NOVOSTE CORP /FL/
Form 10-Q
May 09, 2003
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, 2003

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

For the transition period from_____ to_____.

Commission File Number: 0-20727

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 April 29, 2003 there were 16,330,951 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 per-share data)

	March 31, 2003	December 31, 2002
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,317	$ 21,928
Short-term investments	11,202	11,647
Accounts receivable, net of allowance of $1,070 and $1,135 respectively	8,648	6,758
Inventory, net	3,588	3,927
Prepaid expenses and other current assets	1,061	986
Total current assets	45,816	45,246
Property and equipment, net	9,053	9,542
Radiation and transfer devices, net	9,606	11,353
Receivable from officers	119	283
Other assets	1,073	1,096
	$ 65,667	$ 67,520
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,608	$ 2,176
Accrued expenses	7,210	9,967
Unearned revenue	1,301	2,429
Capital lease obligations	106	178
Total current liabilities	10,225	14,750
Long-term liabilities		
Capital lease obligations	5	5
Total liabilities	10,230	14,755
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; 16,351,953 shares issued	164	164

Additional paid-in capital	187,983	187,813
Accumulated other comprehensive income	232	190
Accumulated deficit	(132,298)	(134,434)
	56,081	53,733
Less: Treasury stock, 51,002 and 118,077 shares of common stock at cost	(186)	(445)
Unearned compensation	(458)	(523)
Total shareholders equity	55,437	52,765
	$ 65,667	$ 67,520

See accompanying notes.

Table of Contents

NOVOSTE CORPORATION

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per-share data)

	Three Months Ended March 31,	
	2003	**2002**
Net sales	$ 20,705	$ 22,932
Cost of sales	7,066	6,678
Gross margin	13,639	16,254
Operating expenses:		
Research and development	3,358	2,659
Sales and marketing	5,934	8,218
General and administrative	2,318	2,197
Total operating expenses	11,610	13,074
Income from operations	2,029	3,180
Interest income	113	371
Interest expense	(7)	(17)
Other income (expense)	2	(81)
Total other income	108	273
Income before taxes	2,137	3,453
Income taxes		50
Net income	$ 2,137	$ 3,403
Net income per share Basic	$ 0.13	$ 0.21
Weighted average shares outstanding Basic	16,269	16,280
Net income per share Diluted	$ 0.13	$ 0.21
Weighted average shares outstanding Diluted	16,836	16,544

See accompanying notes.

4

Table of Contents

NOVOSTE CORPORATION

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	For The Three Months Ended March 31,	
	2003	**2002**
Cash flows from operating activities:		
Net income	$ 2,137	$ 3,403
Adjustments to reconcile net income to net cash used by operating activities:		
Depreciation and amortization	878	425
Issuance of stock for services or compensation		197
Amortization of deferred compensation	65	51
Amortization of radiation and transfer devices	2,459	1,582
Provision for doubtful accounts	30	
Changes in assets and liabilities:		
Accounts receivable	(1,910)	(945)
Inventory	337	(578)
Prepaid expenses	(74)	13
Accounts payable	(582)	380
Accrued expenses	(2,767)	(4,413)
Unearned revenue	(1,133)	(948)
Other	178	(34)
Net cash used by operations	(382)	(867)
Cash flows from investing activities:		
Maturity of short-term investments	4,339	13,801
Purchase of short-term investments	(3,894)	(4,019)
Purchase of property and equipment, net	(381)	(283)
Purchase of radiation and transfer devices	(712)	(1,314)
Net cash (used) provided by investing activities	(648)	8,185
Cash flows from financing activities:		
Proceeds from issuance of common stock	429	359
Proceeds from revolving line of credit		4,000
Repayment of capital lease obligations	(72)	(64)
Net cash provided by financing activities	357	4,295
Effect of exchange rate changes on cash	62	53
Net (decrease) increase in cash and cash equivalents	(611)	11,666
Cash and equivalents at beginning of period	21,928	5,878
Cash and cash equivalents at end of period	$ 21,317	$ 17,544

Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 7	$ 12

See accompanying notes.

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2003

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 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, 2003. The accompanying consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2002 included in Novoste s 2002 Annual Report on Form 10-K/A 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.

