

NOVOSTE CORP /FL/
Form 10-Q
August 08, 2003
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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 June 30, 2003

.. **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
(State or Other Jurisdiction)

of Incorporation or Organization)

59-2787476
(I.R.S. Employer

Identification No.)

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3890 Steve Reynolds Blvd. Norcross, GA
(Address of Principal Executive Offices)

30093
(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 No

(Item 2) Yes No

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

As of August 4, 2003 there were 16,498,688 shares of the Registrant's Common Stock outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

NOVOSTE CORPORATION**CONSOLIDATED BALANCE SHEETS**

(in thousands, except number of shares data)

| | June 30, 2003 | December 31, 2002 |
|--|-------------------|----------------------|
| | <u> </u> | <u> </u> |
| | (Unaudited) | |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 27,330 | \$ 21,928 |
| Short-term investments | 8,355 | 11,647 |
| Accounts receivable, net of allowance of \$643 and \$1,135 respectively | 8,658 | 6,758 |
| Inventory, net | 3,768 | 3,927 |
| Prepaid expenses and other current assets | 864 | 986 |
| | <u> </u> | <u> </u> |
| Total current assets | 48,975 | 45,246 |
| Property and equipment, net | 8,489 | 9,542 |
| Radiation and transfer devices, net | 8,217 | 11,353 |
| Receivable from officers | | 283 |
| Other assets | 650 | 1,096 |
| | <u> </u> | <u> </u> |
| | <u>\$ 66,331</u> | <u>\$ 67,520</u> |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,245 | 2,176 |
| Accrued expenses | 7,368 | 9,967 |
| Unearned revenue | 657 | 2,429 |
| Capital lease obligations | 38 | 178 |
| | <u> </u> | <u> </u> |
| Total current liabilities | 9,308 | 14,750 |
| | <u> </u> | <u> </u> |
| Long-term liabilities | | |
| Capital lease obligations | 5 | 5 |
| | <u> </u> | <u> </u> |
| Total liabilities | 9,313 | 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; 16,362,017 and 16,351,953 shares issued, respectively | 164 | 164 |
| Additional paid-in capital | 187,865 | 187,813 |
| Accumulated other comprehensive income | 364 | 190 |
| Accumulated deficit | (131,145) | (134,434) |

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| | | |
|---|------------------|------------------|
| | <u>57,248</u> | <u>53,733</u> |
| Less: Treasury stock, 18,329 and 118,077 shares of common stock at cost | (66) | (445) |
| Unearned compensation | (164) | (523) |
| | <u>57,018</u> | <u>52,765</u> |
| Total shareholders' equity | <u>\$ 66,331</u> | <u>\$ 67,520</u> |

See accompanying notes.

Table of Contents**NOVOSTE CORPORATION****UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except per-share data)

| | Three Months Ended | | Six Months Ended | |
|---|--------------------|------------|------------------|------------|
| | June 30, | | June 30, | |
| | 2003 | 2002 | 2003 | 2002 |
| Net sales | \$ 17,608 | \$ 16,824 | \$ 38,314 | \$ 39,757 |
| Cost of sales | 6,318 | 6,214 | 13,386 | 12,893 |
| Impairment charge | | 6,900 | | 6,900 |
| Gross margin | 11,290 | 3,710 | 24,928 | 19,964 |
| Operating expenses: | | | | |
| Research and development | 2,806 | 3,464 | 6,164 | 6,123 |
| Sales and marketing | 5,147 | 6,545 | 11,081 | 14,763 |
| General and administrative | 2,246 | 2,293 | 4,565 | 4,491 |
| Total operating expenses | 10,199 | 12,302 | 21,810 | 25,377 |
| Income (loss) from operations | 1,091 | (8,592) | 3,118 | (5,413) |
| Interest income | 70 | 143 | 183 | 514 |
| Interest expense | (2) | (69) | (9) | |
| Other income (expense) | 2 | (33) | 5 | (114) |
| Total other income | 70 | 41 | 179 | 314 |
| Income (loss) before taxes | 1,161 | (8,551) | 3,297 | (5,099) |
| Income taxes | 8 | | 8 | 50 |
| Net income (loss) | \$ 1,153 | \$ (8,551) | \$ 3,289 | \$ (5,149) |
| Net income (loss) per share Basic | \$ 0.07 | \$ (0.52) | \$ 0.20 | \$ (0.32) |
| Weighted average shares outstanding Basic | 16,321 | 16,311 | 16,295 | 16,296 |
| Net income (loss) per share Diluted | \$ 0.07 | \$ (0.52) | \$ 0.19 | \$ (0.32) |
| Weighted average shares outstanding Diluted | 16,951 | 16,311 | 16,893 | 16,296 |

