a discussion of the critical accounting policies that we believe are affected by our more significant judgments and estimates used in the preparation of our financial statements, how we apply such policies and how results differing from our estimates and assumptions would affect the amounts presented in our financial statements. Other accounting policies also have a significant effect on our financial statements, and some of these policies also require the use of estimates and assumptions.

Revenue Recognition

Revenue from the sale of products is recorded when an arrangement exists, delivery has occurred and services have been rendered, the seller s price is fixed and determinable and collectability is reasonably assured. Novoste earns revenue from sales of catheters, stents, and from license and lease agreements to use the radiation source trains and transfer devices included in the Beta-Cath System.

Novoste uses distributors in countries where the distributors experience and knowledge of local radiation and medical device regulatory issues is considered beneficial by Novoste s management. Under the distributor arrangements, there are generally no purchase commitments and no provisions for cancellation of purchases. Novoste or the distributor may cancel the distributor agreements at any time.

Revenue from sales of catheters and stents directly to hospitals is recognized upon shipment after the hospital has leased a Beta-Cath System and completed all licensing and other requirements to use the system. Novoste recognizes revenue from sales of catheters to distributors at the time of shipment to the distributor.

Novoste retains ownership of the radiation source trains and transfer devices and enters into either a lease or license agreement with its customers. Revenue recognition begins once an agreement has been executed, the system has been shipped, and all licensing and other requirements to use the system have been completed. The revenue is recognized ratably over the term of the agreement. Under the terms of the operating lease signed with customers located in the United States, which was dictated by FDA regulatory approval, replacement and servicing of the radiation source train and transfer device is required at six-month intervals or based on frequency of usages. This replacement and servicing cost is included in cost of sales as incurred. No other post-sale obligations exist.

Table of Contents

Novoste sells its catheters with no right of return except in cases of product defect or shipping errors. In connection with the approval to re-launch the 3.5F catheter system on January 6, 2003, Novoste began exchanging with its customers 5.0F catheters for 3.5F catheters. A reserve was recorded against revenue for known returns and an estimate of unknown returns. The exchange of these catheters was completed by September 2003.

Radiation and Transfer Devices and Amortization of Costs

Novoste retains ownership of the RSTs and TDs that are leased to customers. The costs to acquire, test and assemble these assets are recorded as incurred. Novoste has determined that based upon the manufacturer s data, the estimated useful life for RSTs is one year, and TDs is three years. Accordingly, Novoste classifies these assets as long-term assets. Depreciation of the costs of these assets is included in cost of sales and is recognized over their estimated useful lives using the straight-line method. Depreciation begins at the time the Beta-Cath System is placed into service. Valuation reserves are recorded for the balance of unamortized costs of TDs and RSTs that are not available for use by a customer due to expiration or unsatisfactory performance measures.

Novoste has invested significant resources to acquire RSTs and TDs that make up the Beta-Cath System and offers multiple treatment options using either the standard length or the XL version of the 3.5F catheter, which can accommodate a 30mm, 40mm or 60mm train.

During the second quarter of 2002, Novoste decided to concentrate marketing and development efforts on the 3.5F catheter system. Accordingly, Novoste evaluated the recoverability of the carrying value for 5.0F devices and other assets to determine if an impairment charge was necessary. Novoste performed this evaluation in accordance with the provisions of Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. Based on this evaluation, Novoste determined that an impairment and other related charges of $6,900,000 were warranted (See Notes 7 and 14 to unaudited consolidated financial statements).

In August 2002, Novoste initiated a voluntary recall of 3.5F catheters. To meet patient needs, the 5.0F catheter system was reinstalled in sites where the 3.5F catheter system had previously supplanted the older system. Notwithstanding its return to widespread active use, the 5.0F catheter system was still expected to be replaced by a redesigned 3.5F system early in 2003. The new design for the 3.5F system was submitted to the FDA in October 15, 2002 and was approved by the FDA for re-launch on January 6, 2003.

At December 31, 2002, approximately $1,650,000 of unamortized costs for the 5.0F assets remained. During the first quarter of 2003, despite the re-launch of the newly designed 3.5F system in January 2003, it became apparent that the 5.0F assets would be utilized beyond the previously estimated termination date and, in fact, remained in active use through December 31, 2003. Accordingly, the remaining value of the 5.0F catheter assets was amortized over the entire fiscal year 2003, rather than just the first quarter of 2003 as previously estimated. The result of this change in estimated useful life reduced amortization expense from $1,650,000 to $413,000 for the first quarter of 2003 and added $413,000 to amortized expense for the subsequent quarters in 2003 (See Notes 7 and 14 to unaudited consolidated financial statements). Management will continue to evaluate its long-lived assets in accordance with SFAS No. 144.

Stock-Based Compensation

Novoste uses the intrinsic value method for valuing its awards of stock options and restricted stock and recording the related compensation expense, if any, in accordance with Accounting Principles Board No. 25, *Accounting for Stock Issued to Employees*, and related interpretations.