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 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 for a number of its customers. A reserve has been recorded against revenue for known returns and an estimate of unknown returns. The exchange of these catheters is expected to continue in the future until the 3.5F system has been fully launched to a significant majority of customer sites. At March 31, 2003, Novoste had recorded a reserve of approximately $1.0 million to recognize the 5.0F catheters purchased prior to March 31, 2003 that were expected to be returned in the future in exchange for 3.5F catheters. Net sales for the three months ended March 31, 2003 were positively impacted by a net reduction of $1.1 million in the revenue reserve for 5.0F catheters that were replaced with the new 3.5F catheter during the first quarter. (See also Notes 6 and 12.)

Novoste sells its catheters with no right of return except in cases of product malfunction or shipping errors.

In the opinion of management, all adjustments (consisting of normal recurring accruals and estimated write-downs and accruals resulting from the recall) considered necessary for a fair presentation of Novoste s financial results and condition have been recorded.

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, 2002 included in Novoste s 2002 Annual Report on Form 10-K/A filed with the Securities and Exchange Commission.

In June 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards (SFAS) No. 143, *Accounting for Asset Retirement Obligations*. This statement applies to legal obligations associated with the retirement of long-lived assets and requires that the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be determined. The Company adopted SFAS No. 143 on January 1, 2003 and the pronouncement did not have a material effect on the consolidated financial statements.

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2003

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 (APB) No. 25, *Accounting for Stock Issued to Employees,* and related interpretations. SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, amends the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, and APB Opinion No. 28, *Interim Financial Reporting*, to require disclosure in the summary of significant accounting policies of the effects of an entity s policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options vesting period. Novoste s pro forma information follows (in thousands, except per-share data):

	3 Months Ended March 31	
	2003	**2002**
Net income, as reported	$ 2,137	$ 3,403
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	65	51
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(1,208)	(3,125)
Pro forma net income	$ 994	$ 329
Earnings per share:		
Basic-as reported	$ 0.13	$ 0.21
Basic-pro forma	$ 0.06	$ 0.02
Diluted-as reported	$ 0.13	$ 0.21
Diluted-pro forma	$ 0.06	$ 0.02

NOTE 3. CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Cash equivalents are comprised of certain highly liquid investments with maturities of less than three months at the time of their acquisition. 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.

NOTE 4. ACCOUNTS RECEIVABLE

Accounts receivable at March 31, 2003 and December 31, 2002 include receivables due from product sales and amounts due under lease arrangements to hospitals relating to radiation and transfer devices (see Note 6. Radiation and Transfer Devices). The carrying amounts reported in the consolidated balance sheets for accounts receivable approximate their fair value.

There were no significant concentrations of credit risk in the first quarter of 2003 or fiscal year 2002. Novoste

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2003

performs periodic credit evaluations of its customer s financial condition and generally does not require collateral. Management records estimates of expected credit losses and returns of product sold. Bad debt expense for the three-month periods ended March 31, 2003 and 2002 amounted to $30,000 and $0, respectively. Uncollectible accounts written off in those periods totaled $124,000 and $0, respectively.

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, 2003	December 31, 2002
Raw Materials	$ 2,554	$ 2,878
Work in Process	98	202
Finished Goods	936	847
Total	$ 3,588	$ 3,927

Inventory reserves increased from $844,000 at December 31, 2002 to $868,000 at March 31, 2003.

NOTE 6. 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. The annual agreements with Novoste s customers to license the use of radiation and transfer devices are classified by Novoste as operating leases. Income is recognized ratably over the length of the lease. At March 31, 2003, deferred revenue under these leases approximated $200,000.

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

	March 31, 2003	December 31, 2002
Radiation and Transfer Devices	$ 31,546	$ 31,005
Less: Impairment	(5,065)	(5,065)
Net Radiation and Transfer Devices	26,481	25,940
Less: Accumulated Depreciation	(16,875)	(14,587)
	$ 9,606	$ 11,353

Approximately $2.5 million of radiation and transfer devices were available for lease at March 31, 2003.