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See accompanying notes.

Table of Contents**NOVOSTE CORPORATION****UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

| | Six Months Ended June 30, | |
|--|------------------------------|---------------|
| | 2003 | 2002 |
| Cash flows from operating activities: | | |
| Net income (loss) | \$ 3,289 | \$ (5,149) |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 1,765 | 1,100 |
| Issuance (cancellation) of stock for services or compensation | (3) | 197 |
| Amortization of deferred compensation and variable stock awards | 75 | 97 |
| Amortization of radiation and transfer devices | 4,748 | 6,030 |
| Provision for doubtful accounts | (256) | 241 |
| Changes in assets and liabilities: | | |
| Accounts receivable | (1,604) | 2,988 |
| Inventory | 168 | (260) |
| Prepaid expenses | 122 | (220) |
| Accounts payable | (968) | (1,504) |
| Accrued expenses | (2,620) | (4,825) |
| Unearned revenue | (1,783) | (553) |
| Impairment charge | | 5,065 |
| Other | 757 | 397 |
| Net cash provided by operations | 3,690 | 3,604 |
| Cash flows from investing activities: | | |
| Maturity/Sale of short-term investments | 9,486 | 23,079 |
| Purchase of short-term investments | (6,194) | (9,044) |
| Purchase of property and equipment, net | (698) | (1,000) |
| Purchase of radiation and transfer devices | (1,613) | (6,073) |
| Net cash provided by investing activities | 981 | 6,962 |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common stock | 717 | 469 |
| Repayment of capital lease obligations | (139) | (131) |
| Net cash provided by financing activities | 578 | 338 |
| Effect of exchange rate changes on cash | 153 | (187) |
| Net increase in cash and cash equivalents | 5,402 | 10,717 |
| Cash and equivalents at beginning of period | 21,928 | 5,878 |

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| | | |
|---|-----------|-----------|
| Cash and cash equivalents at end of period | \$ 27,330 | \$ 16,595 |
| Supplemental disclosure of cash flow information: | | |
| Cash paid for interest | \$ (9) | \$ (21) |

See accompanying notes.

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 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 consolidated 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 with 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 be completed by September 2003. At June 30, 2003, Novoste had recorded a reserve of approximately \$0.4 million to recognize the 5.0F catheters purchased prior to June 30, 2003 that were expected to be returned in the future in exchange for 3.5F catheters. Net sales for the three months ended June 30, 2003 were positively impacted by a net reduction of \$0.6 million in the revenue reserve for 5.0F catheters that were replaced with the new 3.5F catheters during the second 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.

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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.

IMPACT OF RECENTLY ISSUED ACCOUNTING STANDARDS

In December 2002, the FASB issued Statement No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. This statement amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2003

alternative methods of transition to SFAS No. 123's fair value method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure provisions in SFAS No. 123 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 accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim consolidated financial statements. The adoption of the disclosure provisions of SFAS No. 148 did not have a significant impact on Novoste's consolidated financial statements.