Novoste grants stock options generally for a fixed number of shares to employees, directors, consultants and independent contractors with an exercise price equal to the fair market value of the shares at the date of grant. Compensation expense is recognized for increases in the estimated fair value of common stock for any stock options with variable terms. No compensation expense is recognized for stock option grants to employees for which the terms are fixed and the exercise price is equal to the fair market value of the shares at the date of the grant.

Novoste accounts for equity instruments issued to non-employees in accordance with the provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation,* and as amended by SFAS 148, and Emerging Issues Task Force Issue No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*.

Any compensation expense related to grants that do not vest immediately is amortized over the vesting period of the stock options using the straight-line method as that methodology most closely approximates the way in which the option holder vests in those options.

Table of Contents

Allowance for Doubtful Accounts

Novoste maintains allowances for doubtful accounts for the estimated losses resulting from the inability of our customers to make required payments. Most of our customers are hospitals located in the U.S.; however, some are distributors of our products in foreign countries or hospitals located in Europe. The amount recorded in the allowances is based primarily on management s evaluation of the financial condition of the customers. If the financial condition of any customers deteriorates, additional allowances may be required. Allowances are also maintained for future sales returns and allowances based on an analysis of recent trends of product returns. Actual losses from uncollectible accounts are charged against the allowance when it is determined that the account cannot be collected.

Inventories

Inventories are stated at the lower of cost or market value on a first-in, first-out (FIFO) basis. Provisions are recorded for excess or obsolete inventory equal to the cost of the inventory. Shelf-life expiration or replacement products in the marketplace may cause product obsolescence. If actual product demand and market conditions were less favorable than those projected by management, additional provisions might be required which would negatively impact operating profits. Novoste evaluates the adequacy of these provisions quarterly.

RESULTS OF OPERATIONS

Overview

The first quarter presented significant challenges for Novoste. Revenues were severely impacted by the rapid acceptance of drug-eluting stents (DES) in the medical community and their success in preventing restenosis since their introduction into the U.S. market in April 2003. We expect that sales of our vascular brachytherapy products will continue to decline in 2004 as compared to 2003, resulting in a future reduction in our revenues. As noted below, Novoste began an aggressive cost reduction program at the end of the first quarter and initiated restructuring of operations in the United States in order to bring expenses in line with lower revenues. At the end of the first quarter of 2004, we had approximately $36,250,000 in cash and short-term investments to fund operations and pursue other strategic opportunities. On April 22, 2004, Novoste announced an asset purchase agreement with Guidant Corporation pursuant to which Novoste will acquire information regarding Guidant s vascular brachytherapy business, including the customer list of Guidant in the United States and Canada (See Note 17 to unaudited consolidated financial statements).

Net Sales and Gross Margin

Net sales and gross margin consisted of the following (in thousands):

	Three Months Ended March 31,		
	2004	2003	Increase

			(decrease)
Net sales:			
United States	$ 5,959	$ 19,299	(69.1)%
Rest of World	1,066	1,406	(24.2)%
Total net sales	7,025	20,705	(66.1)%
Cost of sales	3,876	7,066	(45.1)%
Gross margin	$ 3,149	$ 13,639	(76.9)%

Net sales decreased 66% in the first quarter 2004 from the same quarter in the prior year due to the rapid acceptance of drug-eluting stents in the medical community. Although the customer base of approximately 400 sites has changed little since first quarter 2003, utilization of our product has declined significantly. Catheter revenues in the first quarter 2004 declined 65% compared to the same period in the prior year. Also, during the first quarter of 2003, we experienced increased demand for the new 3.5F catheters that had been awaiting FDA approval, and we recognized $1,141,000 in revenues that had been deferred in anticipation of a catheter exchange upon relaunch of the redesigned 3.5F catheter. In addition to drug-eluting stents, we experienced increased competition from Guidant Corporation in the market for vascular brachytherapy products. Lease revenues for radiation devices declined 51% in the first quarter 2004 from the same period of the prior year due to competitive pressure to renew the leases at considerably lower prices. However, given the lower utilization, the market place seems to be accepting the idea of lease and device related service revenue to ensure availability of vascular brachytherapy products, and as such we expect the decline in radiation revenue to stabilize in the future. Rest of World sales declined 24% in the first quarter of 2004 from the same quarter last year due to many of the factors described above, but to a lesser extent than in the U.S. Revenue from stents, a product line first licensed for international sale by Novoste in January 2003, increased by 54%.

Table of Contents

In the quarter ended March 31, 2004, cost of sales declined 45% from the same period of the prior year due to the significant reduction in revenues and the corresponding reduction of costs variable to sales. However, the reduction in total costs was not proportional to the decline in revenues due to the high fixed costs associated with the manufacturing and service operations.

The 77% decline in gross margin was a result of the revenue decline coupled with high fixed costs associated with sales, manufacturing and service operations.