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 new testing and experience, the estimated useful lives of RSTs are twelve months and the TDs are three years. Accordingly, depreciation was recorded over the updated estimated 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 $5.1 million and other related charges of $1.8 million (see Note 12) to adjust the carrying value of these assets to

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2003

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 $1.7 million 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. Factors leading to an extended life include: (a) the time required to convert customers to 3.5F catheter systems following the recall, (b) completion of 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. Taking these factors into account in our quarterly review of the accuracy of our estimates, and after extensive market review and technology assessment, Novoste concluded that the 5.0F catheter assets will most likely remain in active use through December 31, 2003. Accordingly, the remaining value of the 5.0F catheter assets will be amortized through December 31, 2003, rather than through March 31, 2003, as previously estimated. The result of this change in the estimated useful life is to reduce amortization expense to $413,000 from the expected $1,650,000 for the quarter ended March 31, 2003.

The impact of this change in estimate of useful lives in the three months ended March 31, 2003 is as follows (in thousands, except per-share data):

	Three Months Ended
Impact	**March 31, 2003**
Decrease in Cost of Sales	$ (1,237)
Increase in income per share basic	$ 0.08
Increase in income per share diluted	$ 0.07

NOTE 7. 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 tax 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 the plan, the life insurance company would be obligated to repay Novoste for the tax advances prior to settlement of the account with the officer. At March 31, 2003, and December 31, 2002, the receivable from officers balance was $119,000 and $283,000, respectively.

Novoste has ceased accepting further contributions to the plan from executive officers. All officers who participated in the plan have withdrawn from the plan and $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.

NOTE 8. LINE OF CREDIT

In August 2001, Novoste obtained a $10 million revolving line of credit. During the three months ended March 31, 2003 and at December 31, 2002, Novoste had no outstanding borrowings. Novoste may borrow an amount not to

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2003

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. At December 31, 2002, Novoste was in violation of the tangible net worth covenant of its revolving loan agreement and the lender issued a waiver for that violation through February 28, 2003. By agreement between Novoste and the lender, the maturity date of the original loan agreement between the parties has been extended to February 28, 2003, and by further agreement, the maturity date has been extended to February 27, 2004. Also as part of that modification, the tangible net worth covenant was changed, bringing Novoste into compliance, and the interest rate was changed to a base of the greater 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.

NOTE 9. SEGMENT INFORMATION

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information* requires the reporting of 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 are 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)

Novoste s net sales, net income (loss), long-lived assets and total assets by geographic area at and for the three months ended March 31, 2003 and 2002 are as follows (in thousands):

Net sales				
		United States	Rest of World	Consolidated
	2003	$ 19,299	$ 1,406	$ 20,705
	2002	21,447	1,485	22,932
Net income (loss)				
		United States	Rest of World	Consolidated
	2003	$ 2,100	$ 37	$ 2,137
	2002	3,722	(319)	3,403
Long-lived assets				
		United States	Rest of World	Consolidated
	2003	$ 17,346	$ 2,505	$ 19,851

	2002	20,511	3,641	24,152
Total assets				
		United States	Rest of World	Consolidated
	2003	$ 60,368	$ 5,299	$ 65,667
	2002	77,673	8,266	85,939

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

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2003

NOTE 10. EARNINGS PER SHARE

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. However, for the first quarter of 2003, stock options representing approximately 1.2 million shares of Novoste common stock were antidilutive and were excluded from the calculation of diluted earnings per share as their exercise price was higher than the average price of Novoste s common stock during the quarter (2.3 million shares were excluded in the first quarter of 2002). These options could be dilutive in the future if there is an increase in the price of Novoste common stock.

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

	Three Months Ended March 31	
	2003	**2002**
Numerator:		
Net income	$ 2,137	$ 3,403
Denominator:		
Weighted-average shares outstanding	$ 16,269	$ 16,280
Dilutive effect of stock options and unvested restricted stock	567	264
Weighted-average shares outstanding, assuming dilution	$ 16,836	$ 16,544
Net income per share:		
Basic	$ 0.13	$ 0.21
Diluted	$ 0.13	$ 0.21

NOTE 11. SHAREHOLDERS EQUITY

For the three-month period ended March 31, 2003 changes in shareholders equity consisted of the following (in thousands, except per-share data):

Shareholders equity at beginning of period	$ 52,765

Proceeds from exercise of 67,075 stock options ranging from $3.20 to $6.65 per share	429
Amortization of unearned compensation	65
Comprehensive income:	
Unrealized loss on held-for-sale securities	(20)
Translation adjustment	61
Net income	2,137
Total comprehensive income	2,178
Shareholders equity at March 31, 2003	$ 55,437

NOTE 12. 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

Table of Contents

NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2003

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 or fair value, less costs to sell.