Novoste accounts for grants of stock options and restricted stock under the recognition and measurement principles of Accounting Principles Board Opinion 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 | | Six Months Ended | |
|---|---------------------|------------|---------------------|------------|
| | June 30 (unaudited) | | June 30 (unaudited) | |
| | 2003 | 2002 | 2003 | 2002 |
| Net income (loss), as reported | \$ 1,153 | \$ (8,551) | \$ 3,289 | \$ (5,149) |
| Add: Total stock-based employee compensation expense included in reported net income (loss) | 10 | 46 | 75 | 294 |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | (1,070) | 222 | (2,343) | (3,151) |
| Pro forma net income (loss) | \$ 93 | \$ (8,283) | \$ 1,021 | \$ (8,006) |
| Earnings (loss) per share: | | | | |
| Basic-as reported | \$ 0.07 | \$ (0.52) | \$ 0.20 | \$ (0.32) |
| Basic-pro forma | \$ 0.01 | \$ (0.51) | \$ 0.06 | \$ (0.49) |
| Diluted-as reported | \$ 0.07 | \$ (0.52) | \$ 0.19 | \$ (0.32) |
| Diluted-pro forma | \$ 0.01 | \$ (0.51) | \$ 0.06 | \$ (0.49) |

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

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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. We are currently in the process of determining the impact, if any, of FIN 46 on our results of operations or financial position.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under FASB Statement No. 133, *Accounting for Derivative Instruments and Hedging Activities*. The standard becomes effective for us, generally, for contracts entered into or modified after June 30, 2003. The adoption of SFAS 149 is currently not expected to have a significant impact on our results of operations or financial position.

Table of Contents**NOVOSTE CORPORATION****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS****June 30, 2003****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 June 30, 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 at June 30, 2003. 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. Bad debt recovery for the three-month period ended June 30, 2003 was \$308,000 as compared to bad debt expense of \$158,000 in the three-month period ended June 30, 2002. For the six-month period ended June 30, 2003 bad debt recovery was a net of \$256,000, as compared to bad debt expense of \$164,000 in the six-month period ended June 30, 2002. Recoveries occurred as credit policies were strengthened to reduce bad debt exposure.

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):

| | June 30, 2003 | December 31, 2002 |
|-----------------|-------------------|-------------------|
| | <u> </u> | <u> </u> |
| Raw Materials | \$ 2,684 | \$ 2,878 |
| Work in Process | 159 | 202 |
| Finished Goods | 925 | 847 |

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| | | |
|-------|----------|----------|
| Total | \$ 3,768 | \$ 3,927 |
|-------|----------|----------|

Inventory reserves increased from \$844,000 at December 31, 2002 to \$872,000 at June 30, 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 June 30, 2003, deferred revenue under these

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2003

leases approximated \$257,000.

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

| | June 30, 2003 | December 31, 2002 |
|------------------------------------|-------------------|-------------------|
| | <u> </u> | <u> </u> |
| Radiation and Transfer Devices | \$ 31,881 | \$ 31,005 |
| Less: Impairment | (5,065) | (5,065) |
| | <u> </u> | <u> </u> |
| Net Radiation and Transfer Devices | 26,816 | 25,940 |
| Less: Accumulated Depreciation | (18,599) | (14,587) |
| | <u> </u> | <u> </u> |
| | <u>\$ 8,217</u> | <u>\$ 11,353</u> |

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 bench testing, 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 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

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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 reduced amortization expense in the first quarter by \$1,237,000 and increased amortization expense by \$413,000 for the quarter ended June 30, 2003.

The impact of this change in estimate of useful lives of the 5.0F catheter in the six months ended June 30, 2003 is as follows (in thousands, except per-share data):

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2003

| Impact | Six Months Ended |
|--------------------------------------|------------------|
| | June 30, 2003 |
| Decrease in Cost of Sales | \$ (824) |
| Increase in income per share basic | \$ 0.05 |
| Increase in income per share diluted | \$ 0.05 |

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 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 June 30, 2003 the balance of the receivables from officers was \$0.