We believe significant factors impacting cost of sales and gross margins going forward include the utilization of catheters at the sites using the Beta-Cath System and better matching of manufacturing capacity to the market demand. The older 5.0F catheter system has completed its useful commercial life, and Novoste is pursuing its strategy of moving to a single vascular brachytherapy system (3.5F) with the goal of lowering costs as maintenance of a second catheter system is eliminated. In addition, Novoste will continue to introduce product enhancements intended to extend the service life and cost effectiveness of equipment in the field.

Operating Expenses

Operating expenses consisted of the following (in thousands):

	Three Months Ended March 31,		
	2004	2003	Increase (decrease)
Operating expenses:			
Research and development	$ 2,290	$ 3,358	(31.8)%
Sales and marketing	3,427	5,934	(42.2)%
General and administrative	2,124	2,318	(8.4)%
Total operating expenses	$ 7,841	$ 11,610	(32.5)%

The 32% decrease in research and development expenses is primarily in the area of clinical trials, with the suspension of the MOBILE (More Beta Radiation In Lower Extremities) trial in mid-2003 and the BRAVO trials in the first quarter of 2004. In addition, some engineering projects underway in early 2003 have been completed. A reduction in the number of projects and engineers supporting them also contributed to the decrease in expenses. Future research and development efforts will be focused on development of products, which serve the coronary disease market and utilize the marketing and distribution strengths of Novoste.

The 42% decrease in sales and marketing is due to reduced sales and marketing personnel, and to significantly lower variable expenses related to lower revenues, principally commissions and travel expenses. In addition, expenses for the prior year were elevated due to the January 2003 relaunch of the 3.5F catheter, which required extra training and travel to customer sites.

The 8% decline for general and administrative expenses is mainly due to the completion of a computer systems upgrade project and continued efforts at cost reduction.

At the end of the first quarter 2004, Novoste announced a reduction in force to eliminate 84 positions. This reduction is expected to lower annual operating costs by approximately $6,000,000. During the first quarter 2004, approximately 59 of the individuals left Novoste, with the remaining individuals scheduled to leave Novoste between April and July 2004. Approximately $470,000 of severance-related costs is included in the operating costs described in the table above. Termination expenses for the remaining personnel will be recorded as they complete their transition responsibilities and leave Novoste employment.

Other Income and Expenses

Other income for the first quarter 2004 was $78,000 compared to $108,000 for the same period in the prior year. The 28% decrease in other income was mainly due to the lower interest rate environment for short-term investments in the first quarter of 2004 compared to the same period in 2003.

Table of Contents

Net Income (loss)

Net income (loss) consisted of the following (in thousands, except per share amounts):

	Three Months Ended March 31,		
	2004	2003	Increase (decrease)
Net income (loss)	$ (4,614)	$ 2,137	$ (6,751)
Net income (loss) per share - Basic	$ (0.28)	$ 0.13	$ (0.41)
Net income (loss) per share - Diluted	$ (0.28)	$ 0.13	$ (0.41)

The decline of $0.41 per share for the first quarter 2004 compared to the first quarter 2003 was the result of significantly lower revenues which were impacted by the introduction of drug-eluting stents and the resulting decline in sales of our vascular brachytherapy products. The decline in operating income was partially offset by cost reduction initiatives during 2003 and in the first quarter 2004, but the drop in revenue could not be fully offset due to high fixed costs associated with sales, manufacturing and service operations. Net income in the first quarter 2003 was positively affected by recognition of $1,141,000 of revenue previously deferred in 2002 for catheter exchanges completed in 2003 following the relaunch of the 3.5F catheter in January 2003.

LIQUIDITY AND CAPITAL RESOURCES

Operating

Net cash used in operating activities consisted of the following (in thousands):

	Three Months Ended March 31,	
	2004	2003
Cash flows from operating activities:		
Net income (loss)	$ (4,614)	$ 2,137
Depreciation and amortization of property and equipment	670	878
Depreciation of radiation and transfer devices	1,099	2,459
Other non cash items	(29)	95
Net change in operating assets and liabilities	513	(5,951)
Net cash used in operating activities	$ (2,361)	$ (382)

In the first quarter 2004, $2,361,000 in cash was used to fund the quarter s operating loss. This compares to $382,000 in cash used in the first quarter of 2003. The changes in operating assets and liabilities are consistent with the decline in business volume. Amortization on radiation and transfer devices is lower due to the completion of the commercial life of the older 5.0F systems, and the full amortization of these assets. Included in the change in operating assets was $2,361,000 generated from a reduction in receivables compared to the first quarter of 2003 when $1,910,000 was used to fund the receivables to support higher revenues from the relaunch of the 3.5F system in that quarter.