In March 2002, Novoste began commercial distribution of a newer, smaller Beta-Cath™ System equipped with 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, with the first-year goal of installed sites being achieved in less than four months. While the older, larger 5.0F diameter Beth Cath™ Systems are still serviceable, during the second quarter of 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 are 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 is amortized ratably over the estimated useful life of these assets.

On August 19, 2002, Novoste announced the recall of all 3.5F diameter catheter products (see Note 1). As a result, demand for the 5.0F diameter system increased significantly to service the patients needing vascular brachytherapy. This increased demand provided cash flow in excess of the carrying value. In the first quarter of 2003, this increased demand continued due to the factors mentioned in Note 6.

Taking these factors into account in our quarterly review of the accuracy of our estimates, and after extensive market review and technology assessment, Novoste concluded that the 5.0F assets will most likely remain in active use through December 31, 2003. Accordingly, the remaining value of the 5.0F assets will be amortized through December 31, 2003, rather than through March 31, 2003, as previously estimated. At March 31, 2003, approximately $1.3 million of unamortized costs remain for the 5.0F assets.

NOTE 13. TERMINATION COSTS

Thirty-seven employees located in the U.S. were terminated during the quarter ended March 31, 2003, to align Novoste s staffing with current market conditions. One-time termination costs of $196,000 are included in general and administrative expense on the consolidated statement of operations. No additional costs are expected.

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 INFORMATION

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 Novoste s 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 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 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 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.

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

Table of Contents

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. The terms of the operating lease signed with customers located in the United States requires, as dictated by FDA regulatory approval, replacement and servicing of the radiation source train and transfer device at six-month intervals or number of usages. This amount is included in cost of sales as incurred. No other post-sale obligations exist.

Novoste sells its catheters with no right of return except in cases of product malfunction or shipping errors. In connection with the approval to re-launch the 3.5F catheter system on January 6, 2003, Novoste began exchanging some 5.0F catheters for 3.5F catheters for its customers. A reserve has been recorded against revenue for known returns and an estimate of unknown returns. The exchange of these catheters is expected to continue in the future until the 3.5F catheter system has been fully launched to a significant majority of customer sites. At March 31, 2003, Novoste has recorded a reserve for approximately $1.0 million to recognize the 5.0F catheters purchased prior to March 31, 2003 that were expected to be returned in the future in exchange for 3.5F catheters.

Radiation and Transfer Devices and Amortization of Costs

Novoste retains ownership of the RSTs and TDs that are manufactured by third party vendors. The costs to acquire, test and assemble these assets are recorded as incurred. Novoste has determined that based upon experience, testing and discussions with the FDA the estimated useful life of RSTs and TDs exceeds one year and is potentially as long as four 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 length catheters (each of which requires a different TD and RST). The acquisition of these various length systems are based upon demand forecasts derived from available information provided by Novoste s sales and marketing organizations. If actual demand were less favorable, or of a different mixture of treatment lengths than those projected by management, additional valuation allowances might be required which would negatively impact operating profits.

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 $6.9 million was warranted (see Note 6).

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 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 $1.7 million of unamortized costs for the 5.0F assets remained. During the first quarter, despite the re-launch of the newly designed 3.5F system in January, it became apparent that the 5.0F assets would be utilized beyond the previously estimated termination date. Factors leading to an extended life include: (a) delays in converting customers to 3.5F catheter systems due to the recall, (b) completion of training on the new 3.5F replacement systems, and (c) allocations of 3.5F catheter systems to customer sites based on

availability, customer preference and volume potential. Taking these factors into account in our quarterly review of the accuracy of our estimates, and after extensive market review and technology assessment, Novoste concluded that the 5.0F catheter assets will most likely remain in active use through December 31, 2003. Accordingly, the remaining value of the 5.0F catheter assets will be amortized over the year 2003, rather than just the first quarter as previously estimated. The result of this change in estimated useful life is to reduce amortization expense from $1,650,000 to $413,000 for the quarter. Management will continue to evaluate its long-lived assets in accordance with SFAS No. 144.

Table of Contents

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 APB 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 Emerging Issues Task Force (EITF) 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 earns those options.

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

Novoste values its inventories 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.