NOTE 8. LINE OF CREDIT

In August 2001, Novoste obtained a \$10 million revolving line of credit. At June 30, 2003 Novoste had no outstanding borrowings. Novoste may borrow an amount not to exceed 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, 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 2003. 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 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 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 June 30, 2003, Novoste had no outstanding letters of credit.

NOTE 9. 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).

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2003

Novoste's net sales, net income (loss), long-lived assets and total assets by geographic area at and for the six months ended June 30, 2003 and 2002 are as follows (in thousands):

| | | | | |
|--------------------------|------|-------------------|-------------------|-------------------|
| Net sales | | | | |
| | | United States | Rest of World | Consolidated |
| | | <u> </u> | <u> </u> | <u> </u> |
| | 2003 | \$ 35,882 | \$ 2,432 | \$ 38,314 |
| | 2002 | 36,826 | 2,931 | 39,757 |
| Net income (loss) | | | | |
| | | United States | Rest of World | Consolidated |
| | | <u> </u> | <u> </u> | <u> </u> |
| | 2003 | \$ 3,414 | \$ (125) | \$ 3,289 |
| | 2002 | (3,334) | (1,815) | (5,149) |
| Long-lived assets | | | | |
| | | United States | Rest of World | Consolidated |
| | | <u> </u> | <u> </u> | <u> </u> |
| | 2003 | \$ 15,327 | \$ 1,379 | \$ 16,706 |
| | 2002 | 18,013 | 2,156 | 20,169 |
| Total assets | | | | |
| | | United States | Rest of World | Consolidated |
| | | <u> </u> | <u> </u> | <u> </u> |
| | 2003 | \$ 61,984 | \$ 4,347 | \$ 66,331 |
| | 2002 | 68,882 | 5,231 | 74,113 |

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

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. For the calculation of the six months ended June 30, 2003, stock options representing approximately 1.3 million shares of Novoste common stock were excluded as their exercise price was higher than the average price of Novoste's common stock during the six months period (1.6 million shares were excluded in the six months ended June 30, 2002). These options could be dilutive in the future if there is an increase in the price of Novoste common stock.

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The following table sets forth the computation of basic and diluted earnings per share for the six-month periods ended June 30, 2003 and 2002 (in thousands, except per-share data):

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June 30, 2003

| | Six Months Ended June 30 | |
|--|-----------------------------|---------------|
| | 2003 | 2002 |
| Numerator: | | |
| Net income (loss) | \$ 3,289 | \$ (5,149) |
| Denominator: | | |
| Weighted-average shares outstanding | 16,295 | 16,296 |
| Dilutive effect of stock options and unvested restricted stock | 598 | 0 |
| Weighted-average shares outstanding, assuming dilution | 16,893 | 16,296 |
| Net income (loss) per share: | | |
| Basic | \$ 0.20 | \$ (0.32) |
| Diluted | \$ 0.19 | \$ (0.32) |

NOTE 11. SHAREHOLDERS' EQUITY

For the three and six-month periods ended June 30, 2003, changes in shareholders' equity consisted of the following (in thousands):

| | Three Months Ended June 30, 2003 | Six Months Ended June 30, 2003 |
|---|---|-----------------------------------|
| | Shareholders' equity at beginning of period | \$ 55,437 |
| Proceeds from exercise of stock options ranging from \$3.20 to \$6.65 per share | 227 | 655 |
| Proceeds from Employee Stock Purchase Plan at \$5.82 per share | 62 | 62 |
| Amortization of unearned compensation | 40 | 82 |
| Revaluation of Variable Stock Awards | (30) | (7) |
| Cancellation of unvested Restricted Stock Awards | (3) | (3) |
| Comprehensive income: | | |
| Unrealized gain/(loss) on held-for-sale securities | 5 | (14) |
| Translation adjustment | 127 | 189 |
| Net income | 1,153 | 3,289 |
| Total comprehensive income | 1,285 | 3,464 |
| Shareholders' equity at June 30, 2003 | \$ 57,018 | \$ 57,018 |

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 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 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 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.