Investing

Net cash provided by (used in) investing activities consisted of the following (in thousands):

	Three Months Ended March 31,	
	2004	**2003**
Cash flows from investing activities:		
Maturity/sale of short-term investments	$ 3,504	$ 4,339
Purchase of short-term investments	(2,035)	(3,894)
Capital expenditures, net	(725)	(1,093)
Net cash provided by (used in) investing activities	$ 744	$ (648)

Table of Contents

Short-term investments have shifted to cash equivalents to provide flexibility for future strategic investments and to protect against an erosion of capital should interest rates increase. Less cash was used to purchase property and equipment in the three months ended March 31, 2004 as compared to the same period of 2003, primarily due to the completion of in-house production facilities. Also, less cash was used to purchase radiation source trains and transfer devices compared to the same period in the prior year. This decrease reflects the deployment of devices to all active customer sites using vascular brachytherapy products, and fewer new sites than in 2003.

Financing

During the quarter ended March 31, 2004, Novoste received $7,400 in proceeds from the issuance of its common stock as a result of option exercises compared to $429,000 in the first quarter 2003 when more stock options were exercised by employees.

In August 2003, Novoste announced the extension of the stock buy-back program that originally began in August 2002, but was suspended due to the 3.5F catheter recall. The extension authorized the purchase of up to $7,000,000. No shares were repurchased during the quarter ended March 31, 2004. As of March 31, 2004, 185,400 shares had been repurchased for $725,000, which occurred in earlier periods.

In August 2001, Novoste entered into a loan agreement and $10,000,000 revolving line of credit based on eligible accounts receivable with a financial institution (lender). The agreement matured in August 2002. By agreement between Novoste and the lender, the loan agreement between the parties has been amended and the maturity date extended to May 27, 2004. At March 31, 2004, Novoste had no outstanding borrowings (See Note 10 to unaudited consolidated financial statements).

Novoste also has letters of credit available under the revolving line of credit. The lender will issue or has issued letters of credit for Novoste s account subject to certain limitations; however, all such issued letters of credit may not exceed $500,000 in the aggregate. At March 31, 2004, Novoste had no outstanding letters of credit.

Commitments

At March 31, 2004, Novoste had commitments to purchase $10,992,000 of products and services, primarily components for the Beta-Cath System.

On October 14, 1999, Novoste signed a development and manufacturing supply agreement with AEA Technologies QSA GmbH for a source of radioactive supply and for the development of a smaller diameter radiation source. The agreement provided for the construction of a production line that was placed into service in October 2002. In addition, the agreement provides for joint ownership of all intellectual property arising from the development work and requires that AEA may manufacture vascular brachytherapy sources only for Novoste. Novoste expects to meet its contractual commitments for 2004.

On June 20, 2001, Novoste amended its manufacturing and supply agreement with Bebig Isotopen-und Medizintechnik GmbH (Bebig), a German corporation, to manufacture and supply Novoste with radioactive sealed Strontium-90 seed trains. During each calendar year of the

four-year contract, Novoste guarantees to pay to Bebig minimum annual payments of varying amounts that will total $7,500,000 over the term of the agreement. All product purchases are credited against the annual guaranteed payment. In the event that Novoste does not purchase product to exceed the annual guaranteed payment, the deficiency will be due and payable to Bebig within thirty days after the end of each one-year contract period. Novoste expects to fulfill its contractual obligations under the terms of the agreement.

Significant proportions of key components and processes relating to Novoste s products are purchased from a single source due to technology, availability, price, quality, and other considerations. Key components and processes currently obtained from single sources include isotopes, protective tubing for catheters, proprietary connectors, and certain plastics used in the design and manufacture of the transfer device. In the event a supply of a key single-sourced material or component was delayed or curtailed, Novoste s ability to produce the related product in a timely manner could be adversely affected. Novoste attempts to mitigate these risks by working closely with key suppliers regarding Novoste s product needs and the maintenance of strategic inventory levels.

Novoste has entered into a license agreement with a physician pursuant to which he is entitled to receive a royalty on the net sales of the Beta-Cath System (excluding consideration paid for the radioactive isotope), subject to a maximum aggregate payment of $5,000,000. Royalty fees paid to the physician were $69,000 and $191,000 for the three months ended March 31, 2004 and 2003, respectively. As of March 31, 2004, aggregate payments of $2,026,000 have been made under the license agreement and have been expensed in cost of sales.

On January 30, 1996, Novoste entered into a license agreement whereby Emory University assigned its claim to certain technology to Novoste for royalties based on net sales (as defined in the agreement) of products derived from such technology, subject to certain

Table of Contents

minimum royalties. After the first commercial sale of royalty bearing products by Novoste, minimum royalties were due to Emory University in the following amounts: year 2 after the first commercial sale $10,000; year 3 $15,000; year 4 $25,000; and years 5-10, $50,000 per year. The royalty agreement term is consistent with the life of the related patent and applies to assignments of the patent technology to a third party. Royalty fees paid to Emory University were $142,000 and $386,000 for the three months ended March 31, 2004 and 2003, respectively, and have been expensed in cost of sales.

Liquidity

Novoste s principal source of liquidity at March 31, 2004 consisted of cash, cash equivalents and short-term investments of $36,250,000 compared to $39,402,000 at December 31, 2003.