OVERVIEW

Novoste commenced operations as a medical device company in May 1992. Since 1994, we have devoted substantially all of our efforts to developing the Beta-Cath™ System. Novoste commenced the active marketing of the Beta-Cath™ System in Europe in January 1999 for use in patients suffering from in-stent restenosis , a condition in which coronary stents become clogged with new tissue growth. On November 3, 2000,

Novoste received U.S. marketing approval for the 30-millimeter Beta-Cath™ System from the FDA and subsequently shipped its first commercial system on November 27, 2000. The number of commercial sites in the U.S. increased to over 400 in 2002.

Since our inception through June 30, 2001, we experienced significant losses in each period due to product development and clinical trial costs and, beginning in 2000, the costs of launching the Beta-Cath™ System in the U.S. At March 31, 2003, we had an accumulated deficit of approximately $132.3 million. Novoste experienced its first net operating profit in the third quarter of 2001. Novoste is reporting an operating income in the first quarter 2003 driven by higher revenues compared to the fourth quarter of 2002 as a result of the approval to re-launch the 3.5F Beta-Rail catheter in January 2003. Additionally, we experienced lower expenses than the fourth quarter of 2002, as a result of a reduction in force and efficiency reviews which identified cost cutting measures implemented in the quarter.

Table of Contents

Novoste faces intense competition in the field of vascular brachytherapy with companies that have significantly greater capital resources. Several of these companies have introduced vascular brachytherapy (VBT) products that compete with our Beta-Cath™ System. Some of these products include coatings and treatments to coronary stents that could reduce restenosis and possibly be more acceptable to a medical community already experienced at using stents. Clinical trial results have reported a significant reduction in restenosis rates to below 10%. In addition, Johnson & Johnson recently received regulatory approval from the FDA and began distributing a drug-eluting stent in the U.S. market in April, 2003.

RESULTS OF OPERATIONS

Net income for the three months ended March 31, 2003 was $2,137,000 or $0.13 per share, as compared to $3,403,000 or $0.21 per share for the three months ended March 31, 2002. The decrease in net income for the three months ended March 31, 2003 compared to the prior year was due to lower lease income from radiation transfer devices and source trains, reflecting competitive pressures which demanded that Novoste provide no-cost lease renewals for the radiation devices. Other factors contributing to the lower margins were higher amortization expense for radiation and transfer devices and the costs associated with re-launching the 3.5F catheter in January 2003.

Net Sales. Net sales were $20,705,000 for the three months ended March 31, 2003, as compared to net sales of $22,932,000 for the three months ended March 31, 2002. Net sales recorded in the United States for the three-month period ended March 31, 2003 were $19,299,000, as compared to $21,447,000 for the same period ended March 31, 2002. Comparatively, international net sales decreased 5% to $1,406,000 for the three-month period in 2003, compared to $1,485,000 for the three-month period ending March 31, 2002.

Net sales declined for the quarter ended March 31, 2003 due primarily to lower lease and catheter revenue. Lease revenue has declined due to competitive pressures which required Novoste to renew a number of the leases at no cost to the customer. Catheter sales in units were lower than the first quarter of 2002 because of fewer sales promotions and lower utilization per site, which management believes was affected by the uncertainties associated with the 3.5F recall last year and the re-launch in January. Catheter sales were also impacted in the quarter as a result of the 3.5F Beta-Cath system requiring fewer catheters to be inventoried by the customer than the 5.0F Beta-Cath system which represented 100% of the catheter sales in the first quarter of 2002. In addition, competition has had an impact in lowering the average selling price of catheters by approximately 4% from the levels in the first quarter of 2002.

Cost of Sales. Cost of sales of $7,066,000 were incurred in the three months ended March 31, 2003. Gross margin for the three-month period ending March 31, 2003 was $13,639,000, or 66%. Cost of sales for the three months ended March 31, 2002 were $6,678,000, and gross margin was 71%, or $16,254,000 for the same period in 2002. The decrease in the gross margin for the first quarter of 2003 is due to the higher amortization expense for radiation and transfer devices, along with the costs associated with the re-launch of the 3.5F catheter and a lower average selling price of catheters. The increased amortization expense for radiation and transfer devices results from the two 3.5F and 5.0F catheter systems at customer sites, with lower utilization levels for the 5.0F catheter system, as customers are converted to the new 3.5F catheter system. In the three month period ended March 31, 2002, the added amortization expense was $900,000.