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June 30, 2003

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 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 the quarterly review of the accuracy of our estimates, and after extensive market review and technology assessment, Novoste concluded that the 5.0F assets will 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 June 30, 2003, approximately \$0.8 million of unamortized costs remain for the 5.0F assets.

NOTE 13: TERMINATION COSTS

Thirty-nine employees located in the U.S. were terminated during the six-months ended June 30, 2003, to align Novoste's staffing with current market conditions. Termination costs of \$254,000 are included in general and administrative expense on the consolidated statement of operations for that period.

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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, 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 use of 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 the Company'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.

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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.

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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. 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 with its customers 5.0F catheters for 3.5F catheters. A reserve has been recorded against revenue for known returns and an estimate of unknown returns. The exchange of these catheters is expected to be completed by September 2003. At June 30, 2003, Novoste has recorded a reserve for approximately \$0.4 million to recognize the 5.0F catheters purchased prior to June 30, 2003 that are 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 and bench testing 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 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 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 \$1.7 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

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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 the 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 likely remain in active use through December 31, 2003. Accordingly, the

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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 reduced amortization expense from \$1,650,000 to \$413,000 for the first quarter and added \$413,000 to expense for the second and subsequent quarters (see Note 6 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 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

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.

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.

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Net income for the second quarter 2003 increased to \$1,153,000 or \$0.07 per share, basic and diluted, as compared to a net loss of \$8,551,000 or \$0.52 per share, basic and diluted, for the second quarter of 2002. Net income increased to \$3,289,000 or \$0.20 per share, basic, and \$0.19 per share, diluted, as compared to a net loss of \$5,149,000 or \$0.32 per share, basic and diluted, for the six months ended June 30, 2002. Results for the current quarter were positively impacted by a reduction in the catheter exchange reserve set up in prior periods which added \$600,000 to reported revenue (Note 1 to the unaudited consolidated financial statements). After adjusting for the impact of revenue reserves and for the asset impairment charge in the second quarter of 2002, net income in the three-months ended June 30, 2003 compares favorably to an adjusted net loss for the three-months ended June 30, 2002. This improvement in profitability is the result of cost control measures such as controlling marketing costs worldwide, reducing selling expenses in Europe and reducing research and development costs. Year-to-date results are also improved due to lower operating costs and absence of the impairment charge.

Net Sales. Net sales increased 5% to \$17,608,000 and declined 4% to \$38,314,000 in the three and six months ended June 30, 2003, respectively, as compared to net sales of \$16,824,000 and \$39,757,000 for the three and six months ended June 30, 2002, respectively. Net sales recorded in the United States for the three and six months ended June 30, 2003 increased 8% to \$16,583,000 and declined 3% to \$35,882,000, respectively, as compared to net sales of \$15,379,000 and \$36,826,000 for the three and six months ended June 30, 2002, respectively. Comparatively, international net sales for the three and six months ended June 30, 2003 declined 29% to \$1,026,000 and 17% to \$2,432,000, respectively, as compared to net sales of \$1,446,000 and \$2,931,000 for the three and six months ended June 30, 2002, respectively. International sales decreased in the three and six months ended June 30, 2003 as a result of eliminating 37 unprofitable sites since December 31, 2002.

Net sales increased 5% from the same quarter in the prior year. Catheter revenue in the current quarter was positively impacted by lowering the reserve for future catheter exchanges by \$600,000. Excluding revenue reserves in both the current and prior year same quarters, catheter sales for the quarter remained at prior year levels, with growth limited by increased competition and the launch of drug-eluting stents. Lease revenue declined 73% due to competitive pressure to renew the leases of the radiation devices at considerably lower prices.

Net sales for the six months ended June 30, 2003 declined 4% compared to the same period in 2002. Catheter sales were lower by 5%. Novoste believes this decrease was due to increased competition and the launch of drug-eluting stents in the second quarter of 2003, as well as the successful launch of the 3.5F catheter system in March 2002. These declines were offset by recognition of revenue deferred in anticipation of catheter exchanges, resulting in higher reported revenue by 7% (Note 1 to unaudited consolidated financial statements). Lease revenue declined 77% due to lease renewals at nominal cost to the customer.