Novoste s future liquidity and capital requirements will depend upon numerous factors, including the risks discussed at Certain Factors Which May Affect Future Results below, and the following, among others: market demand for our products, especially with the acceptance of drug-eluting stents by our customers and the expected decline in our revenues; the resources required to maintain a direct sales force in the United States and in the larger markets of Europe; the resources required to introduce enhancements to, and expansion of the Beta-Cath System product line; the resources Novoste devotes to the development, manufacture and marketing of its products; resources expended to license or acquire new technologies; and the progress of Novoste s clinical research and product development programs. Novoste may in the future seek to raise additional funds through bank facilities, debt or equity offering or other sources of capital. Additional financing, if, required, may not be available on satisfactory terms, or at all.

During the remainder of 2004, Novoste expects to allocate resources to continue product development and identify products complementary to applications for our Beta-Cath technology, improve operating efficiencies for servicing transfer devices and transition the Guidant s vascular brachytherapy business to the Novoste system. We expect that our cash generated from operations and existing cash reserves will be sufficient to meet our liquidity and capital spending needs at least through the end of 2004.

Table of Contents

CERTAIN FACTORS WHICH MAY AFFECT FUTURE RESULTS

In connection with the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, set forth below are cautionary statements identifying important factors that could cause actual events or results to differ materially from any forward-looking statements made by or on behalf of us, whether oral or written. We wish to ensure that any forward-looking statements are accompanied by meaningful cautionary statements in order to maximize to the fullest extent possible the protections of the safe harbor established in the Private Securities Litigation Reform Act of 1995. Accordingly, any such statements are qualified in their entirety by reference to, and are accompanied by, the following important factors that could cause actual events or results to differ materially from our forward-looking statements. For additional information regarding forward-looking statements, please read the Cautionary Note Regarding Forward-Looking Statements of this report.

We Are Dependent On The Successful Commercialization Of One Product, The Beta-Cath System

We began to commercialize the Beta-Cath System in the United States in November 2000. More than 98% of our revenue in the first quarter 2004 was from sales of this system. We anticipate that for the foreseeable future we will be solely dependent on the continued successful commercialization of the Beta-Cath System; however, in the future we may be unable to manufacture the Beta-Cath System in commercial quantities at acceptable costs or to demonstrate that the Beta-Cath System is an attractive and cost-effective alternative or complement to other procedures, including coronary stents or drug-eluting stents. Because the Beta-Cath System is our sole near-term product focus, we could be required to cease operations if new technology rendered vascular brachytherapy non-competitive. Our failure to continue commercialization of the Beta-Cath System would have a material adverse effect on our business, financial condition and results of operations.

Wide Acceptance By The Medical Community of Drug-Eluting Stents Or Other New Technology Could Render Vascular Brachytherapy Generally Or The Beta-Cath System In Particular Noncompetitive or Obsolete And, In Turn, Could Cause Our Revenues To Decline.

As discussed previously, several companies have developed additional ways to incorporate coatings and drugs into stent platforms as they pursue new innovations in stents. Along with new stent designs, these drug coatings represent revolutionary advancements in the performance of stents as defined by the rate of restenosis. Johnson & Johnson released its drug-eluting stent product in April 2003 and captured over 60% of the stent market with this single product. Boston Scientific Corporation launched its drug-eluting stents version in March 2004. Medtronic and Guidant are expected to follow over the next two years, pending FDA approval. We believe there are also studies being pursued by both Johnson & Johnson and Boston Scientific Corporation to use drug-elution for the treatment of in-stent restenosis. With the rate of restenosis declining and new competitive technologies potentially reducing the in-stent restenosis market in which Novoste operates, we face significant challenges in maintaining our revenues through sales of vascular brachytherapy products.

Since the introduction of drug-eluting stents in April 2003, we have seen a wider acceptance of that product in the medical community and a decline in sales of our vascular brachytherapy products. We expect that sales of our vascular brachytherapy products will continue to decline, due to the market acceptance of drug-eluting stents and competitive pressures from other vascular brachytherapy products, resulting in a future reduction of our revenues.

We May Be Unable To Compete Effectively Against Larger Better Capitalized Companies.

Many of our competitors and potential competitors have substantially greater resources than we do and also have greater resources and expertise in the area of research and development, obtaining regulatory approvals, manufacturing and marketing. Our competitors and potential competitors may succeed in developing, marketing and distributing technologies and products that are more effective than those we will develop and market or that would render our technology and products obsolete or noncompetitive. We may be unable to compete effectively against such competitors and other potential competitors in terms of manufacturing, marketing, distribution, sales and servicing.

Our Patents And Proprietary Technology May Not Adequately Protect Our Proprietary Products

Our policy is to protect our proprietary position by, among other methods, filing United States and foreign patent applications. On November 4, 1997, we were issued United States Patent No. 5,683,345, on May 4, 1999, we received United States Patent No. 5,899,882 (which is jointly owned by us and Emory University) and on January 11, 2000, we received United States Patent No. 6,013,020, all related to the Beta-Cath System. We also have several additional United States applications pending covering other aspects of our Beta-Cath System. The United States Patent and Trademark Office has indicated that certain claims pending in another United States application are allowable. With respect to the above-identified United States Patents and our other pending United States patent applications, we have filed, or will file in due course, counterpart applications in the European Patent Office and certain other countries.