Factors impacting cost of sales and gross margins in future quarters will include the utilization of catheters at the sites using the Beta-Cath™ System and the additional costs to service the two sizes of catheter systems.

Research and Development Expenses. Research and development expenses increased 26% to $3,358,000 for the three months ended March 31, 2003, from $2,659,000 for the three months ended March 31, 2002. The increase for the three-month period was primarily the result of new clinical trials related to expanded application of the Beta-Cath™ system, compared to prior year when trials related to the smaller 3.5F catheter

were winding down. The two primary trials, MOBILE (More Beta radiation In the Lower Extremities) and BRAVO (Beta Radiation for treatment of Arterial-Venous graft Outflow), are currently enrolling additional clinical trial sites and patients with the objective of achieving new clinical applications for the brachytherapy technology in the peripheral vascular and arterial venous

Table of Contents

access graft markets. Additionally, we are developing product improvements and line extensions for our current cardiology market.

Sales and Marketing Expenses. Sales and marketing expenses decreased 28% to $5,934,000 for the three months ended March 31, 2003, from $8,218,000 for the three months ended March 31, 2002. These expenses declined primarily due to a reduction of $1,491,000 in variable expenses such as commissions, travel, and trade shows, and other promotional costs related to lower sales, and a reduction of $612,000 in Europe, resulting from the cost containment effort last year. Novoste expects these costs to remain relatively constant as a percent of revenue for the balance of 2003.

General and Administrative Expenses. General and administrative expenses increased 6% to $2,318,000 for the three months ended March 31, 2003, from $2,197,000 for the three months ended March 31, 2002. The increase for the first quarter 2003 is mainly due to $196,000 of expenses incurred as Novoste restructured, including severance payments and other out-of-pocket termination expenses.

Other Income and Expenses. Other income decreased 60% to $108,000 for the three months ended March 31, 2003, from $273,000 for the three months ended March 31, 2002. The decrease is mainly due to the decline in interest rates for short-term investments and the lower average balances in short-term investments. Net interest income is down 69% from the same quarter last year.

LIQUIDITY AND CAPITAL RESOURCES

Operating

Net cash used by operations was $400,000 for the three months ended March 31, 2003, compared to net cash used by those activities of $900,000 in the prior year period. The improvement in net cash used by operations was a direct result of lower working capital needs arising from the lower revenues in the three months ended March 31, 2003.

Investing

Net cash used in investing activities was $600,000 for the three months ended March 31, 2003, compared to net cash provided by those activities of $8.2 million in the prior year period. The net maturities of short-term investments decreased by $9.3 million and $100,000 more cash was used to purchase property and equipment in the first quarter of 2003 as compared to the first quarter of 2002. Partially offsetting those decreases, $600,000 less cash was used to purchase radiation and transfer devices in the same periods. The decreased purchase of radiation devices in 2003 reflects the slower rate of opening new sites in 2003, and maturity of the market segment, resulting in the need for fewer new transfer devices. Novoste anticipates that the purchase of radiation devices will continue, although at a slower rate, as Novoste continues to convert accounts to the 3.5F catheter system. Novoste has shifted toward cash equivalents, lowering average short-term investments by 57% in the first quarter of 2003 as compared to the first quarter of 2002, to protect the principal amount during this period of low interest rates.

Financing

Novoste s financing activities include equity issuances from stock option exercises and repayments of capital leases. Novoste had no borrowings in the first quarter of 2003, compared to $4.0 million in the first quarter of 2002. During the quarter ended March 31, 2003, Novoste issued 67,000 shares of its common stock at an average price of $6.39 as various employee stock options were exercised.

In August 2001, Novoste entered into a $10 million accounts receivable revolving line of credit with a financial institution (lender) that 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 February 27, 2004. At March 31, 2003, Novoste had no outstanding borrowings (see Note 8).

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, 2003, Novoste had no outstanding letters of credit.

Commitments

At March 31, 2003, Novoste had commitments to purchase $4.4 million of inventory components for the Beta-

Table of Contents

Cath™ System over the next six months.