Cost of Sales. Cost of sales increased 2% to \$6,318,000 and 4% to \$13,386,000 in the three and six months ended June 30, 2003, with the gross margin \$11,290,000, or 64% of revenue, and \$24,928,000 or 65% of revenue, respectively. Cost of sales of \$6,214,000 and \$12,893,000 were incurred in the three and six months ended June 30, 2002, with the gross margin \$3,710,000, or 22% of revenue and \$19,964,000, or 50% of revenue respectively. Last year's gross margin was adversely affected by the impairment and other related charges of \$6.9 million (Note 12 to the unaudited consolidated financial statements).

In the quarter ended June 30, 2003, excluding the impairment and other related charges for the quarter ended June 30, 2002, gross margin increased approximately 6% compared to the quarter ended June 30, 2002, benefiting from the recognition of deferred revenue and lower manufacturing costs. On a year-to-date basis, excluding the impairment charge in 2002, gross margin declined in the six month period ended June 30, 2003 due to lower lease revenue, additional amortization expense for radiation devices and maintenance costs for both the 3.5F and 5F catheter systems.

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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. With the re-launch of the redesigned 3.5F in January 2003, Novoste intends to pursue its strategy of going to a single VBT system with the premise of lowering costs as maintenance on a second catheter system is eliminated.

Research and Development Expenses. Research and development expenses decreased 19% to \$2,806,000 for the three months ended June 30, 2003, from \$3,464,000 for the three months ended June 30, 2002. Research and development expenses increased 1% to \$6,164,000 for the six months ended June 30, 2003, from \$6,123,000 for the six months ended June 30, 2002. The decrease for the three-month period was primarily in the area of clinical trials, although expenses for the six-month period are at about the same level. In addition to efforts for improving the existing product line, most of the expenses are related to expanded application of the Beta-Cath System. 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 access graft markets. Enrollment in the MOBILE trials has been slower than expected, accounting for much of the decline in expenditures in the current quarter. The Company is continuing to evaluate the viability of the current configuration of the MOBILE trials.

Sales and Marketing Expenses. Sales and marketing expenses decreased 21% to \$5,147,000 for the three months ended June 30, 2003, from \$6,545,000 for the three months ended June 30, 2002. Sales and marketing expenses decreased 25% to \$11,081,000 for the six months ended June 30, 2003, from \$14,763,000 for the six months ended June 30, 2002. The decrease for the three-month period is the result of expenses in Europe declining by more than 50%, due to the closing of the Belgium office in early 2002, marketing expenses declining approximately 40% due to fewer tradeshows and promotional activities, and a 5% decline in U.S. marketing expenses. The decrease in year-to-date expense is due to the marketplace being more mature, and less travel and promotional activities necessary to achieve coverage.

General and Administrative Expenses. General and administrative expenses decreased 2% to \$2,246,000 for the three months ended June 30, 2003, from \$2,293,000 for the three months ended June 30, 2002. General and administrative expenses increased 4% to \$4,565,000 for the six months ended June 30, 2003, from \$4,491,000 for the six months ended June 30, 2002. These expenses have remained stable. Cost reduction initiatives and a restructuring of Novoste in the first quarter which reduced headcount by 37 people have offset increased costs related to system consulting and professional services.

Other Income and Expenses. Other income increased 71% to \$70,000 for the three months ended June 30, 2003, from \$41,000 for the three months ended June 30, 2002. The increase was due to the lowering of interest expense as a result of the repayment of the working capital loan in June 2002. Other income decreased 43% to \$179,000 for the six months ended June 30, 2003, from \$314,000 for the six months ended June 30, 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, with more funds in cash equivalents to protect principal. Net interest income is down 51% from the same quarter last year.