Table of Contents

Like other firms that engage in the development of medical devices, we must address issues and risks relating to patents and trade secrets. United States Patent No. 5,683,345 may not offer adequate protection to us because competitors may be able to design functionally equivalent devices that do not infringe that patent. Our patents could also be reexamined, invalidated or circumvented. Furthermore, claims under our other pending applications may not be allowed, or if allowed, may not offer any protection or may be reexamined, invalidated or circumvented. In addition, competitors may have or may obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products in either the United States or international markets.

Compliance With Applicable Government Regulations: Ability To Successfully Complete Clinical Trials And Gain Market Approval For New Products

Our Beta-Cath System is regulated in the United States and foreign jurisdictions as a medical device. As such, we are subject to extensive regulation by the FDA, by other federal, state and local authorities and by foreign governments. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of marketing approvals, a recommendation by the FDA that we not be permitted to enter into government contracts, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device manufactured or distributed.

The process of obtaining a pre-market approval and other required regulatory approvals can be expensive, uncertain and lengthy, and we may be unsuccessful in obtaining additional approvals to market new versions of the Beta-Cath System or new indications for the Beta-Cath System, such as the Beta-Cath System being tested in the Atrial Fibrillation trial. The FDA may not act favorably or quickly on any of our submissions to the agency. We may encounter significant difficulties and costs in our efforts to obtain additional FDA approvals that could delay or preclude us from selling new products in the United States. Furthermore, the FDA may request additional data or require that we conduct further clinical studies, causing us to incur substantial cost and delay. In addition, the FDA may impose strict labeling requirements, onerous operator training requirements or other requirements as a condition of our market approval, any of which could limit our ability to market our systems. Labeling and marketing activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. FDA enforcement policy strictly prohibits the marketing of FDA cleared or approved medical devices for unapproved uses. Further, if a company wishes to modify a product after FDA approval of a pre-market approval, including any changes that could affect safety or effectiveness, additional approvals will be required by the FDA. Such changes include, but are not limited to: new indications for use, the use of a different facility to manufacture the device, changes to manufacturing process, changes to the device package, changes in vendors that supply components, changes in design specifications and certain labeling changes. Failure to receive or delays in receipt of FDA approvals, including the need for additional clinical trials or data as a prerequisite to approval, or any FDA conditions that limit our ability to market our systems, could have a material adverse effect on our business, financial condition and results of operations.

The Hospitals With Which We Do Business May Be Delayed In Obtaining Or May Be Unable To Obtain The Licenses To Hold, Handle And Use Radiation That Are Required For Our Products.

Our business involves the import, export, manufacture, distribution, use and storage of Strontium-90 (Strontium/Yttrium), the beta-emitting radioisotope utilized in the Beta-Cath System s radiation source train. Hospitals in the United States are required to have radiation licenses to hold, handle and use radiation. Many of the hospitals and/or physicians in the United States have been required to amend their radiation licenses to include Strontium-90 prior to receiving and using our Beta-Cath System. Depending on the state in which the hospital is located, its license amendment will be processed by and its use of the isotope will be regulated by either the state, in states that have agreed to such arrangement, with the United States Nuclear Regulatory Commission or directly by the NRC. Obtaining any of the foregoing radiation-related approvals and licenses can be complicated and time consuming.

We May Be Unable To Obtain Foreign Approval To Market Our Products

In order for us to market the Beta-Cath System in foreign jurisdictions, we must obtain and retain required regulatory approvals and clearances and otherwise comply with extensive regulations regarding safety and manufacturing processes and quality. These regulations, including the requirements for approvals or clearance to market and the time required for regulatory review, vary from country to country, and in some instances within a country. We may not be able to obtain regulatory approvals in such countries or may be required to incur significant costs in obtaining or maintaining our foreign regulatory approvals. Delays in receipt of approvals to market our products, failure to receive these approvals or future loss of previously received approvals could have a material adverse effect on our business, financial condition, and results of operations.

Table of Contents

Some Of Our Activities May Subject Us To Risks Under Federal And State Laws Prohibiting Kickbacks And False Or Fraudulent Claims

A federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar state laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of health care products or services. While the federal law applies only to referrals, products or services for which payment may be made by a federal health care program, state laws often apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices, such as us, by limiting the kinds of financial arrangements, including sales programs, with hospitals, physicians, laboratories and other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Since we may provide some coding and billing advice to purchasers of our products, and since we cannot assure that the government will regard any billing errors that may be made as inadvertent, these laws are potentially applicable to us. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance that can be substantial. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition.