On October 14, 1999 Novoste signed a development and manufacturing supply agreement with AEA Technologies QSA GmbH for a second source of radioactive supply and for the development of a smaller diameter radiation source. The agreement provided for the construction of a production line to be finished in two phases. The first phase, the design phase, was completed in February and the second phase was completed in October 2002. The completion of the first phase provided Novoste with access to a limited supply of the smaller diameter radiation source by using the design equipment to produce the smaller diameter radiation seed trains. The cost of this production line was paid as construction progressed. Depreciation of the production line began when the equipment 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 that AEA may manufacture vascular brachytherapy sources only for us. The annual production commitment is 500 source trains at agreed upon prices. Novoste expects to exceed the annual minimum commitment for 2003.

On June 20, 2001, Novoste entered into a 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 under the four-year contract, Novoste guarantees to pay to Bebig minimum annual payments of varying amounts. 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 purchase in line with the guaranteed amounts.

Significant proportions of key components and processes relating to Novoste s products are purchased from single sources 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 to the physician aggregated $191,000 and $209,000 for the three months ended March 31, 2003 and 2002, respectively, and have been expensed in Cost of Sales. As of March 31, 2003, aggregate payments of $1,566,000 have been made under the license agreement.

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 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 to Emory University aggregated $386,000 and $447,000 for the three months ended March 31, 2003 and 2002, respectively, and have been expensed in Cost of Sales.

Liquidity

Novoste s principal source of liquidity at March 31, 2003 consisted of cash, cash equivalents and short-term investments of $32.5 million. As of December 31, 2002, Novoste had cash, cash equivalents and short-term investments of $33.6 million.

Novoste s future liquidity and capital requirements will depend upon numerous factors, including the risks discussed at Certain Factors That May Impact Future Results below, and the following, among others: market demand for our products; 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

Table of Contents

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.

Novoste expects, during the remainder of 2003, to allocate resources to continue clinical trials for validating additional applications for our Beta-Cath technology, to continue the conversion of customers from 5.0F systems to 3.5F systems, and improve operating efficiencies for servicing transfer devices. 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 2003.

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. Substantially all of our revenue in the first three months of 2003 was from sales in the United States. 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, competing vascular brachytherapy devices, or drug coated 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.

Drug-Eluting Stents Or Other New Technology Could Render Vascular Brachytherapy Generally, Or The Beta-Cath System In Particular, Noncompetitive Or Obsolete.

Competition in the medical device industry, and specifically the markets for cardiovascular devices, is intense and characterized by extensive research and development efforts and rapidly advancing technology. New developments in technology could render vascular brachytherapy generally, or the Beta-Cath System in particular, noncompetitive or obsolete.

Vascular brachytherapy competes with other treatment methods designed to improve outcomes from coronary artery procedures that are well established in the medical community, such as coronary stents. Stents are the predominant treatment currently utilized to reduce the incidence of coronary restenosis following Percutaneous Transluminal Coronary Angioplasty (PTCA) and were used in greater than 80% of all PTCA procedures performed worldwide in 2001. Manufacturers of stents include Johnson & Johnson, Medtronic, Inc., Guidant Corporation and Boston

Scientific Corporation. Stent manufacturers often sell many products used in the cardiac catheterization labs, commonly referred to as cath labs, and as discussed below, certain of these companies have developed vascular brachytherapy devices.

Johnson & Johnson and Guidant compete directly with Novoste for market acceptance of vascular brachytherapy and each has substantially greater capital resources and greater resources and experience at introducing new products than does Novoste.

Many of these same companies and others are researching coatings and treatments to coronary stents that could

Table of Contents

reduce restenosis and possibly be more acceptable to a medical community already experienced at using stents. Clinical trial results have reported a significant reduction in restenosis rates to below 10%. In addition, Johnson & Johnson recently received unanimous recommendation for approval by a FDA advisory panel that its drug-eluting stent be approved for distribution in the U.S. Full FDA approval was granted in April 2003. This could potentially have a material adverse effect on Novoste s business.

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.

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 them. They 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.

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

Many of our competitors and potential competitors have substantially greater capital 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. Additionally, many of the competitors have the capability to bundle a wide variety of products in sales to cath labs or to effectively reduce the price of competing VBT products. We have experienced significant pricing pressure from the largest VBT competitor, Guidant. We may be unable to compete effectively against such competitors and other potential competitors in terms of manufacturing, marketing, distribution, sales and servicing.

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 other 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 CORONA™ being tested in the BRAVO and MOBILE clinical trials. 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

Table of Contents

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, the FDA will require additional approvals. Such changes include, but are not limited to: new indications for use, the use of a different facility to manufacture the device, changes to process or package the device, changes in vendors that supply components, changes in manufacturing methods, 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.