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LIQUIDITY AND CAPITAL RESOURCES

Operating

Net cash provided by operations was \$3,690,000 for the six months ended June 30, 2003, compared to \$3,604,000 in the prior year period.

Investing

Net cash provided by investing activities was \$981,000 for the three months ended June 30, 2003, compared to net cash provided by those activities of \$6,962,000 in the prior year period, when the company began shifting from short term investments toward cash equivalents. The net maturities of short-term investments exceeded purchases of these investments by \$3.3 million. Novoste has shifted toward cash equivalents, lowering average short-term investments by 28% at the end of the second quarter of 2003 as compared to the second quarter of 2002. Less cash was used to purchase property and equipment in the second quarter of 2003 as compared to the second quarter of 2002 by \$302,000, primarily due to completing the production facility for radiation source trains in September 2002. Less cash was used to purchase radiation and transfer devices in the same periods by \$4,460,000. This decreased purchase of radiation devices in 2003 reflects the deployment of devices to most of the sites using VBT and fewer new sites in 2003. The maturity of the VBT market segment reduces the need for 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.

Financing

Novoste's financing activities include equity issuances from stock option exercises and repayments of capital leases. During the quarter ended June 30, 2003, Novoste issued 32,673 shares of its common stock at an average price of \$6.94 as various employee stock options were exercised and 10,664 shares of its common stock at an average price of \$5.82 under the Employee Stock Purchase Plan.

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 June 30, 2003, Novoste had no outstanding borrowings (see Note 8 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 June 30, 2003, Novoste had no outstanding letters of credit.

Commitments

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At June 30, 2003, Novoste had commitments to purchase \$4.4 million of inventory 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 to be finished in two phases. The first phase, the design phase, was completed in February 2001 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 requires that AEA may manufacture vascular

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brachytherapy sources only for Novoste. The annual production commitment through 2007 is 500 source trains at agreed upon prices. Novoste expects to exceed the annual minimum commitment for 2003.

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 which will total \$7.5 million 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 purchases to exceed minimum 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 paid to the physician were \$163,000 and \$170,000 for the three months ended June 30, 2003 and 2002, respectively, and \$357,000 and \$379,000 for the six months ended June 30 2003 and 2002, respectively, and have been expensed in Cost of Sales. As of June 30, 2003, aggregate payments of \$1,729,000 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 paid to Emory University were \$343,000 and \$348,000 for the three months ended June 30, 2003 and 2002, respectively, and \$729,000 and \$795,000 for the six months ended June 30, 2003 and 2002 respectively, and have been expensed in Cost of Sales.

Liquidity

Novoste's principal source of liquidity at June 30, 2003 consisted of cash, cash equivalents and short-term investments of \$35.7 million compared to \$34.2 million at June 30, 2002.

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 programs. Novoste

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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 catheter systems to 3.5F catheter 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.

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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 six 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 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

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restenosis rates to below 10%. In addition, Johnson & Johnson received FDA approval in April 2003 for its drug-eluting stent in the U.S. 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

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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 Beta-Cath Peripheral System 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 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 may require additional approvals. Such changes include, but are not limited to: new indications for use, the use of a

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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

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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).

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 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

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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

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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.

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.

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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.

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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 June 30, 2003, Novoste had \$27.3 million in cash equivalents with a weighted average interest rate of 0.536% and \$8.4 million in available-for-sale investments with a weighted average interest rate of 1.520%.

Foreign Currency Risk

International revenues from Novoste's foreign direct sales and distributor sales comprised 6% and 11% of total revenues for the three month periods ended June 30, 2003 and 2002, respectively. Sales to customers outside Europe and Canada are denominated in U.S. dollars, while European sales are denominated in Euros and Canadian sales are in Canadian dollars. Novoste experienced an immaterial amount of transaction gains and losses for the three months ended June 30, 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 June 30, 2003 was not material.

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.

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(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.

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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 matter described below, we are not aware of any such assertions that would have a material effect on Novoste.