Product Liability Suits Against Us Could Result In Expensive And Time-Consuming Litigation, Payment Of Substantial Damages And Increases In Our Insurance Rates

The sale and use of our products could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect. A product liability claim could result in substantial damages and be costly and time-consuming to defend, either of which could materially harm our business or financial condition. We cannot assure that our product liability insurance would protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

Our Quarterly Operating Results May Vary

Our operating results have fluctuated significantly in the past on a quarterly basis. We expect that our operating results may fluctuate significantly from quarter to quarter and we may experience profits or losses in the future depending on a number of factors, including the extent to which (a) our products are able to compete effectively against drug-eluting stents (b) the timing and level of reimbursement for our products by third-party payors vary, and (c) other factors occur, many of which are outside our control.

We Are Highly Dependent On Key Personnel

We are highly dependent on the principal members of our management and scientific staff. Loss of our key personnel would likely impede achievement of our research and development, operational, or strategic objectives. To be successful, we must retain key employees and attract additional qualified employees.

Our Lack Of Redundant Manufacturing Facilities Could Harm Our Business

We assemble all of our products at our facilities in Norcross, Georgia. The loss of these facilities would likely impede our manufacturing and sales efforts, which would materially and adversely affect our business and financial condition. Should this occur we would have to depend on outsourcing to produce our catheter products.

Issuance Of Preferred Stock May Adversely Affect The Rights Of Holders Of Common Stock Or Delay Or Prevent A Change Of Control Of The Company

In October 1996, our board of directors authorized 1,000,000 shares of Series A Participating Preferred Stock in connection with its adoption of a shareholder rights plan, under which we issued rights to purchase Series A Participating Preferred Stock to holders of the common stock. Upon certain triggering events, such rights become exercisable to purchase common stock (or, in the discretion of our board of directors, Series A Participating Preferred Stock) at a price substantially discounted from the then current market price of the common stock. Our shareholder rights plan could generally discourage a merger or tender offer involving our securities that is not approved by our board of directors by increasing the cost of effecting any such transaction and, accordingly, could have an adverse impact on shareholders who might want to vote in favor of such merger or participate in such tender offer.

Table of Contents

Under our amended and restated articles of incorporation, our board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences and privileges of those shares without any further vote or action by our shareholders. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any shares of preferred stock that may be issued in the future.

While we have no present intention to authorize any additional series of preferred stock, such issuance, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could also have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock. The preferred stock may have other rights, including economic rights senior to the common stock, and, as a result, the issuance thereof could have a material adverse effect on the market value of the common stock.

Certain Provisions Of Our Charter, By-laws And Florida Law May Delay Or Prevent A Change Of Control Of The Company

The amended and restated articles of incorporation provide for a classified board of directors, the existence of which could discourage attempts to acquire us. Additionally, in October 2002, our Board of Directors enacted two amendments to Novoste s by-laws intended to strengthen the provisions of the by-laws that protect Novoste and its shareholders from unfair or coercive takeover tactics. In general, the amendments set forth certain notice requirements for shareholders when calling a special meeting of Novoste s shareholders or submitting shareholder proposals (either a shareholder nomination of director or other business) at our annual meetings. In addition, the amended by-laws establish certain timing requirements for the setting of the record and meeting dates. We are also subject to the anti-takeover provisions of the Florida Business Corporation Act, the application of which may have the effect of delaying or preventing a merger, takeover or other change of control of Novoste and therefore could discourage attempts to acquire Novoste.

Item 3. Quantitative And Qualitative Disclosures About Market Risk

Derivative Financial Instruments, Other Financial Instruments, and Derivative Commodity Instruments

Novoste does not participate in derivative financial instruments, other financial instruments for which the fair value disclosure would be required under SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, or derivative commodity instruments. All of Novoste s investments are in short-term, investment grade commercial paper, corporate bonds, certificates of deposit and U.S. Government and agency securities that are carried at fair value on our books.

Interest Rate Risk

Novoste s cash equivalents and short-term investments are subject to market risk, primarily interest rate and credit risk. Novoste s investments are managed by outside professional managers within investment guidelines set by Novoste. Such guidelines include security type, credit quality and maturity, and are intended to limit market risk by restricting Novoste s investments to high credit quality securities with relatively short-term maturities.

At March 31, 2004, Novoste had $31,494,000 in cash equivalents with a weighted average interest rate of 0.77% and $4,756,000 in available-for-sale investments with a weighted average interest rate of 1.29%. With most investments having less than 90 days to maturity, we believe the risk to principal associated with an increase in interest rates is minimal.

Foreign Currency Risk

International revenues from Novoste s foreign direct sales and distributor sales comprised 15% and 7% of total revenues for the three month periods ended March 31, 2004 and 2003, respectively. Sales to customers outside Europe and Canada are denominated in U.S. dollars, while European sales are denominated in Euros and Pounds, and Canadian sales are in Canadian dollars. Novoste experienced an immaterial amount of transaction gains and losses for the three months ended March 31, 2004. Novoste is also exposed to foreign exchange rate fluctuations as the financial results of its Dutch, Belgian, German and French subsidiaries are translated into U.S. dollars in consolidation. As exchange rates vary, these results, when translated, may vary from expectations and adversely impact overall expected profitability. The net effect of foreign exchange rate fluctuations on Novoste during the three months ended March 31, 2004 was not material.