Additionally, in October 2002, the FDA began to require the payment of fees for the review of submissions requesting clearance or approval to market medical devices, called user fees. Submissions requesting clearance or approval for marketing will be assessed a fee of approximately $2,200 for a section 510(k) pre-market notification (an application to market product based upon a prior FDA approval of similar product) or approximately $33,000 to approximately $154,000 for a pre-market approval application or supplement (depending on the type of submission).

The Hospitals With Which We Do Business May Be Delayed In Obtaining 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 The State Department of Natural Resources, in states that have agreed to such arrangement, or by The United States Nuclear Regulatory Commission. 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 Japan and certain other 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.

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

Table of Contents

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 you 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 losses in the future depending on a number of factors, including the extent to which our products continue to gain market acceptance, the rate and size of expenditures incurred as we expand our domestic and establish our international sales and distribution networks, the timing and level of reimbursement for our products by third-party payors, and other factors, 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.

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.

Table of Contents

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 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, 2003, Novoste had $21.3 million in cash equivalents with a weighted average interest rate of 0.622% and $11.2 million in available-for-sale investments with a weighted average interest rate of 1.770%.

Foreign Currency Risk

International revenues from Novoste s foreign direct sales and distributor sales comprised 7%, 6% and 13% of total revenues for the three month periods ended March 31, 2003, 2002 and 2001, respectively. All sales to customers outside Europe are denominated in U.S. dollars, while European sales are denominated in Euros. Novoste experienced an immaterial amount of transaction gains and losses for the three months ended March 31, 2003. 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, 2003 was not material.

Item 4. Controls and Procedures

(a) Disclosure Controls and Procedures. During the first quarter of 2003, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure

Table of Contents

controls and procedures. Based on this evaluation, our Chief Executive Officer and 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) Internal Controls. There have been no significant changes in our internal controls or in other factors that could significantly affect those controls, including any corrective actions with regard to significant deficiencies and material weaknesses, subsequent to the date of their evaluation.

(c) Limitations on the Effectiveness of Controls. Novoste s disclosure controls and procedures are designed to provide a reasonable level of assurance of reaching Novoste s desired disclosure control objectives and are effective in reaching that level of reasonable assurance. However, Novoste s management, including the Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Some inherent limitations in all control systems include the realities that: (i) judgments in decision-making can be faulty; (ii) breakdowns can occur because of simple error or mistake; and (iii) controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Novoste is subject to legal claims and assertions in the ordinary course of business. We are not aware of any such assertions that would have a material effect on Novoste.

Item 2. Changes in Securities and Use of Proceeds

None.

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, 2000.*
4.1	Form of Specimen Common Stock Certificate of Registrant. (3)
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. (4)
4.17(b)	Amended and Restated Summary of Rights to Purchase Preferred Shares of Novoste Corporation. (4)
4.20	Registration Rights Agreement dated as of March 28, 2000 by and among Novoste Corporation and the investors listed on the signature pages thereto. (5)
10.38	Fourth Loan Modification Agreement entered into as of February 28, 2003.*
99.1	Statements of Alfred J. Novak, Chief Executive Officer, and Edwin B. Cordell, Jr., 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 31, 2003.

(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 Registration Statement on Form S-1 (File No. 333-03374).

(4) Filed as same numbered Exhibit to the Registrant s Registration Statement on Form 8-A/A (File No. 000-20727).

(5) Filed as same numbered Exhibit to the Registrant s Report on Form 8-K filed April 6, 2000.

* Filed herewith.

(b) Reports on Form 8-K.

None.

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/ EDWIN B. CORDELL, JR.

EDWIN B. CORDELL, JR.

Vice President Finance and Chief Financial Officer

(Principal Financial & Accounting Officer)

May 9, 2003

Date

Table of Contents

CERTIFICATIONS

I, Alfred J. Novak, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Novoste Corporation;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 9, 2003

/s/ ALFRED J. NOVAK

ALFRED J. NOVAK

Chief Executive Officer

Table of Contents

I, Edwin B. Cordell, Jr., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Novoste Corporation;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 9, 2003

/s/ EDWIN B. CORDELL, JR.

EDWIN B. CORDELL, JR.

Chief Financial Officer