On June 9, 2003, Calmedica, LLC, a California Limited Liability Corporation, filed suit against Novoste in the United States District Court for the Northern District of Illinois alleging that Novoste products infringed two (2) patents assigned to Calmedica, LLC. The Company has retained counsel to represent its interest in this matter and in conjunction with outside counsel has begun evaluation of the claims made in the litigation. Neither Novoste nor its counsel believe that the claims of infringement have merit. Novoste intends to respond to these allegations and vigorously defend the action. While Novoste believes that the claims are without merit the costs of defending the action could be material and, in the event that the plaintiff, Calmedica, LLC, is successful in the action, a finding of infringement could have a materially adverse effect on the Company's financial condition.

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

At Novoste's annual meeting of shareholders held on June 10, 2003 (the 2003 Annual Meeting), our shareholders took the following actions:

- The approval of management's nominees as Class I directors and Class II directors to the board of directors with the nominees receiving the following votes:

| | <i>For</i> | <i>Withheld</i> |
|------------------------------|------------|-----------------|
| J. Stephen Holmes (Class I) | 13,129,532 | 81,181 |
| Stephen I. Shapiro (Class I) | 12,564,213 | 646,500 |
| William E. Whitmer (Class I) | 13,149,532 | 61,181 |
| Alfred J. Novak (Class II) | 10,649,293 | 2,561,420 |
| Judy Lindstrom (Class II) | 12,544,213 | 666,500 |

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Each of the Class I directors will serve for a three-year term expiring at Novoste's annual meeting of shareholders in 2006, or until his or her successor has been duly elected and qualified or until his or her earlier resignation or removal, and each of the Class II directors will complete the remaining one-year term expiring at Novoste's annual meeting of shareholders in 2004, or until his or her successor has been duly elected and qualified or until his or her earlier resignation or removal. Election of the directors was determined by a plurality of the votes cast at the 2003 Annual Meeting. No other persons were nominated or received votes as directors of Novoste at the 2003 Annual Meeting.

2. Novoste's shareholders ratified the selection of Ernst & Young LLP as Novoste's independent auditors for the fiscal year ending December 31, 2003. With respect to such matter, the votes were cast as follows: 13,129,532 shares were voted for the proposal, 41,497 shares were voted against the proposal and 3,489 shares were abstained from voting on the proposal.

Item 5. Other Information

None.

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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) |
| | 31.1 | Certification of Alfred J. Novak, Chief Executive Officer, pursuant to Rules 13a-14 and 15d-14 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 and 15d-14 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 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 Report on Form 10-Q filed on May 9, 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).

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(6) 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.

There were three reports on Form 8-K filed by Novoste during the quarter ended June 30, 2003;

On April 2, 2003, we filed a current report on Form 8-K to disclose that we issued a press release announcing the proceedings in a webcast analyst meeting held by the Company at the American College of Cardiology meeting in Chicago, Illinois, at which meeting, the Company updated its first quarter projections, confirmed its 2003 year-end guidance and presented information relating to the vascular brachytherapy coronary market and the use of vascular brachytherapy to treat peripheral artery disease. A copy of the release was furnished as an exhibit under Item 9 of such Form 8-K.

On April 21, 2003, 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 March 31, 2003. A copy of the release was furnished as an exhibit pursuant to Item 12 under Item 9 of such

Form 8-K.

On May 20, 2003, we filed a current report on Form 8-K to disclose that we have agreed to enter into amended and restated termination agreements with our executive officers. The forms of amended and restated termination agreements were filed as exhibits to such Form 8-K.

Subsequent Form 8-K Filing

On July 31, 2003, 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 June 30, 2003 and that we conducted a conference call to discuss, among other things, Novoste's earnings for the quarter ended June 30, 2003. A copy of the release was furnished as an exhibit pursuant to Item 12 under Item 9 and a transcript of the conference call was furnished under Item 9 of such Form 8-K.

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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

August 8, 2003

Date