At March 31, 2004, Novoste s total purchase commitments include $8,461,000 denominated in Euros. This amount was derived from converting such purchase obligations using a March 31, 2004 conversion rate of $1.22 USD to 1 Euro. Some of these purchase obligations extend to 2007, and the actual settlement amount may be different from the amount presented, which is based on the conversion rate of March 31, 2004.

Table of Contents

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures. As of the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Acting Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a 15(e) and 15d 15(e) of the Securities Exchange Act of 1934). Based on this evaluation, our Chief Executive Officer and Acting Chief Financial Officer have concluded that our disclosure controls and procedures are effective in timely notification to them of information we are required to disclose in our periodic Securities and Exchange Commission filings and in ensuring that this information is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and regulations.

(b) Changes in Internal Control. During the period covered by this report, there have been no significant changes in our internal control over financial reporting that have materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Novoste is subject to legal claims and assertions in the ordinary course of business. Except for the matters described in the annual report for the year ended December 31, 2003, filed with the Securities and Exchange Commission, we are not aware of any such claims or assertions that would have a material effect on Novoste.

Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

(e) In August 2002, Novoste initiated a stock buy-back program. Under the program, we have the authority to purchase shares up to $7 million. The program may be suspended at any time and from time to time without prior notice. The program was suspended in connection with the 3.5F catheter recall. No shares were purchased during the first quarter of 2004. As of March 31, 2004, 185,400 shares had been repurchased for $725,000.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

None.

Item 5. Other Information

None.

Table of Contents

Item 6. Exhibits and Reports on Form 8-K

(a)	EXHIBIT NUMBER	DESCRIPTION
	3.1	Amended and Restated Articles of Incorporation of Registrant, filed on May 28, 1996. (1)
	3.2(a)	Copy of First Amendment to Amended and Restated Articles of Incorporation of Registrant filed with the Department of State of the State of Florida on November 1, 1996. (2)
	3.3	Copy of Third Amended and Restated By-Laws of Registrant dated May 5, 2003. (3)
	4.1	Form of Specimen Common Stock Certificate of Registrant. (4)
	4.17(a)	Amended and Restated Rights Agreement, dated as of July 29, 1999, between Novoste Corporation and American Stock Transfer and Trust Company, which includes as Exhibit B thereto the Form of Right Certificate. (5)
	4.17(b)	Amended and Restated Summary of Rights to Purchase Preferred Shares of Novoste Corporation. (5)
	4.20	Registration Rights Agreement dated as of March 28, 2000 by and between Novoste Corporation and the investors listed on the signature pages thereto. (6)
	10.1	Retention Bonus Agreement, date April 1, 2004, between Novoste Corporation and Al Novak.
	10.2	Form of Retention Bonus Agreement, dated April 1, 2004, between Novoste Corporation and its executive officers other than Al Novak.
	10.3	Asset purchase agreement, dated April 22, 2004, between Novoste Corporation and Guidant Corporation (7)
	31.1	Certification of Alfred J. Novak, Chief Executive Officer, pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
	31.2	Certification of Subhash C. Sarda, Acting Chief Financial Officer, pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
	32.1	Statements of Alfred J. Novak, Chief Executive Officer, and Subhash C. Sarda, Acting Chief Financial Officer, pursuant to 18 U.S.C. Section 1350.

(1) Filed as same numbered Exhibit to the Registrant s Report on Form 10-K filed on March 11, 2004.
(2) Filed as same numbered Exhibit to the Registrant s Report on Form 8-A filed on November 5, 1996.
(3) Filed as same numbered Exhibit to the Registrant s Report on Form 10-Q filed on November 4, 2003.
(4) Filed as same numbered Exhibit to the Registrant s Registration Statement on Form S-1 (File No. 333-03374).
(5) Filed as same numbered Exhibit to the Registrant s Registration Statement on Form 8-A/A (File No. 000-20727).
(6) Filed as same numbered Exhibit to the Registrant s Report on Form 8-K filed April 6, 2000.
(7) Filed as Exhibit 99.1 to the Registrant s Report on Form 8-K filed May 5, 2004.

(b) Reports on Form 8-K.

Form 8-K Filing

On March 10, 2004, we filed a current report on Form 8-K to disclose that we issued a press release announcing Novoste s earnings for the quarter ended December 31, 2003. A copy of the release was furnished as an exhibit pursuant to Item 12 under Item 9 of such Form 8-K.

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 hereunto duly authorized.

NOVOSTE CORPORATION

/s/ SUBHASH C. SARDA

SUBHASH C. SARDA
Acting Chief Financial Officer

Principal Financial and Accounting Officer

May 7, 2004

Date